Declaration of Conformity

Manufacturer's Name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturer's Address	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Manufacturer's SRN	CN-MF-000006950
EU Authorized Representative's Name	Shanghai International Holding Corp. GmbH (Europe)
EU Authorized Representative's Address	Eiffestrasse 80, 20537 Hamburg Germany
EU Authorized Representative's SRN	DE-AR-000000001
Product Name	Single-Use Biopsy Forceps Disposable Biopsy Forceps
Product Trade Name	TruBite™ Single-Use Biopsy Forceps TechBite™ Single-Use Biopsy Forceps OptiBite* Disposable Biopsy Forceps
Basic UDI-DI	6902284BF387119Q
Catalogue Number	See attachment 2
GMDN code	38711
EMDN Code	G03080101: Gastrointestinal Endoscopy, Biopsy Forceps, Single-Use R07020101: Bronchoscopic Surgery Bioptic Forceps, Single-Use
Classification and Rule	Class IIa (According to Annex VIII, Rule 6 of MDR 2017/745)
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
Intended Purpose	These single-use biopsy forceps are used to collect living tissue samples of digestive tract and respiratory tract under the endoscopy.

The Declaration of Conformity is issued under the sole responsibility of Micro-Tech (Nanjing) Co., Ltd. The device that is covered by the present declaration is in conformity with the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

General applicable Regulation:

REGULATION (EU) 2017/745 of medical device

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

The detail harmonized standards see Attachment 1.

Notified Body (Name & Address):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identification Number:	CE 0344
Certificate Number :	6082015CE01
Certificate Issue Date:	2023-07-24
Certificate Expiry Date:	2027-09-01

Signature:

Becky Li

NAME: Becky Li
Person Responsible for Regulatory Compliance

Place and date of issue:

Nanjing, Jiangsu province, PRC, 2023-11-02

Attachment 1

• EN ISO 13485:2016+A11:2021 Medical devices – Quality management systems- Requirements for regulatory purposes

• EN ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

• EN ISO 20417:2021 Information supplied by the manufacturer with medical devices

• EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices

• ISO/TR 24971-2020 Medical devices — Guidance on the application of ISO 14971

• EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing

• EN ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

• EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

• EN ISO 10993-7:2008+AC: 2009 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residual

• EN ISO 10993-10:2013 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

• EN ISO 10993-11:2018 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity

• EN ISO 11135:2014/AMD 1:2019 Sterilization of health care products — Ethylene oxide —Requirements for development, validation and routine control of a sterilization process for medical devices

• EN ISO 11737-1:2018 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

• EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

• EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

• EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

• ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials

• ASTM F1886/F1886M-16 Standard test method for determining integrity of seals for flexible packaging by visual inspection

• ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages

• ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration

• ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices

• EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness

• EN 17141:2020 Cleanrooms and associated controlled environments - Biocontamination control - Part 1 : General principles and methods

• EN ISO 80369-7:2017 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications

• MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI

• MDCG-2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI

• MDCG-2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance

• MDCG 2020-5 Guidance on Clinical Evaluation

•IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation

• MEDDEV 2.12-1 Rev8 2013+Additional Guidance on MEDDEV 2.12/1 Rev.8 July 2019 Guidelines on a medical devices vigilance system

• MEDDEV 2.7.1 Rev 4 Clinical evaluation: a guide for manufacturers and notified bodies

• ISO/TR 20416 Medical devices — Post-market surveillance for manufacturers

Attachment 2 Catalogue Number

NO	REF	NO	REF	NO	REF
1	BF01-11018120	2	BF01-11018160	3	BF01-11018180
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424	NBF73-11123180	425	NBF73-11123230	426	EBF03-11018260
427	100575	428	100576	429	100577

Declaration of Conformity

Manufacturer's Name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturer's Address	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Manufacturer's SRN	CN-MF-000006950
EU Authorized Representative's Name	Shanghai International Holding Corp. GmbH (Europe)
EU Authorized Representative's Address	Eiffestrasse 80, 20537 Hamburg Germany
EU Authorized Representative's SRN	DE-AR-000000001
Product Name	Single-Use Biopsy Forceps Disposable Biopsy Forceps
Product Trade Name	TruBite™ Single-Use Biopsy Forceps TechBite™ Single-Use Biopsy Forceps OptiBite* Disposable Biopsy Forceps
Basic UDI-DI	6902284BF387119Q
Catalogue Number	See attachment 2
GMDN code	38711
EMDN Code	G03080101: Gastrointestinal Endoscopy, Biopsy Forceps, Single-Use R07020101: Bronchoscopic Surgery Bioptic Forceps, Single-Use
Classification and Rule	Class IIa (According to Annex VIII, Rule 6 of MDR 2017/745)
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
Intended Purpose	These single-use biopsy forceps are used to collect living tissue samples of digestive tract and respiratory tract under the endoscopy.

The Declaration of Conformity is issued under the sole responsibility of Micro-Tech (Nanjing) Co., Ltd. The device that is covered by the present declaration is in conformity with the Regulation (EU) MDR 2017/745 for medical devices.
All supporting documentation is retained at the premises of the manufacturer.

General applicable Regulation:

REGULATION (EU) 2017/745 of medical device

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

The detail harmonized standards see Attachment 1.

Notified Body (Name & Address):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identification Number:	CE 0344
Certificate Number :	6082015CE01
Certificate Issue Date:	2023-07-24
Certificate Expiry Date:	2027-09-01

Declaração de Conformidade

Nome do fabricante	Micro-Tech (Nanjing) Co., Ltd.
Endereço do fabricante	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
SRN do fabricante	CN-MF-000006950
Nome do representante autorizado da UE	Shanghai International Holding Corp. GmbH (Europe)
Endereço do representante autorizado da UE	Eiffestrasse 80, 20537 Hamburg Germany
SRN do representante autorizado da UE	DE-AR-000000001
Nome do produto	Pinça de biópsia de uso único
Nome comercial do produto	Pinça de biópsia de uso único TechBite™ Pinça de biópsia de uso único TruBite™
UDI-DI básico	6902284BF387119Q
Número de catálogo	Attachment 2
Código GMDN	38711
Código EMDN	G03080101, R07020101
Classificação	Classe IIa, Regra 6 de acordo com o AnexoVIII do MDR 2017/745
Rota de avaliação de conformidade	Anexo IX (Sem cap. II) do MDR 2017/745
Uso Pretendido e Indicações	Estas Pinça de biópsia de uso único são usadas para recolher amostras de tecidos vivos do trato digestivo e respiratório durante a endoscopia.

A Declaração de Conformidade é emitida sob a exclusiva responsabilidade da Micro-Tech (Nanjing) Co., Ltd. O dispositivo coberto pela presente declaração está em conformidade com o Regulamento (UE) MDR 2017/745 para dispositivos médicos.
Toda a documentação de suporte é mantida nas instalações do fabricante.

Regulamento geral aplicável:

Padrão aplicado:

Todas as outras legislações sindicais aplicáveis, normas harmonizadas e especificações comuns (publicadas no Diário Oficial das Comunidades Europeias)

Para obter detalhes das normas harmonizadas, consulte o Anexo 1.

Organismo notificado (nome e endereço):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Número de identificação:	CE 0344
Número do certificado:	6082015CE01
Data de emissão do certificado:	2023-07-24
Prazo de validade do certificado:	2027-09-01

Декларация за съответствие

Име на производителя	Micro-Tech (Nanjing) Co., Ltd.
Адрес на производителя	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
РН на производителя	CN-MF-000006950
Име на упълномощен представител в ЕС	Shanghai International Holding Corp. GmbH (Europe)
Адрес на оторизиран представител в ЕС	Eiffestrasse 80, 20537 Hamburg Germany
РН на упълномощен представител в ЕС	DE-AR-000000001
Име на продукта	Щипки за биопсия за еднократна употреба
Търговско име на продукта	Щипки за биопсия за еднократна употреба TechBite™ Щипки за биопсия за еднократна употреба TruBite™
Основен UDI-DI	6902284BF387119Q
Каталожен номер	Attachment 2
GMDN код	38711
EMDN код	G03080101, R07020101
Класификация	Клас IIa, Правило 6 съгласно ПриложениеVIII от
Маршрут за оценка на съответствието	Приложение IX (Без гл. II) от MDR 2017/745
Предназначение И Индикации	Тези Щипки за биопсия за еднократна употребасе използват за събиране на проби от живи тъкани от храносмилателния тракт и дихателните пътища под ендоскопия.

Декларацията за съответствие се издава под изключителната отговорност на Micro-Tech (Nanjing) Co., Ltd. Устройството, което се обхваща от настоящата декларация, е в съответствие с Регламент (ЕС) MDR 2017/745 за медицински изделия.

Цялата придружаваща документация се съхранява в помещенията на производителя.

Общ приложим регламент:

Приложен стандарт:

Всички други приложими законодателства, хармонизирани стандарти и общи спецификации на Съюза (публикувани в Официален вестник на Европейските общности)

За подробните хармонизирани стандарти вижте Приложение 1.

Нотифициран орган (име и адрес):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Идентификационен номер:	CE 0344
Номер на сертификата:	6082015CE01
Дата на издаване на сертификата:	2023-07-24
Дата на изтичане на сертификата:	2027-09-01

Overensstemmelseserklæring

Producentens navn	Micro-Tech (Nanjing) Co., Ltd.
Producentens adresse	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Producent SRN	CN-MF-000006950
Navn på EU-autoriseret repræsentant	Shanghai International Holding Corp. GmbH (Europe)
EU-autoriseret repræsentants adresse	Eiffestrasse 80, 20537 Hamburg Germany
EU-autoriseret repræsentant SRN	DE-AR-000000001
Produktnavn	Biopsipincet til engangsbrug
Produktets handelsnavn	TechBite™ Biopsipincet til engangsbrug TruBite™ Biopsipincet til engangsbrug
Grundlæggende UDI-DI	6902284BF387119Q
Katalognummer	Attachment 2
GMDN-kode	38711
EMDN-kode	G03080101, R07020101
Klassifikation	Klasse IIa, Regel 6 i henhold til Bilag VIII i MDR 2017/745
Rute for overensstemmelsesvurdering	Bilag IX (Uden kap. II) i MDR 2017/745
Tilsigtet Anvendelse & Indikationer	Disse Biopsipincet til engangsbrug bruges til at indsamle levende vævsprøver i fordøjelseskanalen og luftvejene under endoskopien.

Overensstemmelseserklæringen er udstedt under eget ansvar af Micro-Tech (Nanjing) Co., Ltd. Enheden, der er omfattet af denne erklæring, er i overensstemmelse med forordning (EU) MDR 2017/745 for medicinsk udstyr.
Al understøttende dokumentation opbevares hos producenten.

Generelt gældende forordning:

Standard anvendt:

Al anden gældende unionslovgivning, harmoniserede standarder og fælles specifikationer (offentliggjort i De Europæiske Fællesskabers Officielle Tidende)

De detaljerede harmoniserede standarder se Bilag 1.

Bemyndiget organ (navn og adresse):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikationsnummer:	CE 0344
Certifikatnummer:	6082015CE01
Udstedelsesdato for certifikatet:	2023-07-24
Certifikatets udløbsdato:	2027-09-01

Konformitätserklärung

Herstellername	Micro-Tech (Nanjing) Co., Ltd.
Herstelleradresse	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Hersteller SRN	CN-MF-000006950
Name des bevollmächtigten EU-Vertreters	Shanghai International Holding Corp. GmbH (Europe)
Adresse des bevollmächtigten EU-Vertreters	Eiffestrasse 80, 20537 Hamburg Germany
Bevollmächtigter EU-Vertreter SRN	DE-AR-000000001
Produktname	Biopsiezange zum einmaligen Gebrauch
Handelsname des Produkts	TechBite™ Biopsiezange zum einmaligen Gebrauch TruBite™ Biopsiezange zum einmaligen Gebrauch
Basis-UDI-DI	6902284BF387119Q
Katalognummer	Attachment 2
GMDN-Code	38711
EMDN-Code	G03080101, R07020101
Einstufung	Klasse IIa, Vorschrift 6 gemäß dem Anhang VIIIder MDR 2017/745
Konformitätsbewertungsroute	Anhang IX (Ohne Kap. II) der MDR 2017/745
Verwendungszweck Und Angaben	Diese Biopsiezange zum einmaligen Gebrauch werden zur Entnahme lebender Gewebeproben aus dem Verdauungstrakt und den Atemwegen während der Endoskopie verwendet.

Die Konformitätserklärung wird unter der alleinigen Verantwortung von Micro-Tech (Nanjing) Co., Ltd. ausgestellt. Das Instrument, auf das sich die vorliegende Erklärung bezieht, entspricht der Verordnung (EU) MDR 2017/745 für Medizinprodukte.
Alle unterstützenden Unterlagen werden in den Räumlichkeiten des Herstellers aufbewahrt.

Allgemein geltende Verordnung:

Angewendete Norm:

Alle anderen anwendbaren Unionsgesetzgebungen, harmonisierten Normen und gemeinsamen Spezifikationen (veröffentlicht im Amtsblatt der Europäischen Gemeinschaften)

Die detaillierten harmonisierten Normen finden Sie in Anhang 1.

Benannte Behörde (Name und Anschrift):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikationsnummer:	CE 0344
Zertifikatsnummer:	6082015CE01
Ausstellungsdatum des Zertifikats:	2023-07-24
Ablaufdatum des Zertifikats:	2027-09-01

Déclaration de conformité

Nom du fabricant	Micro-Tech (Nanjing) Co., Ltd.
Adresse du fabricant	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
N° d'immatriculation du dabricant	CN-MF-000006950
Nom du représentant autorisé de l'UE	Shanghai International Holding Corp. GmbH (Europe)
Adresse du représentant autorisé de l'UE	Eiffestrasse 80, 20537 Hamburg Germany
N° d'immatriculation du mandataire UE agréé	DE-AR-000000001
Nom du produit	Pinces à biopsie à usage unique
Nom commercial du produit	Pinces à biopsie à usage unique TechBite™ Pinces à biopsie à usage unique TruBite™
UDI-DI de base	6902284BF387119Q
Numéro de catalogue	Attachment 2
Code GMDN	38711
Code EMDN	G03080101, R07020101
Classification	Classe IIa, règle 6 selon l'annexeVIII du MDR 2017/745
Itinéraire d'évaluation de la conformité	Annexe IX (Sans chap. II) du MDR 2017/745
Utilisation Prévue Et Indications	Ces pinces à biopsie à usage unique sont utilisées pour prélever des échantillons de tissus vivants du tube digestif et des voies respiratoires sous endoscopie.

La déclaration de conformité est émise sous la seule responsabilité de Micro-Tech (Nanjing) Co., Ltd. Le dispositif faisant l'objet de la présente déclaration est conforme au Règlement (UE) MDR 2017/745 relatif aux dispositifs médicaux.
Toutes les pièces justificatives sont conservées dans les locaux du fabricant.

Réglementation générale applicable :

Norme appliquée :
Toutes les autres législations de l'Union applicables, les normes harmonisées et les spécifications communes (publiées au Journal officiel des Communautés européennes)

Le détail des normes harmonisées voir l'annexe 1.

Organisme notifié (nom et adresse) :	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Numéro d'identification:	CE 0344
Numéro de certificat:	6082015CE01
Date d'édition du certificat :	2023-07-24
Date d'expiration du certificat :	2027-09-01

Vaatimustenmukaisuusvakuutus

Valmistajan nimi	Micro-Tech (Nanjing) Co., Ltd.
Valmistajan osoite	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Valmistajan SRN	CN-MF-000006950
EU:ssa valtuutetun edustajan nimi	Shanghai International Holding Corp. GmbH (Europe)
EU:ssa valtuutetun edustajan osoite	Eiffestrasse 80, 20537 Hamburg Germany
EU-valtuutettu edustaja SRN	DE-AR-000000001
Tuotteen nimi	Kertakäyttöiset biopsiapihdit
Tuotteen kauppanimi	TechBite™ kertakäyttöiset biopsiapihdit TruBite™ kertakäyttöiset biopsiapihdit
Perus UDI-DI	6902284BF387119Q
Luettelonumero	Attachment 2
GMDN-koodi	38711
EMDN-koodi	G03080101, R07020101
Luokitus	Luokka IIa, sääntö 6 liitteen VIII MDR 2017/745 mukaisesti
Vaatimustenmukaisuuden arviointireitti	Liite IX (ilman lukua II) MDR 2017/745:sta
Tarkoitettu Käyttö Ja Käyttökohteet	Näitä Kertakäyttöiset biopsiapihdit käytetään elävien kudosnäytteiden keräämiseen ruoansulatuskanavasta ja hengitysteistä endoskopiassa.

Vaatimustenmukaisuusvakuutus on yksinomaisesti Micro-Tech (Nanjing) Co., Ltd:n vastuulla. Laite, jota tämä vakuutus koskee, on lääkinnällisiä laitteita koskevan asetuksen (EU) MDR 2017/745 mukainen.
Kaikki tätä tukevat asiakirjat säilytetään valmistajan tiloissa.

Yleisesti sovellettava asetus:

Sovellettu standardi:

Kaikki muu sovellettava unionin lainsäädäntö, yhdenmukaistetut standardit ja yhteiset määritelmät (julkaistu

Euroopan yhteisöjen virallisessa lehdessä)

Yksityiskohtaiset yhdenmukaistetut standardit katso liite 1.

Taho jolle ilmoitettu (nimi ja osoite):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Tunnusnumero:	CE 0344
Todistuksen numero:	6082015CE01
Todistuksen myöntämispäivämäärä:	2023-07-24
Todistuksen viimeinen voimassaolopäivä:	2027-09-01

Prohlášení o shodě

Název výrobce	Micro-Tech (Nanjing) Co., Ltd.
Adresa výrobce	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Jediné registrační číslo výrobce	CN-MF-000006950
Název zplnomocněného zástupce v EU	Shanghai International Holding Corp. GmbH (Europe)
Adresa zplnomocněného zástupce v EU	Eiffestrasse 80, 20537 Hamburg Germany
Jediné registrační číslo zplnomocněného zástupce v EU	DE-AR-000000001
Název výrobku	Jednorázové bioptické kleště
Obchodní název produktu	Jednorázové bioptické kleště TechBite™ Jednorázové bioptické kleště TruBite™
Základní UDI-DI:	6902284BF387119Q
Katalogové číslo	Attachment 2
Kód GMDN	38711
Kód EMDN	G03080101, R07020101
Klasifikace	Třída IIa, pravidlo 6 podle přílohyVIII MDR 2017/745
Postup posuzování shody	Příloha IX (bez kap. II) MDR 2017/745
Účel Použití A Indikace	Tyto jednorázové bioptické kleště se používají ke sběru vzorků živé tkáně zažívacího a dýchacího traktu při endoskopii.

Prohlášení o shodě se vydává na výhradní odpovědnost společnosti Micro-Tech (Nanjing) Co., Ltd. Prostředek, na který se vztahuje toto prohlášení, je v souladu s nařízením (EU) MDR 2017/745 o zdravotnických prostředcích.
Veškerá podpůrná dokumentace je uchovávána v prostorách výrobce.

Obecně platné nařízení:

Použité normy:

Všechny ostatní platné unijní právní předpisy, harmonizované normy a společné specifikace (zveřejněné v Úředním věstníku Evropských společenství)

Podrobné harmonizované normy viz příloha 1.

Oznámený subjekt (název a adresa):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikační číslo:	CE 0344
Číslo certifikátu:	6082015CE01
Datum vydání certifikátu:	2023-07-24
Datum vypršení platnosti certifikátu:	2027-09-01

Atbilstības deklarācija

Ražotāja nosaukums	Micro-Tech (Nanjing) Co., Ltd.
Ražotāja adrese	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Ražotāja SRN	CN-MF-000006950
ES pilnvarotā pārstāvja vārds	Shanghai International Holding Corp. GmbH (Europe)
ES pilnvarotā pārstāvja adrese	Eiffestrasse 80, 20537 Hamburg Germany
ES pilnvarotā pārstāvja SRN	DE-AR-000000001
Izstrādājuma nosaukums	Vienreizējas lietošanas biopsijas knaibles
Izstrādājuma tirdzniecības nosaukums	TechBite™ vienreizējas lietošanas biopsijas knaibles TruBite™ vienreizējas lietošanas biopsijas knaibles
Pamata UDI-DI	6902284BF387119Q
Kataloga numurs	Attachment 2
GMDN kods	38711
EMDN kods	G03080101, R07020101
Klasifikācija	IIa klase, 6. noteikums saskaņā ar pielikumuVIII MDR 2017/745
Atbilstības novērtēšanas maršruts	IX pielikums (bez sad. II) MDR 2017/745
Paredzētā Lietošana Un Indikācijas	Šīs vienreizējas lietošanas biopsijas knaibles tiek izmantotas, lai savāktu dzīvo audu paraugus no gremošanas trakta un elpceļu endoskopijas.

Atbilstības deklarācija tiek izdota, Micro-Tech (Nanjing) Co., Ltd. uzņemoties pilnu atbildību. Ierīce, uz kuru attiecas šī deklarācija, atbilst Regulai (ES) MDR 2017/745 par medicīnas ierīcēm.
Visa apliecinošā dokumentācija tiek glabāta ražotāja telpās.

Vispārīgi piemērojamie noteikumi:

Piemērots standarts:
Visi pārējie piemērojamie Savienības tiesību akti, saskaņotie standarti un kopējās specifikācijas (publicētas Eiropas Kopienu Oficiālajā Vēstnesī)
Sīki izstrādātus saskaņotos standartus skatīt 1. pielikumā.

Pilnvarotā iestāde (nosaukums un adrese):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikācijas numurs:	CE 0344
Sertifikāta numurs:	6082015CE01
Sertifikāta izdošanas datums:	2023-07-24
Sertifikāta derīguma termiņš:	2027-09-01

Declaración de conformidad

Nombre del fabricante	Micro-Tech (Nanjing) Co., Ltd.
Dirección del fabricante	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Número de serie del fabricante	CN-MF-000006950
Nombre del representante autorizado en la UE	Shanghai International Holding Corp. GmbH (Europe)
Dirección del representante autorizado en la UE	Eiffestrasse 80, 20537 Hamburg Germany
Número de serie del representante autorizado en la UE	DE-AR-000000001
Nombre del producto	Pinzas de biopsia de un solo uso
Nombre comercial del producto	Pinzas de biopsia de un solo uso TechBite™ Pinzas de biopsia de un solo uso TruBite™
UDI-DI básico	6902284BF387119Q
Número de catálogo	Attachment 2
Código GMDN	38711
Código EMDN	G03080101, R07020101
Clasificación	Clase IIa, Norma 6 según el AnexoVIII de MDR 2017/745
Ruta de evaluación de conformidad	Anexo IX (sin cap. II) de MDR 2017/745
Uso Previsto E Indicaciones	Estas Pinzas de biopsia de un solo uso se utilizan para recoger muestras de tejido vivo del tracto digestivo y del tracto respiratorio mediante una endoscopia.

La Declaración de Conformidad se emite bajo la exclusiva responsabilidad de Micro-Tech (Nanjing) Co., Ltd. El dispositivo cubierto por la presente declaración cumple con la norma (UE) MDR 2017/745 para dispositivos médicos.
Todos los comprobantes se conservan en las instalaciones del fabricante.

Normas generales vigentes:

Norma aplicada:

Todas las demás legislaciones, normas armonizadas y especificaciones comunes vigentes de la Unión (publicadas en el Diario Oficial de las Comunidades Europeas)

Ver el detalle de las normas armonizadas en el Anexo 1.

Organismo notificado (nombre y dirección):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Número de identificación:	CE 0344
Número certificado:	6082015CE01
Fecha de emisión del certificado:	2023-07-24
Fecha de vencimiento del certificado:	2027-09-01

Atitikties deklaracija

Gamintojo pavadinimas	Micro-Tech (Nanjing) Co., Ltd.
Gamintojo adresas	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Gamintojas unikalusis registracijos numeris (SRN)	CN-MF-000006950
ES įgaliotojo atstovo vardas ir pavardė	Shanghai International Holding Corp. GmbH (Europe)
ES įgaliotojo atstovo adresas	Eiffestrasse 80, 20537 Hamburg Germany
ES įgaliotojo atstovo unikalusis registracijos numeris (SRN)	DE-AR-000000001
Produkto pavadinimas	Vienkartinio naudojimo biopsijos žnyplės
Komercinis produkto pavadinimas	TechBite™ vienkartinio naudojimo biopsijos žnyplės TruBite™ vienkartinio naudojimo biopsijos žnyplės
Bazinis UDI-DI	6902284BF387119Q
Katalogo numeris	Attachment 2
GMDN kodas	38711
EMDN kodas	G03080101, R07020101
Klasifikacija	IIa klasė, 6 taisyklė pagal VIII MDR 2017/745 priedą
Atitikties vertinimo būdas	MDR 2017/745 IX priedas (be II skyriaus)
Numatytas Naudojimas Ir Indikacijos	Šios Vienkartinio naudojimo biopsijos žnyplės virškinamojo trakto ir kvėpavimo takų gyvų audinių mėginiams surinkti endoskopijos metu.

Už atitikties deklaracijos išdavimą atsako tik „Micro-Tech (Nanjing) Co., Ltd.“ Prietaisas, kuriam taikoma ši

deklaracija, atitinka ES medicinos priemonių reglamento 2017/745 (MDR) reikalavimus.
Visi patvirtinamieji dokumentai saugomi gamintojo patalpose.

Bendrasis taikomas reglamentas:

Taikomas standartas:
Visi kiti taikomi Sąjungos teisės aktai, darnieji standartai ir bendroji specifikacija (paskelbta Europos Bendrijų oficialiajame leidinyje)
Išsamius darniuosius standartus žr. 1 priede.

Notifikuotoji įstaiga (pavadinimas ir adresas):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikavimo numeris:	CE 0344
Sertifikato numeris:	6082015CE01
Sertifikato išdavimo data:	2023-07-24
Sertifikatas galioja iki:	2027-09-01

Konformitätserklärung

Numm vum Fabrikant	Micro-Tech (Nanjing) Co., Ltd.
Adress vum Fabrikant	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
SRN vum Fabrikant	CN-MF-000006950
Numm vum EU-autoriséierte Vertrieder	Shanghai International Holding Corp. GmbH (Europe)
Adress vum EU-autoriséierte Vertrieder	Eiffestrasse 80, 20537 Hamburg Germany
SRN vum EU-autoriséierte Vertrieder	DE-AR-000000001
Produktnumm	Biopsie-Pince fir eng eenzeg Benotzung
Produkt-Handelsnumm	TechBite™ Biopsie-Pince fir eng eenzeg Benotzung TruBite™ Biopsie-Pince fir eng eenzeg Benotzung
Basis UDI-DI	6902284BF387119Q
Katalognummer	Attachment 2
GMDN-Code	38711
EMDN-Code	G03080101, R07020101
Klassifikatioun	Klass IIa, Reegel 6 geméiss AnnexVIII vun MDR 2017/745
Konformitéits-Bewäertungsroute	Annex IX (ouni Kap. II) vun MDR 2017/745
Virgesinne Benotzung & Indikatiounen	Dës Biopsie-Pince fir eng eenzeg Benotzung gëtt benotzt, fir lieweg Gewebeprouwen aus dem Verdauungstrakt an dem Otmungstrakt ënnert der Endoskopie ze sammelen.

D'Konformitéitserklärung gëtt ënner der elengeger Verantwortung vu Micro-Tech (Nanjing) Co., Ltd. Den Apparat, dee vun dëser Deklaratioun ofgedeckt ass, entsprécht der Regulatioun (EU) MDR 2017/745 fir medizinesch Geräter.
All ënnerstëtzend Dokumentatioun gëtt an de Raimlechkeete vum Hiersteller gespäichert.

Allgemeng applicabel Regulatioun:

Standard ugewant:

All aner applicabel Gewerkschaftsgesetzer, harmoniséiert Normen a gemeinsam Spezifizéierung (am Offizielle Journal vun den Europäesche Gemeinschaften veröffentlecht)

Déi detailléiert harmoniséiert Normen, Anhang 1.

Notifizéierte Kierper (Numm & Adress):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikatiounsnummer:	CE 0344
Zertifikatsnummer:	6082015CE01
Zertifikatveröffentlechungsdatum:	2023-07-24
Zertifikatsoflafdatum:	2027-09-01

Declarație de conformitate

Numele producătorului	Micro-Tech (Nanjing) Co., Ltd.
Adresa producătorului	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
SRN producător	CN-MF-000006950
Numele reprezentantului autorizat în UE	Shanghai International Holding Corp. GmbH (Europe)
Adresa reprezentantului autorizat în UE	Eiffestrasse 80, 20537 Hamburg Germany
SRN reprezentant autorizat în UE	DE-AR-000000001
Nume produs	Forceps pentru biopsie de unică folosință
Numele comercial al produsului	Forceps pentru biopsie de unică folosință TechBite™ Forceps pentru biopsie de unică folosință TruBite™
UDI-DI de bază	6902284BF387119Q
Număr catalog	Attachment 2
Cod GMDN	38711
Cod EMDN	G03080101, R07020101
Clasificare	Clasa IIa, Regula 6 conform AnexeiVIII din MDR 2017/745
Traseul de evaluare a conformității	Anexa IX (Fără cap. II) din MDR 2017/745
Utilizare Preconizată Și Indicații	Aceste Forceps pentru biopsie de unică folosință sunt utilizate pentru a colecta probe de țesut viu ale tractului digestiv și ale tractului respirator în regim endoscopic.

Declarația de conformitate este emisă sub responsabilitatea exclusivă a Micro-Tech (Nanjing) Co., Ltd. Dispozitivul care face obiectul prezentei declarații este conform cu Regulamentul (UE) MDR 2017/745 pentru dispozitive medicale.
Toată documentația justificativă este păstrată la sediul producătorului.

Regulament general aplicabil:

Standard aplicat:

Toate celelalte legislații aplicabile ale Uniunii, standarde armonizate și specificații comune (publicate în Jurnalul Oficial al Comunității Europene)

Standardele armonizate detaliate vezi Anexa 1.

Organism notificat (nume și adresă):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Număr de identificare:	CE 0344
Numărul certificatului:	6082015CE01
Data emiterii certificatului:	2023-07-24
Data de expirare a certificatului:	2027-09-01

Dikjarazzjoni ta' Konformità

Isem tal-Manifattur	Micro-Tech (Nanjing) Co., Ltd.
Indirizz tal-Manifattur	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
SRN tal-Manifattur	CN-MF-000006950
Isem ir-Rappreżentant Awtorizzat tal-UE	Shanghai International Holding Corp. GmbH (Europe)
Indirizz tar-Rappreżentant Awtorizzat tal-UE	Eiffestrasse 80, 20537 Hamburg Germany
SRN tar-Rappreżentant Awtorizzat tal-UE	DE-AR-000000001
Isem tal-Prodott	Forċipi għal Bijopsija ta' Użu Uniku
Isem tal-Kummerċ tal-Prodott	TechBite™ Forċipi għal Bijopsija ta' Użu Uniku TruBite™ Forċipi għal Bijopsija ta' Użu Uniku
UDI-DI bażiku	6902284BF387119Q
Numru tal-Katalogu	Attachment 2
Kodiċi GMDN	38711
Kodiċi EMDN	G03080101, R07020101
Klassifikazzjoni	Klassi IIa, Artikolu 6 skont l-Anness VIII tal-MDR 2017/745
Rotta ta' Valutazzjoni tal-Konformità	Anness IX (Mingħajr kap. II) ta' MDR 2017/745
Użu Maħsub U Indikazzjonijiet	Dawn il-forċipi għal bijopsija ta' użu uniku huma użati biex jinġabru kampjuni ta' tessut ħaj mill-apparat diġestiv u apparat respiratorju taħt l-endoskopija.

Id-Dikjarazzjoni ta' Konformità tinħareġ taħt ir-responsabbiltà unika ta' Micro-Tech (Nanjing) Co., Ltd. L-apparat li huwa kopert minn din id-dikjarazzjoni huwa konformi mar-Regolament (UE) MDR 2017/745 għall-apparat mediku.
Id-dokumentazzjoni ta' appoġġ kollha tinżamm fil-post tal-manifattur.

Regolament ġenerali applikabbli:

Standard Applikat:

Il-leġiżlazzjonijiet l-oħra kollha applikabbli, l-istandards armonizzati u l-ispeċifikazzjoni komuni tal-Unjoni (ippubblikati fil-Ġurnal Uffiċjali tal-Komunitajiet Ewropej)

L-istandards armonizzati fid-dettall ara d-Dokument Mehmuż 1.

Korp Notifikat (Isem u Indirizz):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Numru ta' Identifikazzjoni:	CE 0344
Numru taċ-Ċertifikat:	6082015CE01
Ċertifikat Maħruġ Data:	2023-07-24
Data tal-Iskadenza taċ-Ċertifikat:	2027-09-01

Erklæring om samsvar

Produsentens navn	Micro-Tech (Nanjing) Co., Ltd.
Produsentens adresse	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Produsent SRN	CN-MF-000006950
EU autorisert representant navn	Shanghai International Holding Corp. GmbH (Europe)
EU autorisert representant adresse	Eiffestrasse 80, 20537 Hamburg Germany
EU autorisert representant SRN	DE-AR-000000001
Produktnavn	Biopsi tang til engangsbruk
Produktets handel navn	TechBite™ Biopsi tang til engangsbruk TruBite™ Biopsi tang til engangsbruk
Grunnleggende UDI DI	6902284BF387119Q
Katalog nummer	Attachment 2
GMDN kode	38711
EMDN kode	G03080101, R07020101
Klassifisering	Klasse IIa, regel 6 i henhold til vedleggVIII av MDR 2017/745
Rute for samsvar vurdering	Vedlegg IX (Uten kap. II) av MDR 2017/745
Tiltenkt Bruk Og Indikasjoner	Disse Biopsi tang til engangsbrukbrukes til å samle levende vevsprøver av fordøyelseskanalen og luftveiene under endoskopien.

Erklæring om samsvar er utstedt under eget ansvar av Micro-Tech (Nanjing) Co., Ltd. Enheten som dekkes av denne erklæringen er i samsvar med forordning (EU) MDR 2017/745 for medisinsk utstyr.
All støtte dokumentasjon oppbevares hos produsenten.

Generelt gjeldende forskrift:

Standard brukt:

All annen gjeldende fagforening lovgivning, harmoniserte standarder og felles spesifikasjoner (publisert i De Europeiske Fellesskaps Tidende)

De detaljerte harmoniserte standardene se vedlegg 1.

Varslet organ (navn og adresse):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikasjon nummer:	CE 0344
Sertifikat nummer:	6082015CE01
Sertifikat utstedt dato:	2023-07-24
Sertifikatets utløp dato:	2027-09-01

Försäkran om överensstämmelse

Namn på tillverkare	Micro-Tech (Nanjing) Co., Ltd.
Tillverkarens adress	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Tillverkarens SRN	CN-MF-000006950
Namn på EU-auktoriserad representant	Shanghai International Holding Corp. GmbH (Europe)
Adress för EU-auktoriserad representant	Eiffestrasse 80, 20537 Hamburg Germany
EU-auktoriserad representant SRN	DE-AR-000000001
Produktnamn	Biopsipincett för engångsbruk
Produktens handelsnamn	TechBite™ biopsipincett för engångsbruk TruBite™ biopsipincett för engångsbruk
Grundläggande UDI-DI	6902284BF387119Q
Katalognummer	Attachment 2
GMDN-kod	38711
EMDN-kod	G03080101, R07020101
Klassificering	Klass IIa, regel 6 enligt bilagaVIII till MDR 2017/745
Väg för bedömning av överensstämmelse	Bilaga IX (Utan kap. II) till MDR 2017/745
Avsedd Användning & Indikationer	Dessa biopsipincett för engångsbruk används för att samla levande vävnadsprover i matsmältningskanalen och luftvägarna under endoskopi.

Försäkran om överensstämmelse utfärdas under eget ansvar av Micro-Tech (Nanjing) Co., Ltd. Enheten som omfattas av denna deklaration överensstämmer med förordningen (EU) MDR 2017/745 för medicintekniska produkter.
All styrkande dokumentation förvaras i tillverkarens lokaler.

Allmän tillämplig förordning:

Tillämpad standard:

All annan tillämplig facklig lagstiftning, överensstämmande standarder och gemensamma specifikationer (publicerade i Europeiska gemenskapernas officiella tidning)

Detaljerade överensstämmande standarder se bilaga 1.

Anmält organ (namn och adress):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifieringsnummer:	CE 0344
Certifikatnummer:	6082015CE01
Certifikat utfärdat datum:	2023-07-24
Certifikatets utgångsdatum:	2027-09-01

Vyhlásenie o zhode

Názov výrobcu	Micro-Tech (Nanjing) Co., Ltd.
Adresa výrobcu	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Výrobca SRN	CN-MF-000006950
Meno splnomocneného zástupcu EÚ	Shanghai International Holding Corp. GmbH (Europe)
Adresa autorizovaného zástupcu EÚ	Eiffestrasse 80, 20537 Hamburg Germany
Splnomocnený zástupca EÚ SRN	DE-AR-000000001
Názov produktu	Bioptické kliešte na jedno použitie
Obchodný názov produktu	TechBite™ Bioptické kliešte na jedno použitie TruBite™ Bioptické kliešte na jedno použitie
Základné UDI-DI	6902284BF387119Q
Katalógové číslo	Attachment 2
Kód GMDN	38711
Kód EMDN	G03080101, R07020101
Klasifikácia	Trieda IIa, pravidlo 6 podľa prílohyVIII MDR 2017/745
Postup posudzovania zhody	Príloha IX (bez kap. II) MDR 2017/745
Zamýšľané Použitie A Indikácie	Tieto Bioptické kliešte na jedno použitie sa používajú na odber vzoriek živého tkaniva z tráviaceho a dýchacieho traktu pri endoskopii.

Vyhlásenie o zhode sa vydáva na výhradnú zodpovednosť spoločnosti Micro-Tech (Nanjing) Co., Ltd. Pomôcka, na ktorú sa vzťahuje toto vyhlásenie, je v súlade s nariadením (EÚ) MDR 2017/745 pre zdravotnícke pomôcky.
Všetka sprievodná dokumentácia sa uchováva v priestoroch výrobcu.

Všeobecne záväzné nariadenie:

Aplikovaná norma:

Všetky ostatné uplatniteľné právne predpisy Únie, harmonizované normy a spoločné špecifikácie (uverejnené v Úradnom vestníku Európskych spoločenstiev)

Podrobné harmonizované normy pozri v prílohe 1.

Notifikovaný orgán (meno a adresa):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikačné číslo:	CE 0344
Číslo certifikátu:	6082015CE01
Dátum vydania certifikátu:	2023-07-24
Dátum vypršania platnosti certifikátu:	2027-09-01

Izjava o skladnosti

Ime proizvajalca	Micro-Tech (Nanjing) Co., Ltd.
Naslov proizvajalca	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Proizvajalec SRN	CN-MF-000006950
Ime pooblaščenega zastopnika EU	Shanghai International Holding Corp. GmbH (Europe)
Naslov pooblaščenega predstavnika EU	Eiffestrasse 80, 20537 Hamburg Germany
Pooblaščeni predstavnik EU SRN	DE-AR-000000001
Ime izdelka	Biopsijskih klešč za enkratno uporabo
Trgovsko ime izdelka	Biopsijskih klešč za enkratno uporabo TechBite™ Biopsijskih klešč za enkratno uporabo TRUBite™
Osnovni UDI-DI	6902284BF387119Q
Kataloška številka	Attachment 2
Koda GMDN	38711
Koda EMDN	G03080101, R07020101
Razvrstitev	Razred IIa, pravilo 6 v skladu s prilogoVIII MDR 2017/745
Pot ugotavljanja skladnosti	Priloga IX (brez poglavja II) MDR 2017/745
Namen Uporabe In Indikacije	Te Biopsijskih klešč za enkratno uporabo se uporabljajo za zbiranje vzorcev živih tkiv prebavnega trakta in dihalnih poti pod endoskopijo.

Izjava o skladnosti je izdana pod izključno odgovornostjo Micro-Tech (Nanjing) Co., Ltd. Naprava, ki je zajeta v tej izjavi, je v skladu z Uredbo (EU) MDR 2017/745 za medicinske pripomočke.
Vsa spremljajoča dokumentacija se hrani v prostorih proizvajalca.

Splošna veljavna uredba:

Uporabljen standard:

Vse druge veljavne zakonodaje Unije, usklajeni standardi in skupne specifikacije (objavljene v Uradnem listu Evropskih skupnosti)

Podrobne harmonizirane standarde glej prilogo 1.

Priglašeni organ (ime in naslov):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Identifikacijska številka:	CE 0344
Številka potrdila:	6082015CE01
Datum izdaje potrdila:	2023-07-24
Datum poteka veljavnosti potrdila:	2027-09-01

Uygunluk beyanı

Üretici Adı	Micro-Tech (Nanjing) Co., Ltd.
Üretici Adresi	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Üretici SRN	CN-MF-000006950
AB Yetkili Temsilci Adı	Shanghai International Holding Corp. GmbH (Europe)
AB Yetkili Temsilcisi Adresi	Eiffestrasse 80, 20537 Hamburg Germany
AB Yetkili Temsilcisi SRN	DE-AR-000000001
Ürün Adı	Tek Kullanımlık Biyopsi Forsepsi
Ürün Ticari Adı	TechBite™ Tek Kullanımlık Biyopsi Forsepsi TruBite™ Tek Kullanımlık Biyopsi Forsepsi
Temel UDI-DI	6902284BF387119Q
Katalog Numarası	Attachment 2
GMDN Kodu	38711
EMDN Kodu	G03080101, R07020101
Sınıflandırma	Ek VIII uyarınca Sınıf IIa, Kural 6 MDR 2017/745
Uygunluk Değerlendirme Rotası	Ek IX (Böl. II olmaksızın) MDR 2017/745
Kullanım Amacı & Endikasyonları	Bu Tek Kullanımlık Biyopsi Forsepsi, endoskopi altında sindirim sistemi ve solunum yollarından canlı doku örnekleri almak için kullanılır.

Uygunluk Beyanı, tamamen Micro-Tech (Nanjing) Co., Ltd.'nin sorumluluğunda yayınlanmıştır. Bu beyanın kapsadığı cihaz, tıbbi cihazlar için MDR 2017/745 (AB) Yönetmeliğine uygundur.
Tüm müstenit belgeler, üreticinin tesislerinde muhafaza edilir.

Genel geçerli Yönetmelik:

Uygulanan Standart:
Diğer tüm geçerli birlik mevzuatı, uyumlaştırılmış standartlar ve ortak şartname (Avrupa Toplulukları Resmi

Gazetesinde yayınlanmıştır)

Ayrıntılı uyumlaştırılmış standartlar için Ek 1'e bakınız.

Onaylanmış Kuruluş (Ad ve Adres):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Kimlik Numarası:	CE 0344
Sertifika numarası:	6082015CE01
Sertifika Verilme Tarihi:	2023-07-24
Sertifika Bitiş Tarihi:	2027-09-01

Δήλωση συμμόρφωσης

Όνομα κατασκευαστή	Micro-Tech (Nanjing) Co., Ltd.
Διεύθυνση κατασκευαστή	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
SRN κατασκευαστή	CN-MF-000006950
Όνομα εξουσιοδοτημένου αντιπροσώπου στην ΕΕ	Shanghai International Holding Corp. GmbH (Europe)
Διεύθυνση εξουσιοδοτημένου αντιπροσώπου στην ΕΕ	Eiffestrasse 80, 20537 Hamburg Germany
SRN εξουσιοδοτημένου αντιπροσώπου στην ΕΕ	DE-AR-000000001
Όνομα προϊόντος	Λαβίδα βιοψίας μίας χρήσης
Εμπορική ονομασία προϊόντος	TechBite™ Λαβίδα βιοψίας μίας χρήσης TruBite™ Λαβίδα βιοψίας μίας χρήσης
Βασικό UDI-DI	6902284BF387119Q
Αριθμός καταλόγου	Attachment 2
Κωδικός GMDN	38711
Κωδικός EMDN	G03080101, R07020101
Ταξινόμηση	Κατηγορία IIa, Κανόνας 6 σύμφωνα με το Παράρτημα VIII του κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα
Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα IX (Χωρίς το κεφάλαιο II) του κανονισμού για τα ιατροτεχνολογικά προϊόντα
Προβλεπομενη Χρηση Και Ενδειξεισ	Αυτή η Λαβίδα βιοψίας μίας χρήσης χρησιμοποιείται για τη συλλογή δειγμάτων ζωντανού ιστού του πεπτικού συστήματος και της αναπνευστικής οδού στο πλαίσιο της ενδοσκόπησης.

Η δήλωση συμμόρφωσης εκδίδεται με αποκλειστική ευθύνη της Micro-Tech (Nanjing) Co., Ltd. Το προϊόν που καλύπτεται από την παρούσα δήλωση συμμορφώνεται με τον Κανονισμό (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα.

Όλα τα δικαιολογητικά φυλάσσονται στις εγκαταστάσεις του κατασκευαστή.

Κανονισμός γενικής ισχύος:

Πρότυπο που εφαρμόζεται:

Όλες οι άλλες ισχύουσες νομοθεσίες της Ένωσης, τα εναρμονισμένα πρότυπα και οι κοινές προδιαγραφές (που δημοσιεύονται στην Επίσημη Εφημερίδα των Ευρωπαϊκών Κοινοτήτων)

Τα αναλυτικά εναρμονισμένα πρότυπα βλέπε Προσάρτημα 1.

Κοινοποιημένος οργανισμός (όνομα και διεύθυνση):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Αριθμός ταυτοποίησης:	CE 0344
Αριθμός πιστοποιητικού:	6082015CE01
Ημερομηνία έκδοσης πιστοποιητικού:	2023-07-24
Ημερομηνία λήξης πιστοποιητικού:	2027-09-01

Megfelelőségi nyilatkozat

Gyártó neve	Micro-Tech (Nanjing) Co., Ltd.
Gyártó címe	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Gyártó egyedi regisztrációs száma	CN-MF-000006950
Az EU meghatalmazott képviselőjének neve	Shanghai International Holding Corp. GmbH (Europe)
Az EU meghatalmazott képviselőjének címe	Eiffestrasse 80, 20537 Hamburg Germany
Az EU meghatalmazott képviselőjének egyedi regisztrációs száma	DE-AR-000000001
Terméknév	Eldobható biopsziás csipesz
Termék kereskedelmi neve	TechBite™ eldobható biopsziás csipesz TruBite™ eldobható biopsziás csipesz
Alap UDI-DI	6902284BF387119Q
Katalógusszám	Attachment 2
GMDN-kód	38711
EMDN-kód	G03080101, R07020101
Besorolás	IIa. osztály, az MDR 2017/745 mellékleteVIII szerinti 6. szabály
Megfelelőségértékelési eljárás	Az MDR 2017/745 IX. melléklete (a II. fejezet nélkül)
Rendeltetésszerű Használat És Javallatok	Ez az eldobható biopsziás csipesz az emésztőrendszer és a légutak élő szövetmintáinak endoszkópiával történő összegyűjtésére szolgál.

A megfelelőségi nyilatkozat a Micro-Tech (Nanjing) Co., Ltd. kizárólagos felelősségvállalásával került kibocsátásra. A jelen nyilatkozat tárgyát képező eszköz megfelel az orvostechnikai eszközökre vonatkozó (EU) MDR 2017/745 rendeletnek.
A kísérő dokumentáció a gyártó létesítményeiben található.

Altalános hatályú rendelet:

Alkalmazott szabvány:

Minden egyéb alkalmazandó uniós jogszabály, harmonizált szabvány és közös előírás (az Európai Közösségek Hivatalos Lapjában került közzétételre)

A részletes harmonizált szabványokat az 1. melléklet tartalmazza.

Bejelentett szervezet (név és cím):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Azonosítószám:	CE 0344
Tanúsítvány száma:	6082015CE01
Tanúsítvány kiállításának dátuma:	2023-07-24
Tanúsítvány érvényességi ideje:	2027-09-01

Dichiarazione di conformità

nome del produttore	Micro-Tech (Nanjing) Co., Ltd.
Indirizzo del produttore	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Produttore SRN	CN-MF-000006950
Nome del rappresentante autorizzato UE	Shanghai International Holding Corp. GmbH (Europe)
Indirizzo del rappresentante autorizzato UE	Eiffestrasse 80, 20537 Hamburg Germany
Rappresentante autorizzato per l'UE SRN	DE-AR-000000001
Nome prodotto	Forcipe per biopsia monouso
Nome commerciale del prodotto	TechBite™ Forcipe per biopsia monouso TruBite™ Forcipe per biopsia monouso
UDI-DI di base	6902284BF387119Q
Numero di catalogo	Attachment 2
Codice GMDN	38711
Codice EMDN	G03080101, R07020101
Classificazione	Classe IIa, Regola 6 secondo l'allegatoVIII del MDR 2017/745
Percorso di valutazione della conformità	Allegato IX (Senza cap. II) del MDR 2017/745
Uso Previsto E Indicazioni	Questi Forcipe per biopsia monouso vengono utilizzati per raccogliere campioni di tessuto vivo del tratto digestivo e del tratto respiratorio sotto l'endoscopia.

La Dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva di Micro-Tech (Nanjing) Co., Ltd. Il dispositivo oggetto della presente dichiarazione è conforme al Regolamento (UE) MDR 2017/745 per i dispositivi medici.
Tutta la documentazione di supporto è conservata presso la sede del produttore.

Regolamento generale applicabile:

Standard applicato:

Tutte le altre legislazioni sindacali applicabili, le norme armonizzate e le specifiche comuni (pubblicate nella Gazzetta Ufficiale delle Comunità Europee)

Per le norme armonizzate di dettaglio si veda l'allegato 1.

Ente preposto (nome e indirizzo):	**DEKRA Certification B.V.** Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Numero identificativo:	CE 0344
Numero di certificato:	6082015CE01
Data di emissione del certificato:	2023-07-24
Data di scadenza del certificato:	2027-09-01

Signature:

Becky Li

NAME: Becky Li
Person Responsible for Regulatory Compliance

Place and date of issue:

Nanjing, JiangSu province, PRC, 2023-09-28

Attachment 1

• EN ISO 13485:2016+A11:2021 Medical devices – Quality management systems- Requirements for regulatory purposes

• EN ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

• EN ISO 20417:2021 Information supplied by the manufacturer with medical devices

• EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices

• ISO/TR 24971-2020 Medical devices — Guidance on the application of ISO 14971

• EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing

• EN ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

• EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

• EN ISO 10993-7:2008+AC: 2009 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residual

• EN ISO 10993-10:2013 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

• EN ISO 10993-11:2018 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity

• EN ISO 11135:2014/AMD 1:2019 Sterilization of health care products — Ethylene oxide —Requirements for development, validation and routine control of a sterilization process for medical devices

• EN ISO 11737-1:2018 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

• EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

• EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

• EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

• ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials

• ASTM F1886/F1886M-16 Standard test method for determining integrity of seals for flexible packaging by visual inspection

• ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages

• ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration

• ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices

• EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness

• EN 17141:2020 Cleanrooms and associated controlled environments - Biocontamination control - Part 1 : General principles and methods

• EN ISO 80369-7:2017 Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications

• MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI

• MDCG-2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI

• MDCG-2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance

• MDCG 2020-5 Guidance on Clinical Evaluation

•IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation

• MEDDEV 2.12-1 Rev8 2013+Additional Guidance on MEDDEV 2.12/1 Rev.8 July 2019 Guidelines on a medical devices vigilance system

• MEDDEV 2.7.1 Rev 4 Clinical evaluation: a guide for manufacturers and notified bodies

• ISO/TR 20416 Medical devices — Post-market surveillance for manufacturers

Attachment 2 Catalogue Number

Specification list of Biopsy Forceps MTN-0020914

Revision History

Revision	Date	Description
A/0	2023-05-18	Initial
A/1	2023-09-13	Add EU Authorized Representative's SRN.
A/2	2023-09-15	Translate into multiple languages

Declaration of Conformity

Manufacturer	Micro-Tech (Nanjing) Co., Ltd.
Address	NO. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
European Representative	Shanghai International Holding Corp. GmbH (Europe)
Address	Eiffestrasse 80, 20537 Hamburg Germany
Product name	Disposable Hot Biopsy Forceps
Model Number	Please see Attachment 2
UMDNS code	11502
Classification	Class IIb (Annex IX, Rule 9 of MDD 93/42/EEC)
Conformity Assessment Route	Annex II (without II.4) of MDD 93/42/EEC

We herewith declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable Directives:

Medical Device Directive: Council Directive 93/42/EEC

Standard Applied:

- EN ISO13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices

The detail harmonized standards see Attachment 1.

Notified Body:	SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium
Identification number:	CE 1639
Certificate Number :	CN19/41071
Expire date of the certificate:	2028-12-31
Place, Date of Certificate:	Nanjing, 2009-01-09

Signature: Frank Liu **Date** 2023-07-27

Name: Frank Liu

Position: Management Representative

Attachment 1

✧ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

✧ EN ISO13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes

✧ EN ISO 15223-1: 2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

✧ EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices

✧ ISO 10993-1: 2020 Biological evaluation of medical devices - Part 1: Evaluation and testing

✧ EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

✧ EN ISO 10993-7:2008/A1: 2022 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residual

✧ EN ISO 10993-10:2013 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

✧ EN ISO 11135: 2014/A1:2019 Sterilization of health care products -Ethylene oxide —Requirements for development, validation and routine control of a sterilization process for medical devices

✧ EN ISO 11607-1:2020: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

✧ EN ISO 11607-2:2020: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

✧ ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged-Products 150lb (68kg) or less)

✧ ASTM F1140/F1140M-13, Standard Test Methods For Internal Pressurization Failure Resistance Of Unrestrained Packages.

✧ ASTM F1886/F1886M: 2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

✧ EN ISO 20417:2021 Information supplied by the manufacturer with medical devices

✧ SG5/N2R8:2007 Clinical Evaluation

✧ EN ISO 11737-1:2018 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

✧ EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of

sterility performed in the definition, validation and maintenance of a sterilization process

✧ ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

✧ EN 62366-1:2015/AMD 1:2020 Medical devices – Application of usability engineering to medical devices

✧ MEDDEV 2.7.1 (Rev. 4, 2016) Clinical evaluation: a guide for manufacturers and notified bodies

✧ MEDDEV 2.12.1 (Rev. 8, 2013) Guidelines on a medical devices vigilance system

✧ MEDDEV 2.12.2 (Rev. 2, 2012) Post market clinical follow-up studies a guide for manufacturers and notified bodies

✧ ISO 8600-1: 2015 Optics and photonics —Medical endoscopes and endotherapy devices —Part 1: General requirements

✧ EN IEC 60601-2-2:2018 Medical electrical equipment Part 2-2: Particular requirements for the safety of high frequency surgical equipment

✧ EN 60601-2-18:2015 Medical electrical equipment Part 2-18: Particular requirements for the safety of endoscopic equipment

✧ EN 60601-1-2:2015 Medical Electrical Equipment.Part 1-2: General Requirements Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

✧ EN 60601-1:2006+A12:2014 Medical Electrical Equipment- Part 1: Medical electrical equipment – general requirements for the basic safety and essential performance

Attachment 2:

Disposable Hot Biopsy Forceps Product List

No.	REF	Classification of Handle	Classification of jaws	Opening width of cup jaws (unit:mm）	Configuration Type	Configuration Needle	Diameter Of Jaws (unit:mm)	Effective length (unit:mm)
1	NHBF05-10018030	New	MIM Oval	4.5	Two Wire	without	1.8	300
2	NHBF05-10018050	New	MIM Oval	4.5	Two Wire	without	1.8	500
3	NHBF05-10018080	New	MIM Oval	4.5	Two Wire	without	1.8	800
4	NHBF05-10018100	New	MIM Oval	4.5	Two Wire	without	1.8	1000
5	NHBF05-10018120	New	MIM Oval	4.5	Two Wire	without	1.8	1200
6	NHBF05-10018160	New	MIM Oval	4.5	Two Wire	without	1.8	1600
7	NHBF05-10018180	New	MIM Oval	4.5	Two Wire	without	1.8	1800
8	NHBF05-10018200	New	MIM Oval	4.5	Two Wire	without	1.8	2000
9	NHBF05-10018230	New	MIM Oval	4.5	Two Wire	without	1.8	2300
10	NHBF05-10018260	New	MIM Oval	4.5	Two Wire	without	1.8	2600
11	NHBF05-10023030	New	MIM Oval	6.7	Two Wire	without	2.3	300
12	NHBF05-10023050	New	MIM Oval	6.7	Two Wire	without	2.3	500
13	NHBF05-10023080	New	MIM Oval	6.7	Two Wire	without	2.3	800
14	NHBF05-10023100	New	MIM Oval	6.7	Two Wire	without	2.3	1000
15	NHBF05-10023120	New	MIM Oval	6.7	Two Wire	without	2.3	1200
16	NHBF05-10023160	New	MIM Oval	6.7	Two Wire	without	2.3	1600
17	NHBF05-10023180	New	MIM Oval	6.7	Two Wire	without	2.3	1800
18	NHBF05-10023200	New	MIM Oval	6.7	Two Wire	without	2.3	2000
19	NHBF05-10023230	New	MIM Oval	6.7	Two Wire	without	2.3	2300

20	NHBF05-10023260	New	MIM Oval	6.7	Two Wire	without	2.3	2600
21	NHBF05-00030030	New	MIM Oval	8.5	Two Wire	without	3	300
22	NHBF05-00030050	New	MIM Oval	8.5	Two Wire	without	3	500
23	NHBF05-00030080	New	MIM Oval	8.5	Two Wire	without	3	800
24	NHBF05-00030100	New	MIM Oval	8.5	Two Wire	without	3	1000
25	NHBF05-00030120	New	MIM Oval	8.5	Two Wire	without	3	1200
26	NHBF05-00030160	New	MIM Oval	8.5	Two Wire	without	3	1600
27	NHBF05-00030180	New	MIM Oval	8.5	Two Wire	without	3	1800
28	NHBF05-00030200	New	MIM Oval	8.5	Two Wire	without	3	2000
29	NHBF05-00030230	New	MIM Oval	8.5	Two Wire	without	3	2300
30	NHBF05-00030260	New	MIM Oval	8.5	Two Wire	without	3	2600
31	NHBF05-10118030	New	MIM Oval	4.5	Two Wire	with	1.8	300
32	NHBF05-10118050	New	MIM Oval	4.5	Two Wire	with	1.8	500
33	NHBF05-10118080	New	MIM Oval	4.5	Two Wire	with	1.8	800
34	NHBF05-10118100	New	MIM Oval	4.5	Two Wire	with	1.8	1000
35	NHBF05-10118120	New	MIM Oval	4.5	Two Wire	with	1.8	1200
36	NHBF05-10118160	New	MIM Oval	4.5	Two Wire	with	1.8	1600
37	NHBF05-10118180	New	MIM Oval	4.5	Two Wire	with	1.8	1800
38	NHBF05-10118200	New	MIM Oval	4.5	Two Wire	with	1.8	2000
39	NHBF05-10118230	New	MIM Oval	4.5	Two Wire	with	1.8	2300
40	NHBF05-10118260	New	MIM Oval	4.5	Two Wire	with	1.8	2600
41	NHBF05-10123030	New	MIM Oval	6.7	Two Wire	with	2.3	300
42	NHBF05-10123050	New	MIM Oval	6.7	Two Wire	with	2.3	500
43	NHBF05-10123080	New	MIM Oval	6.7	Two Wire	with	2.3	800
44	NHBF05-10123100	New	MIM Oval	6.7	Two Wire	with	2.3	1000
45	NHBF05-10123120	New	MIM Oval	6.7	Two Wire	with	2.3	1200

46	NHBF05-10123160	New	MIM Oval	6.7	Two Wire	with	2.3	1600
47	NHBF05-10123180	New	MIM Oval	6.7	Two Wire	with	2.3	1800
48	NHBF05-10123200	New	MIM Oval	6.7	Two Wire	with	2.3	2000
49	NHBF05-10123230	New	MIM Oval	6.7	Two Wire	with	2.3	2300
50	NHBF05-10123260	New	MIM Oval	6.7	Two Wire	with	2.3	2600
51	NHBF05-00130030	New	MIM Oval	8.5	Two Wire	with	3	300
52	NHBF05-00130050	New	MIM Oval	8.5	Two Wire	with	3	500
53	NHBF05-00130080	New	MIM Oval	8.5	Two Wire	with	3	800
54	NHBF05-00130100	New	MIM Oval	8.5	Two Wire	with	3	1000
55	NHBF05-00130120	New	MIM Oval	8.5	Two Wire	with	3	1200
56	NHBF05-00130160	New	MIM Oval	8.5	Two Wire	with	3	1600
57	NHBF05-00130180	New	MIM Oval	8.5	Two Wire	with	3	1800
58	NHBF05-00130200	New	MIM Oval	8.5	Two Wire	with	3	2000
59	NHBF05-00130230	New	MIM Oval	8.5	Two Wire	with	3	2300
60	NHBF05-00130260	New	MIM Oval	8.5	Two Wire	with	3	2600
61	NHBF05-11018030	New	MIM Oval	4.5	Four-bar linkage	without	1.8	300
62	NHBF05-11018050	New	MIM Oval	4.5	Four-bar linkage	without	1.8	500
63	NHBF05-11018080	New	MIM Oval	4.5	Four-bar linkage	without	1.8	800
64	NHBF05-11018100	New	MIM Oval	4.5	Four-bar linkage	without	1.8	1000
65	NHBF05-11018120	New	MIM Oval	4.5	Four-bar linkage	without	1.8	1200
66	NHBF05-11018160	New	MIM Oval	4.5	Four-bar linkage	without	1.8	1600
67	NHBF05-11018180	New	MIM Oval	4.5	Four-bar linkage	without	1.8	1800
68	NHBF05-11018200	New	MIM Oval	4.5	Four-bar linkage	without	1.8	2000
69	NHBF05-11018230	New	MIM Oval	4.5	Four-bar linkage	without	1.8	2300
70	NHBF05-11018260	New	MIM Oval	4.5	Four-bar linkage	without	1.8	2600
71	NHBF05-11023030	New	MIM Oval	6.7	Four-bar linkage	without	2.3	300

72	NHBF05-11023050	New	MIM Oval	6.7	Four-bar linkage	without	2.3	500
73	NHBF05-11023080	New	MIM Oval	6.7	Four-bar linkage	without	2.3	800
74	NHBF05-11023100	New	MIM Oval	6.7	Four-bar linkage	without	2.3	1000
75	NHBF05-11023120	New	MIM Oval	6.7	Four-bar linkage	without	2.3	1200
76	NHBF05-11023160	New	MIM Oval	6.7	Four-bar linkage	without	2.3	1600
77	NHBF05-11023180	New	MIM Oval	6.7	Four-bar linkage	without	2.3	1800
78	NHBF05-11023200	New	MIM Oval	6.7	Four-bar linkage	without	2.3	2000
79	NHBF05-11023230	New	MIM Oval	6.7	Four-bar linkage	without	2.3	2300
80	NHBF05-11023260	New	MIM Oval	6.7	Four-bar linkage	without	2.3	2600
81	NHBF05-01030030	New	MIM Oval	8.5	Four-bar linkage	without	3	300
82	NHBF05-01030050	New	MIM Oval	8.5	Four-bar linkage	without	3	500
83	NHBF05-01030080	New	MIM Oval	8.5	Four-bar linkage	without	3	800
84	NHBF05-01030100	New	MIM Oval	8.5	Four-bar linkage	without	3	1000
85	NHBF05-01030120	New	MIM Oval	8.5	Four-bar linkage	without	3	1200
86	NHBF05-01030160	New	MIM Oval	8.5	Four-bar linkage	without	3	1600
87	NHBF05-01030180	New	MIM Oval	8.5	Four-bar linkage	without	3	1800
88	NHBF05-01030200	New	MIM Oval	8.5	Four-bar linkage	without	3	2000
89	NHBF05-01030230	New	MIM Oval	8.5	Four-bar linkage	without	3	2300
90	NHBF05-01030260	New	MIM Oval	8.5	Four-bar linkage	without	3	2600
91	NHBF05-11118030	New	MIM Oval	4.5	Four-bar linkage	with	1.8	300
92	NHBF05-11118050	New	MIM Oval	4.5	Four-bar linkage	with	1.8	500
93	NHBF05-11118080	New	MIM Oval	4.5	Four-bar linkage	with	1.8	800
94	NHBF05-11118100	New	MIM Oval	4.5	Four-bar linkage	with	1.8	1000
95	NHBF05-11118120	New	MIM Oval	4.5	Four-bar linkage	with	1.8	1200
96	NHBF05-11118160	New	MIM Oval	4.5	Four-bar linkage	with	1.8	1600
97	NHBF05-11118180	New	MIM Oval	4.5	Four-bar linkage	with	1.8	1800

98	NHBF05-11118200	New	MIM Oval	4.5	Four-bar linkage	with	1.8	2000
99	NHBF05-11118230	New	MIM Oval	4.5	Four-bar linkage	with	1.8	2300
100	NHBF05-11118260	New	MIM Oval	4.5	Four-bar linkage	with	1.8	2600
101	NHBF05-11123030	New	MIM Oval	6.7	Four-bar linkage	with	2.3	300
102	NHBF05-11123050	New	MIM Oval	6.7	Four-bar linkage	with	2.3	500
103	NHBF05-11123080	New	MIM Oval	6.7	Four-bar linkage	with	2.3	800
104	NHBF05-11123100	New	MIM Oval	6.7	Four-bar linkage	with	2.3	1000
105	NHBF05-11123120	New	MIM Oval	6.7	Four-bar linkage	with	2.3	1200
106	NHBF05-11123160	New	MIM Oval	6.7	Four-bar linkage	with	2.3	1600
107	NHBF05-11123180	New	MIM Oval	6.7	Four-bar linkage	with	2.3	1800
108	NHBF05-11123200	New	MIM Oval	6.7	Four-bar linkage	with	2.3	2000
109	NHBF05-11123230	New	MIM Oval	6.7	Four-bar linkage	with	2.3	2300
110	NHBF05-11123260	New	MIM Oval	6.7	Four-bar linkage	with	2.3	2600
111	NHBF05-01130030	New	MIM Oval	8.5	Four-bar linkage	with	3	300
112	NHBF05-01130050	New	MIM Oval	8.5	Four-bar linkage	with	3	500
113	NHBF05-01130080	New	MIM Oval	8.5	Four-bar linkage	with	3	800
114	NHBF05-01130100	New	MIM Oval	8.5	Four-bar linkage	with	3	1000
115	NHBF05-01130120	New	MIM Oval	8.5	Four-bar linkage	with	3	1200
116	NHBF05-01130160	New	MIM Oval	8.5	Four-bar linkage	with	3	1600
117	NHBF05-01130180	New	MIM Oval	8.5	Four-bar linkage	with	3	1800
118	NHBF05-01130200	New	MIM Oval	8.5	Four-bar linkage	with	3	2000
119	NHBF05-01130230	New	MIM Oval	8.5	Four-bar linkage	with	3	2300
120	NHBF05-01130260	New	MIM Oval	8.5	Four-bar linkage	with	3	2600
121	NHBF15-10018030	New	MIM Alligator	4.5	Two Wire	without	1.8	300
122	NHBF15-10018050	New	MIM Alligator	4.5	Two Wire	without	1.8	500
123	NHBF15-10018080	New	MIM Alligator	4.5	Two Wire	without	1.8	800

124	NHBF15-10018100	New	MIM Alligator	4.5	Two Wire	without	1.8	1000
125	NHBF15-10018120	New	MIM Alligator	4.5	Two Wire	without	1.8	1200
126	NHBF15-10018160	New	MIM Alligator	4.5	Two Wire	without	1.8	1600
127	NHBF15-10018180	New	MIM Alligator	4.5	Two Wire	without	1.8	1800
128	NHBF15-10018200	New	MIM Alligator	4.5	Two Wire	without	1.8	2000
129	NHBF15-10018230	New	MIM Alligator	4.5	Two Wire	without	1.8	2300
130	NHBF15-10018260	New	MIM Alligator	4.5	Two Wire	without	1.8	2600
131	NHBF15-10023030	New	MIM Alligator	6.7	Two Wire	without	2.3	300
132	NHBF15-10023050	New	MIM Alligator	6.7	Two Wire	without	2.3	500
133	NHBF15-10023080	New	MIM Alligator	6.7	Two Wire	without	2.3	800
134	NHBF15-10023100	New	MIM Alligator	6.7	Two Wire	without	2.3	1000
135	NHBF15-10023120	New	MIM Alligator	6.7	Two Wire	without	2.3	1200
136	NHBF15-10023160	New	MIM Alligator	6.7	Two Wire	without	2.3	1600
137	NHBF15-10023180	New	MIM Alligator	6.7	Two Wire	without	2.3	1800
138	NHBF15-10023200	New	MIM Alligator	6.7	Two Wire	without	2.3	2000
139	NHBF15-10023230	New	MIM Alligator	6.7	Two Wire	without	2.3	2300
140	NHBF15-10023260	New	MIM Alligator	6.7	Two Wire	without	2.3	2600
141	NHBF15-00030030	New	MIM Alligator	8.5	Two Wire	without	3	300
142	NHBF15-00030050	New	MIM Alligator	8.5	Two Wire	without	3	500
143	NHBF15-00030080	New	MIM Alligator	8.5	Two Wire	without	3	800
144	NHBF15-00030100	New	MIM Alligator	8.5	Two Wire	without	3	1000
145	NHBF15-00030120	New	MIM Alligator	8.5	Two Wire	without	3	1200
146	NHBF15-00030160	New	MIM Alligator	8.5	Two Wire	without	3	1600
147	NHBF15-00030180	New	MIM Alligator	8.5	Two Wire	without	3	1800
148	NHBF15-00030200	New	MIM Alligator	8.5	Two Wire	without	3	2000
149	NHBF15-00030230	New	MIM Alligator	8.5	Two Wire	without	3	2300

150	NHBF15-00030260	New	MIM Alligator	8.5	Two Wire	without	3	2600
151	NHBF15-10118030	New	MIM Alligator	4.5	Two Wire	with	1.8	300
152	NHBF15-10118050	New	MIM Alligator	4.5	Two Wire	with	1.8	500
153	NHBF15-10118080	New	MIM Alligator	4.5	Two Wire	with	1.8	800
154	NHBF15-10118100	New	MIM Alligator	4.5	Two Wire	with	1.8	1000
155	NHBF15-10118120	New	MIM Alligator	4.5	Two Wire	with	1.8	1200
156	NHBF15-10118160	New	MIM Alligator	4.5	Two Wire	with	1.8	1600
157	NHBF15-10118180	New	MIM Alligator	4.5	Two Wire	with	1.8	1800
158	NHBF15-10118200	New	MIM Alligator	4.5	Two Wire	with	1.8	2000
159	NHBF15-10118230	New	MIM Alligator	4.5	Two Wire	with	1.8	2300
160	NHBF15-10118260	New	MIM Alligator	4.5	Two Wire	with	1.8	2600
161	NHBF15-10123030	New	MIM Alligator	6.7	Two Wire	with	2.3	300
162	NHBF15-10123050	New	MIM Alligator	6.7	Two Wire	with	2.3	500
163	NHBF15-10123080	New	MIM Alligator	6.7	Two Wire	with	2.3	800
164	NHBF15-10123100	New	MIM Alligator	6.7	Two Wire	with	2.3	1000
165	NHBF15-10123120	New	MIM Alligator	6.7	Two Wire	with	2.3	1200
166	NHBF15-10123160	New	MIM Alligator	6.7	Two Wire	with	2.3	1600
167	NHBF15-10123180	New	MIM Alligator	6.7	Two Wire	with	2.3	1800
168	NHBF15-10123200	New	MIM Alligator	6.7	Two Wire	with	2.3	2000
169	NHBF15-10123230	New	MIM Alligator	6.7	Two Wire	with	2.3	2300
170	NHBF15-10123260	New	MIM Alligator	6.7	Two Wire	with	2.3	2600
171	NHBF15-00130030	New	MIM Alligator	8.5	Two Wire	with	3	300
172	NHBF15-00130050	New	MIM Alligator	8.5	Two Wire	with	3	500
173	NHBF15-00130080	New	MIM Alligator	8.5	Two Wire	with	3	800
174	NHBF15-00130100	New	MIM Alligator	8.5	Two Wire	with	3	1000
175	NHBF15-00130120	New	MIM Alligator	8.5	Two Wire	with	3	1200

176	NHBF15-00130160	New	MIM Alligator	8.5	Two Wire	with	3	1600
177	NHBF15-00130180	New	MIM Alligator	8.5	Two Wire	with	3	1800
178	NHBF15-00130200	New	MIM Alligator	8.5	Two Wire	with	3	2000
179	NHBF15-00130230	New	MIM Alligator	8.5	Two Wire	with	3	2300
180	NHBF15-00130260	New	MIM Alligator	8.5	Two Wire	with	3	2600
181	NHBF15-11018030	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	300
182	NHBF15-11018050	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	500
183	NHBF15-11018080	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	800
184	NHBF15-11018100	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	1000
185	NHBF15-11018120	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	1200
186	NHBF15-11018160	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	1600
187	NHBF15-11018180	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	1800
188	NHBF15-11018200	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	2000
189	NHBF15-11018230	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	2300
190	NHBF15-11018260	New	MIM Alligator	4.5	Four-bar linkage	without	1.8	2600
191	NHBF15-11023030	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	300
192	NHBF15-11023050	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	500
193	NHBF15-11023080	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	800
194	NHBF15-11023100	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	1000
195	NHBF15-11023120	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	1200
196	NHBF15-11023160	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	1600
197	NHBF15-11023180	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	1800
198	NHBF15-11023200	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	2000
199	NHBF15-11023230	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	2300
200	NHBF15-11023260	New	MIM Alligator	6.7	Four-bar linkage	without	2.3	2600
201	NHBF15-01030030	New	MIM Alligator	8.5	Four-bar linkage	without	3	300

202	NHBF15-01030050	New	MIM Alligator	8.5	Four-bar linkage	without	3	500
203	NHBF15-01030080	New	MIM Alligator	8.5	Four-bar linkage	without	3	800
204	NHBF15-01030100	New	MIM Alligator	8.5	Four-bar linkage	without	3	1000
205	NHBF15-01030120	New	MIM Alligator	8.5	Four-bar linkage	without	3	1200
206	NHBF15-01030160	New	MIM Alligator	8.5	Four-bar linkage	without	3	1600
207	NHBF15-01030180	New	MIM Alligator	8.5	Four-bar linkage	without	3	1800
208	NHBF15-01030200	New	MIM Alligator	8.5	Four-bar linkage	without	3	2000
209	NHBF15-01030230	New	MIM Alligator	8.5	Four-bar linkage	without	3	2300
210	NHBF15-01030260	New	MIM Alligator	8.5	Four-bar linkage	without	3	2600
211	NHBF15-11118030	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	300
212	NHBF15-11118050	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	500
213	NHBF15-11118080	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	800
214	NHBF15-11118100	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	1000
215	NHBF15-11118120	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	1200
216	NHBF15-11118160	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	1600
217	NHBF15-11118180	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	1800
218	NHBF15-11118200	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	2000
219	NHBF15-11118230	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	2300
220	NHBF15-11118260	New	MIM Alligator	4.5	Four-bar linkage	with	1.8	2600
221	NHBF15-11123030	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	300
222	NHBF15-11123050	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	500
223	NHBF15-11123080	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	800
224	NHBF15-11123100	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	1000
225	NHBF15-11123120	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	1200
226	NHBF15-11123160	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	1600
227	NHBF15-11123180	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	1800

228	NHBF15-11123200	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	2000
229	NHBF15-11123230	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	2300
230	NHBF15-11123260	New	MIM Alligator	6.7	Four-bar linkage	with	2.3	2600
231	NHBF15-01130030	New	MIM Alligator	8.5	Four-bar linkage	with	3	300
232	NHBF15-01130050	New	MIM Alligator	8.5	Four-bar linkage	with	3	500
233	NHBF15-01130080	New	MIM Alligator	8.5	Four-bar linkage	with	3	800
234	NHBF15-01130100	New	MIM Alligator	8.5	Four-bar linkage	with	3	1000
235	NHBF15-01130120	New	MIM Alligator	8.5	Four-bar linkage	with	3	1200
236	NHBF15-01130160	New	MIM Alligator	8.5	Four-bar linkage	with	3	1600
237	NHBF15-01130180	New	MIM Alligator	8.5	Four-bar linkage	with	3	1800
238	NHBF15-01130200	New	MIM Alligator	8.5	Four-bar linkage	with	3	2000
239	NHBF15-01130230	New	MIM Alligator	8.5	Four-bar linkage	with	3	2300
240	NHBF15-01130260	New	MIM Alligator	8.5	Four-bar linkage	with	3	2600
241	NHBF55-10018030	New	Stamping Oval	4.5	Two Wire	without	1.8	300
242	NHBF55-10018050	New	Stamping Oval	4.5	Two Wire	without	1.8	500
243	NHBF55-10018080	New	Stamping Oval	4.5	Two Wire	without	1.8	800
244	NHBF55-10018100	New	Stamping Oval	4.5	Two Wire	without	1.8	1000
245	NHBF55-10018120	New	Stamping Oval	4.5	Two Wire	without	1.8	1200
246	NHBF55-10018160	New	Stamping Oval	4.5	Two Wire	without	1.8	1600
247	NHBF55-10018180	New	Stamping Oval	4.5	Two Wire	without	1.8	1800
248	NHBF55-10018200	New	Stamping Oval	4.5	Two Wire	without	1.8	2000
249	NHBF55-10018230	New	Stamping Oval	4.5	Two Wire	without	1.8	2300
250	NHBF55-10018260	New	Stamping Oval	4.5	Two Wire	without	1.8	2600
251	NHBF55-10023030	New	Stamping Oval	6.7	Two Wire	without	2.3	300
252	NHBF55-10023050	New	Stamping Oval	6.7	Two Wire	without	2.3	500
253	NHBF55-10023080	New	Stamping Oval	6.7	Two Wire	without	2.3	800

254	NHBF55-10023100	New	Stamping Oval	6.7	Two Wire	without	2.3	1000
255	NHBF55-10023120	New	Stamping Oval	6.7	Two Wire	without	2.3	1200
256	NHBF55-10023160	New	Stamping Oval	6.7	Two Wire	without	2.3	1600
257	NHBF55-10023180	New	Stamping Oval	6.7	Two Wire	without	2.3	1800
258	NHBF55-10023200	New	Stamping Oval	6.7	Two Wire	without	2.3	2000
259	NHBF55-10023230	New	Stamping Oval	6.7	Two Wire	without	2.3	2300
260	NHBF55-10023260	New	Stamping Oval	6.7	Two Wire	without	2.3	2600
261	NHBF55-00030030	New	Stamping Oval	8.5	Two Wire	without	3	300
262	NHBF55-00030050	New	Stamping Oval	8.5	Two Wire	without	3	500
263	NHBF55-00030080	New	Stamping Oval	8.5	Two Wire	without	3	800
264	NHBF55-00030100	New	Stamping Oval	8.5	Two Wire	without	3	1000
265	NHBF55-00030120	New	Stamping Oval	8.5	Two Wire	without	3	1200
266	NHBF55-00030160	New	Stamping Oval	8.5	Two Wire	without	3	1600
267	NHBF55-00030180	New	Stamping Oval	8.5	Two Wire	without	3	1800
268	NHBF55-00030200	New	Stamping Oval	8.5	Two Wire	without	3	2000
269	NHBF55-00030230	New	Stamping Oval	8.5	Two Wire	without	3	2300
270	NHBF55-00030260	New	Stamping Oval	8.5	Two Wire	without	3	2600
271	NHBF55-10118030	New	Stamping Oval	4.5	Two Wire	with	1.8	300
272	NHBF55-10118050	New	Stamping Oval	4.5	Two Wire	with	1.8	500
273	NHBF55-10118080	New	Stamping Oval	4.5	Two Wire	with	1.8	800
274	NHBF55-10118100	New	Stamping Oval	4.5	Two Wire	with	1.8	1000
275	NHBF55-10118120	New	Stamping Oval	4.5	Two Wire	with	1.8	1200
276	NHBF55-10118160	New	Stamping Oval	4.5	Two Wire	with	1.8	1600
277	NHBF55-10118180	New	Stamping Oval	4.5	Two Wire	with	1.8	1800
278	NHBF55-10118200	New	Stamping Oval	4.5	Two Wire	with	1.8	2000
279	NHBF55-10118230	New	Stamping Oval	4.5	Two Wire	with	1.8	2300

280	NHBF55-10118260	New	Stamping Oval	4.5	Two Wire	with	1.8	2600
281	NHBF55-10123030	New	Stamping Oval	6.7	Two Wire	with	2.3	300
282	NHBF55-10123050	New	Stamping Oval	6.7	Two Wire	with	2.3	500
283	NHBF55-10123080	New	Stamping Oval	6.7	Two Wire	with	2.3	800
284	NHBF55-10123100	New	Stamping Oval	6.7	Two Wire	with	2.3	1000
285	NHBF55-10123120	New	Stamping Oval	6.7	Two Wire	with	2.3	1200
286	NHBF55-10123160	New	Stamping Oval	6.7	Two Wire	with	2.3	1600
287	NHBF55-10123180	New	Stamping Oval	6.7	Two Wire	with	2.3	1800
288	NHBF55-10123200	New	Stamping Oval	6.7	Two Wire	with	2.3	2000
289	NHBF55-10123230	New	Stamping Oval	6.7	Two Wire	with	2.3	2300
290	NHBF55-10123260	New	Stamping Oval	6.7	Two Wire	with	2.3	2600
291	NHBF55-00130030	New	Stamping Oval	8.5	Two Wire	with	3	300
292	NHBF55-00130050	New	Stamping Oval	8.5	Two Wire	with	3	500
293	NHBF55-00130080	New	Stamping Oval	8.5	Two Wire	with	3	800
294	NHBF55-00130100	New	Stamping Oval	8.5	Two Wire	with	3	1000
295	NHBF55-00130120	New	Stamping Oval	8.5	Two Wire	with	3	1200
296	NHBF55-00130160	New	Stamping Oval	8.5	Two Wire	with	3	1600
297	NHBF55-00130180	New	Stamping Oval	8.5	Two Wire	with	3	1800
298	NHBF55-00130200	New	Stamping Oval	8.5	Two Wire	with	3	2000
299	NHBF55-00130230	New	Stamping Oval	8.5	Two Wire	with	3	2300
300	NHBF55-00130260	New	Stamping Oval	8.5	Two Wire	with	3	2600
301	NHBF55-11018030	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	300
302	NHBF55-11018050	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	500
303	NHBF55-11018080	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	800
304	NHBF55-11018100	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	1000
305	NHBF55-11018120	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	1200

306	NHBF55-11018160	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	1600
307	NHBF55-11018180	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	1800
308	NHBF55-11018200	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	2000
309	NHBF55-11018230	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	2300
310	NHBF55-11018260	New	Stamping Oval	4.5	Four-bar linkage	without	1.8	2600
311	NHBF55-11023030	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	300
312	NHBF55-11023050	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	500
313	NHBF55-11023080	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	800
314	NHBF55-11023100	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	1000
315	NHBF55-11023120	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	1200
316	NHBF55-11023160	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	1600
317	NHBF55-11023180	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	1800
318	NHBF55-11023200	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	2000
319	NHBF55-11023230	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	2300
320	NHBF55-11023260	New	Stamping Oval	6.7	Four-bar linkage	without	2.3	2600
321	NHBF55-01030030	New	Stamping Oval	8.5	Four-bar linkage	without	3	300
322	NHBF55-01030050	New	Stamping Oval	8.5	Four-bar linkage	without	3	500
323	NHBF55-01030080	New	Stamping Oval	8.5	Four-bar linkage	without	3	800
324	NHBF55-01030100	New	Stamping Oval	8.5	Four-bar linkage	without	3	1000
325	NHBF55-01030120	New	Stamping Oval	8.5	Four-bar linkage	without	3	1200
326	NHBF55-01030160	New	Stamping Oval	8.5	Four-bar linkage	without	3	1600
327	NHBF55-01030180	New	Stamping Oval	8.5	Four-bar linkage	without	3	1800
328	NHBF55-01030200	New	Stamping Oval	8.5	Four-bar linkage	without	3	2000
329	NHBF55-01030230	New	Stamping Oval	8.5	Four-bar linkage	without	3	2300
330	NHBF55-01030260	New	Stamping Oval	8.5	Four-bar linkage	without	3	2600
331	NHBF55-11118030	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	300

332	NHBF55-11118050	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	500
333	NHBF55-11118080	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	800
334	NHBF55-11118100	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	1000
335	NHBF55-11118120	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	1200
336	NHBF55-11118160	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	1600
337	NHBF55-11118180	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	1800
338	NHBF55-11118200	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	2000
339	NHBF55-11118230	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	2300
340	NHBF55-11118260	New	Stamping Oval	4.5	Four-bar linkage	with	1.8	2600
341	NHBF55-11123030	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	300
342	NHBF55-11123050	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	500
343	NHBF55-11123080	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	800
344	NHBF55-11123100	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	1000
345	NHBF55-11123120	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	1200
346	NHBF55-11123160	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	1600
347	NHBF55-11123180	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	1800
348	NHBF55-11123200	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	2000
349	NHBF55-11123230	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	2300
350	NHBF55-11123260	New	Stamping Oval	6.7	Four-bar linkage	with	2.3	2600
351	NHBF55-01130030	New	Stamping Oval	8.5	Four-bar linkage	with	3	300
352	NHBF55-01130050	New	Stamping Oval	8.5	Four-bar linkage	with	3	500
353	NHBF55-01130080	New	Stamping Oval	8.5	Four-bar linkage	with	3	800
354	NHBF55-01130100	New	Stamping Oval	8.5	Four-bar linkage	with	3	1000
355	NHBF55-01130120	New	Stamping Oval	8.5	Four-bar linkage	with	3	1200
356	NHBF55-01130160	New	Stamping Oval	8.5	Four-bar linkage	with	3	1600
357	NHBF55-01130180	New	Stamping Oval	8.5	Four-bar linkage	with	3	1800

358	NHBF55-01130200	New	Stamping Oval	8.5	Four-bar linkage	with	3	2000
359	NHBF55-01130230	New	Stamping Oval	8.5	Four-bar linkage	with	3	2300
360	NHBF55-01130260	New	Stamping Oval	8.5	Four-bar linkage	with	3	2600
361	NHBF65-10018030	New	Stamping Alligator	4.5	Two Wire	without	1.8	300
362	NHBF65-10018050	New	Stamping Alligator	4.5	Two Wire	without	1.8	500
363	NHBF65-10018080	New	Stamping Alligator	4.5	Two Wire	without	1.8	800
364	NHBF65-10018100	New	Stamping Alligator	4.5	Two Wire	without	1.8	1000
365	NHBF65-10018120	New	Stamping Alligator	4.5	Two Wire	without	1.8	1200
366	NHBF65-10018160	New	Stamping Alligator	4.5	Two Wire	without	1.8	1600
367	NHBF65-10018180	New	Stamping Alligator	4.5	Two Wire	without	1.8	1800
368	NHBF65-10018200	New	Stamping Alligator	4.5	Two Wire	without	1.8	2000
369	NHBF65-10018230	New	Stamping Alligator	4.5	Two Wire	without	1.8	2300
370	NHBF65-10018260	New	Stamping Alligator	4.5	Two Wire	without	1.8	2600
371	NHBF65-10023030	New	Stamping Alligator	6.7	Two Wire	without	2.3	300
372	NHBF65-10023050	New	Stamping Alligator	6.7	Two Wire	without	2.3	500
373	NHBF65-10023080	New	Stamping Alligator	6.7	Two Wire	without	2.3	800
374	NHBF65-10023100	New	Stamping Alligator	6.7	Two Wire	without	2.3	1000
375	NHBF65-10023120	New	Stamping Alligator	6.7	Two Wire	without	2.3	1200
376	NHBF65-10023160	New	Stamping Alligator	6.7	Two Wire	without	2.3	1600
377	NHBF65-10023180	New	Stamping Alligator	6.7	Two Wire	without	2.3	1800
378	NHBF65-10023200	New	Stamping Alligator	6.7	Two Wire	without	2.3	2000
379	NHBF65-10023230	New	Stamping Alligator	6.7	Two Wire	without	2.3	2300
380	NHBF65-10023260	New	Stamping Alligator	6.7	Two Wire	without	2.3	2600
381	NHBF65-00030030	New	Stamping Alligator	8.5	Two Wire	without	3	300
382	NHBF65-00030050	New	Stamping Alligator	8.5	Two Wire	without	3	500
383	NHBF65-00030080	New	Stamping Alligator	8.5	Two Wire	without	3	800

384	NHBF65-00030100	New	Stamping Alligator	8.5	Two Wire	without	3	1000
385	NHBF65-00030120	New	Stamping Alligator	8.5	Two Wire	without	3	1200
386	NHBF65-00030160	New	Stamping Alligator	8.5	Two Wire	without	3	1600
387	NHBF65-00030180	New	Stamping Alligator	8.5	Two Wire	without	3	1800
388	NHBF65-00030200	New	Stamping Alligator	8.5	Two Wire	without	3	2000
389	NHBF65-00030230	New	Stamping Alligator	8.5	Two Wire	without	3	2300
390	NHBF65-00030260	New	Stamping Alligator	8.5	Two Wire	without	3	2600
391	NHBF65-10118030	New	Stamping Alligator	4.5	Two Wire	with	1.8	300
392	NHBF65-10118050	New	Stamping Alligator	4.5	Two Wire	with	1.8	500
393	NHBF65-10118080	New	Stamping Alligator	4.5	Two Wire	with	1.8	800
394	NHBF65-10118100	New	Stamping Alligator	4.5	Two Wire	with	1.8	1000
395	NHBF65-10118120	New	Stamping Alligator	4.5	Two Wire	with	1.8	1200
396	NHBF65-10118160	New	Stamping Alligator	4.5	Two Wire	with	1.8	1600
397	NHBF65-10118180	New	Stamping Alligator	4.5	Two Wire	with	1.8	1800
398	NHBF65-10118200	New	Stamping Alligator	4.5	Two Wire	with	1.8	2000
399	NHBF65-10118230	New	Stamping Alligator	4.5	Two Wire	with	1.8	2300
400	NHBF65-10118260	New	Stamping Alligator	4.5	Two Wire	with	1.8	2600
401	NHBF65-10123030	New	Stamping Alligator	6.7	Two Wire	with	2.3	300
402	NHBF65-10123050	New	Stamping Alligator	6.7	Two Wire	with	2.3	500
403	NHBF65-10123080	New	Stamping Alligator	6.7	Two Wire	with	2.3	800
404	NHBF65-10123100	New	Stamping Alligator	6.7	Two Wire	with	2.3	1000
405	NHBF65-10123120	New	Stamping Alligator	6.7	Two Wire	with	2.3	1200
406	NHBF65-10123160	New	Stamping Alligator	6.7	Two Wire	with	2.3	1600
407	NHBF65-10123180	New	Stamping Alligator	6.7	Two Wire	with	2.3	1800
408	NHBF65-10123200	New	Stamping Alligator	6.7	Two Wire	with	2.3	2000
409	NHBF65-10123230	New	Stamping Alligator	6.7	Two Wire	with	2.3	2300

410	NHBF65-10123260	New	Stamping Alligator	6.7	Two Wire	with	2.3	2600
411	NHBF65-00130030	New	Stamping Alligator	8.5	Two Wire	with	3	300
412	NHBF65-00130050	New	Stamping Alligator	8.5	Two Wire	with	3	500
413	NHBF65-00130080	New	Stamping Alligator	8.5	Two Wire	with	3	800
414	NHBF65-00130100	New	Stamping Alligator	8.5	Two Wire	with	3	1000
415	NHBF65-00130120	New	Stamping Alligator	8.5	Two Wire	with	3	1200
416	NHBF65-00130160	New	Stamping Alligator	8.5	Two Wire	with	3	1600
417	NHBF65-00130180	New	Stamping Alligator	8.5	Two Wire	with	3	1800
418	NHBF65-00130200	New	Stamping Alligator	8.5	Two Wire	with	3	2000
419	NHBF65-00130230	New	Stamping Alligator	8.5	Two Wire	with	3	2300
420	NHBF65-00130260	New	Stamping Alligator	8.5	Two Wire	with	3	2600
421	NHBF65-11018030	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	300
422	NHBF65-11018050	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	500
423	NHBF65-11018080	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	800
424	NHBF65-11018100	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1000
425	NHBF65-11018120	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1200
426	NHBF65-11018160	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1600
427	NHBF65-11018180	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1800
428	NHBF65-11018200	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	2000
429	NHBF65-11018230	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	2300
430	NHBF65-11018260	New	Stamping Alligator	4.5	Four-bar linkage	without	1.8	2600
431	NHBF65-11023030	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	300
432	NHBF65-11023050	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	500
433	NHBF65-11023080	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	800
434	NHBF65-11023100	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1000
435	NHBF65-11023120	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1200

436	NHBF65-11023160	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1600
437	NHBF65-11023180	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1800
438	NHBF65-11023200	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	2000
439	NHBF65-11023230	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	2300
440	NHBF65-11023260	New	Stamping Alligator	6.7	Four-bar linkage	without	2.3	2600
441	NHBF65-01030030	New	Stamping Alligator	8.5	Four-bar linkage	without	3	300
442	NHBF65-01030050	New	Stamping Alligator	8.5	Four-bar linkage	without	3	500
443	NHBF65-01030080	New	Stamping Alligator	8.5	Four-bar linkage	without	3	800
444	NHBF65-01030100	New	Stamping Alligator	8.5	Four-bar linkage	without	3	1000
445	NHBF65-01030120	New	Stamping Alligator	8.5	Four-bar linkage	without	3	1200
446	NHBF65-01030160	New	Stamping Alligator	8.5	Four-bar linkage	without	3	1600
447	NHBF65-01030180	New	Stamping Alligator	8.5	Four-bar linkage	without	3	1800
448	NHBF65-01030200	New	Stamping Alligator	8.5	Four-bar linkage	without	3	2000
449	NHBF65-01030230	New	Stamping Alligator	8.5	Four-bar linkage	without	3	2300
450	NHBF65-01030260	New	Stamping Alligator	8.5	Four-bar linkage	without	3	2600
451	NHBF65-11118030	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	300
452	NHBF65-11118050	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	500
453	NHBF65-11118080	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	800
454	NHBF65-11118100	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1000
455	NHBF65-11118120	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1200
456	NHBF65-11118160	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1600
457	NHBF65-11118180	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1800
458	NHBF65-11118200	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	2000
459	NHBF65-11118230	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	2300
460	NHBF65-11118260	New	Stamping Alligator	4.5	Four-bar linkage	with	1.8	2600
461	NHBF65-11123030	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	300

462	NHBF65-11123050	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	500
463	NHBF65-11123080	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	800
464	NHBF65-11123100	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1000
465	NHBF65-11123120	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1200
466	NHBF65-11123160	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1600
467	NHBF65-11123180	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1800
468	NHBF65-11123200	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	2000
469	NHBF65-11123230	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	2300
470	NHBF65-11123260	New	Stamping Alligator	6.7	Four-bar linkage	with	2.3	2600
471	NHBF65-01130030	New	Stamping Alligator	8.5	Four-bar linkage	with	3	300
472	NHBF65-01130050	New	Stamping Alligator	8.5	Four-bar linkage	with	3	500
473	NHBF65-01130080	New	Stamping Alligator	8.5	Four-bar linkage	with	3	800
474	NHBF65-01130100	New	Stamping Alligator	8.5	Four-bar linkage	with	3	1000
475	NHBF65-01130120	New	Stamping Alligator	8.5	Four-bar linkage	with	3	1200
476	NHBF65-01130160	New	Stamping Alligator	8.5	Four-bar linkage	with	3	1600
477	NHBF65-01130180	New	Stamping Alligator	8.5	Four-bar linkage	with	3	1800
478	NHBF65-01130200	New	Stamping Alligator	8.5	Four-bar linkage	with	3	2000
479	NHBF65-01130230	New	Stamping Alligator	8.5	Four-bar linkage	with	3	2300
480	NHBF65-01130260	New	Stamping Alligator	8.5	Four-bar linkage	with	3	2600
481	HBF05-10018030	Normal	MIM Oval	4.5	Two Wire	without	1.8	300
482	HBF05-10018050	Normal	MIM Oval	4.5	Two Wire	without	1.8	500
483	HBF05-10018080	Normal	MIM Oval	4.5	Two Wire	without	1.8	800
484	HBF05-10018100	Normal	MIM Oval	4.5	Two Wire	without	1.8	1000
485	HBF05-10018120	Normal	MIM Oval	4.5	Two Wire	without	1.8	1200
486	HBF05-10018160	Normal	MIM Oval	4.5	Two Wire	without	1.8	1600
487	HBF05-10018180	Normal	MIM Oval	4.5	Two Wire	without	1.8	1800

488	HBF05-10018200	Normal	MIM Oval	4.5	Two Wire	without	1.8	2000
489	HBF05-10018230	Normal	MIM Oval	4.5	Two Wire	without	1.8	2300
490	HBF05-10018260	Normal	MIM Oval	4.5	Two Wire	without	1.8	2600
491	HBF05-10023030	Normal	MIM Oval	6.7	Two Wire	without	2.3	300
492	HBF05-10023050	Normal	MIM Oval	6.7	Two Wire	without	2.3	500
493	HBF05-10023080	Normal	MIM Oval	6.7	Two Wire	without	2.3	800
494	HBF05-10023100	Normal	MIM Oval	6.7	Two Wire	without	2.3	1000
495	HBF05-10023120	Normal	MIM Oval	6.7	Two Wire	without	2.3	1200
496	HBF05-10023160	Normal	MIM Oval	6.7	Two Wire	without	2.3	1600
497	HBF05-10023180	Normal	MIM Oval	6.7	Two Wire	without	2.3	1800
498	HBF05-10023200	Normal	MIM Oval	6.7	Two Wire	without	2.3	2000
499	HBF05-10023230	Normal	MIM Oval	6.7	Two Wire	without	2.3	2300
500	HBF05-10023260	Normal	MIM Oval	6.7	Two Wire	without	2.3	2600
501	HBF05-00030030	Normal	MIM Oval	8.5	Two Wire	without	3	300
502	HBF05-00030050	Normal	MIM Oval	8.5	Two Wire	without	3	500
503	HBF05-00030080	Normal	MIM Oval	8.5	Two Wire	without	3	800
504	HBF05-00030100	Normal	MIM Oval	8.5	Two Wire	without	3	1000
505	HBF05-00030120	Normal	MIM Oval	8.5	Two Wire	without	3	1200
506	HBF05-00030160	Normal	MIM Oval	8.5	Two Wire	without	3	1600
507	HBF05-00030180	Normal	MIM Oval	8.5	Two Wire	without	3	1800
508	HBF05-00030200	Normal	MIM Oval	8.5	Two Wire	without	3	2000
509	HBF05-00030230	Normal	MIM Oval	8.5	Two Wire	without	3	2300
510	HBF05-00030260	Normal	MIM Oval	8.5	Two Wire	without	3	2600
511	HBF05-10118030	Normal	MIM Oval	4.5	Two Wire	with	1.8	300
512	HBF05-10118050	Normal	MIM Oval	4.5	Two Wire	with	1.8	500
513	HBF05-10118080	Normal	MIM Oval	4.5	Two Wire	with	1.8	800

514	HBF05-10118100	Normal	MIM Oval	4.5	Two Wire	with	1.8	1000
515	HBF05-10118120	Normal	MIM Oval	4.5	Two Wire	with	1.8	1200
516	HBF05-10118160	Normal	MIM Oval	4.5	Two Wire	with	1.8	1600
517	HBF05-10118180	Normal	MIM Oval	4.5	Two Wire	with	1.8	1800
518	HBF05-10118200	Normal	MIM Oval	4.5	Two Wire	with	1.8	2000
519	HBF05-10118230	Normal	MIM Oval	4.5	Two Wire	with	1.8	2300
520	HBF05-10118260	Normal	MIM Oval	4.5	Two Wire	with	1.8	2600
521	HBF05-10123030	Normal	MIM Oval	6.7	Two Wire	with	2.3	300
522	HBF05-10123050	Normal	MIM Oval	6.7	Two Wire	with	2.3	500
523	HBF05-10123080	Normal	MIM Oval	6.7	Two Wire	with	2.3	800
524	HBF05-10123100	Normal	MIM Oval	6.7	Two Wire	with	2.3	1000
525	HBF05-10123120	Normal	MIM Oval	6.7	Two Wire	with	2.3	1200
526	HBF05-10123160	Normal	MIM Oval	6.7	Two Wire	with	2.3	1600
527	HBF05-10123180	Normal	MIM Oval	6.7	Two Wire	with	2.3	1800
528	HBF05-10123200	Normal	MIM Oval	6.7	Two Wire	with	2.3	2000
529	HBF05-10123230	Normal	MIM Oval	6.7	Two Wire	with	2.3	2300
530	HBF05-10123260	Normal	MIM Oval	6.7	Two Wire	with	2.3	2600
531	HBF05-00130030	Normal	MIM Oval	8.5	Two Wire	with	3	300
532	HBF05-00130050	Normal	MIM Oval	8.5	Two Wire	with	3	500
533	HBF05-00130080	Normal	MIM Oval	8.5	Two Wire	with	3	800
534	HBF05-00130100	Normal	MIM Oval	8.5	Two Wire	with	3	1000
535	HBF05-00130120	Normal	MIM Oval	8.5	Two Wire	with	3	1200
536	HBF05-00130160	Normal	MIM Oval	8.5	Two Wire	with	3	1600
537	HBF05-00130180	Normal	MIM Oval	8.5	Two Wire	with	3	1800
538	HBF05-00130200	Normal	MIM Oval	8.5	Two Wire	with	3	2000
539	HBF05-00130230	Normal	MIM Oval	8.5	Two Wire	with	3	2300

540	HBF05-00130260	Normal	MIM Oval	8.5	Two Wire	with	3	2600
541	HBF05-11018030	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	300
542	HBF05-11018050	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	500
543	HBF05-11018080	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	800
544	HBF05-11018100	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	1000
545	HBF05-11018120	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	1200
546	HBF05-11018160	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	1600
547	HBF05-11018180	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	1800
548	HBF05-11018200	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	2000
549	HBF05-11018230	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	2300
550	HBF05-11018260	Normal	MIM Oval	4.5	Four-bar linkage	without	1.8	2600
551	HBF05-11023030	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	300
552	HBF05-11023050	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	500
553	HBF05-11023080	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	800
554	HBF05-11023100	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	1000
555	HBF05-11023120	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	1200
556	HBF05-11023160	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	1600
557	HBF05-11023180	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	1800
558	HBF05-11023200	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	2000
559	HBF05-11023230	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	2300
560	HBF05-11023260	Normal	MIM Oval	6.7	Four-bar linkage	without	2.3	2600
561	HBF05-01030030	Normal	MIM Oval	8.5	Four-bar linkage	without	3	300
562	HBF05-01030050	Normal	MIM Oval	8.5	Four-bar linkage	without	3	500
563	HBF05-01030080	Normal	MIM Oval	8.5	Four-bar linkage	without	3	800
564	HBF05-01030100	Normal	MIM Oval	8.5	Four-bar linkage	without	3	1000
565	HBF05-01030120	Normal	MIM Oval	8.5	Four-bar linkage	without	3	1200

566	HBF05-01030160	Normal	MIM Oval	8.5	Four-bar linkage	without	3	1600
567	HBF05-01030180	Normal	MIM Oval	8.5	Four-bar linkage	without	3	1800
568	HBF05-01030200	Normal	MIM Oval	8.5	Four-bar linkage	without	3	2000
569	HBF05-01030230	Normal	MIM Oval	8.5	Four-bar linkage	without	3	2300
570	HBF05-01030260	Normal	MIM Oval	8.5	Four-bar linkage	without	3	2600
571	HBF05-11118030	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	300
572	HBF05-11118050	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	500
573	HBF05-11118080	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	800
574	HBF05-11118100	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	1000
575	HBF05-11118120	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	1200
576	HBF05-11118160	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	1600
577	HBF05-11118180	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	1800
578	HBF05-11118200	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	2000
579	HBF05-11118230	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	2300
580	HBF05-11118260	Normal	MIM Oval	4.5	Four-bar linkage	with	1.8	2600
581	HBF05-11123030	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	300
582	HBF05-11123050	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	500
583	HBF05-11123080	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	800
584	HBF05-11123100	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	1000
585	HBF05-11123120	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	1200
586	HBF05-11123160	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	1600
587	HBF05-11123180	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	1800
588	HBF05-11123200	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	2000
589	HBF05-11123230	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	2300
590	HBF05-11123260	Normal	MIM Oval	6.7	Four-bar linkage	with	2.3	2600
591	HBF05-01130030	Normal	MIM Oval	8.5	Four-bar linkage	with	3	300

592	HBF05-01130050	Normal	MIM Oval	8.5	Four-bar linkage	with	3	500
593	HBF05-01130080	Normal	MIM Oval	8.5	Four-bar linkage	with	3	800
594	HBF05-01130100	Normal	MIM Oval	8.5	Four-bar linkage	with	3	1000
595	HBF05-01130120	Normal	MIM Oval	8.5	Four-bar linkage	with	3	1200
596	HBF05-01130160	Normal	MIM Oval	8.5	Four-bar linkage	with	3	1600
597	HBF05-01130180	Normal	MIM Oval	8.5	Four-bar linkage	with	3	1800
598	HBF05-01130200	Normal	MIM Oval	8.5	Four-bar linkage	with	3	2000
599	HBF05-01130230	Normal	MIM Oval	8.5	Four-bar linkage	with	3	2300
600	HBF05-01130260	Normal	MIM Oval	8.5	Four-bar linkage	with	3	2600
601	HBF15-10018030	Normal	MIM Alligator	4.5	Two Wire	without	1.8	300
602	HBF15-10018050	Normal	MIM Alligator	4.5	Two Wire	without	1.8	500
603	HBF15-10018080	Normal	MIM Alligator	4.5	Two Wire	without	1.8	800
604	HBF15-10018100	Normal	MIM Alligator	4.5	Two Wire	without	1.8	1000
605	HBF15-10018120	Normal	MIM Alligator	4.5	Two Wire	without	1.8	1200
606	HBF15-10018160	Normal	MIM Alligator	4.5	Two Wire	without	1.8	1600
607	HBF15-10018180	Normal	MIM Alligator	4.5	Two Wire	without	1.8	1800
608	HBF15-10018200	Normal	MIM Alligator	4.5	Two Wire	without	1.8	2000
609	HBF15-10018230	Normal	MIM Alligator	4.5	Two Wire	without	1.8	2300
610	HBF15-10018260	Normal	MIM Alligator	4.5	Two Wire	without	1.8	2600
611	HBF15-10023030	Normal	MIM Alligator	6.7	Two Wire	without	2.3	300
612	HBF15-10023050	Normal	MIM Alligator	6.7	Two Wire	without	2.3	500
613	HBF15-10023080	Normal	MIM Alligator	6.7	Two Wire	without	2.3	800
614	HBF15-10023100	Normal	MIM Alligator	6.7	Two Wire	without	2.3	1000
615	HBF15-10023120	Normal	MIM Alligator	6.7	Two Wire	without	2.3	1200
616	HBF15-10023160	Normal	MIM Alligator	6.7	Two Wire	without	2.3	1600
617	HBF15-10023180	Normal	MIM Alligator	6.7	Two Wire	without	2.3	1800

618	HBF15-10023200	Normal	MIM Alligator	6.7	Two Wire	without	2.3	2000
619	HBF15-10023230	Normal	MIM Alligator	6.7	Two Wire	without	2.3	2300
620	HBF15-10023260	Normal	MIM Alligator	6.7	Two Wire	without	2.3	2600
621	HBF15-00030030	Normal	MIM Alligator	8.5	Two Wire	without	3	300
622	HBF15-00030050	Normal	MIM Alligator	8.5	Two Wire	without	3	500
623	HBF15-00030080	Normal	MIM Alligator	8.5	Two Wire	without	3	800
624	HBF15-00030100	Normal	MIM Alligator	8.5	Two Wire	without	3	1000
625	HBF15-00030120	Normal	MIM Alligator	8.5	Two Wire	without	3	1200
626	HBF15-00030160	Normal	MIM Alligator	8.5	Two Wire	without	3	1600
627	HBF15-00030180	Normal	MIM Alligator	8.5	Two Wire	without	3	1800
628	HBF15-00030200	Normal	MIM Alligator	8.5	Two Wire	without	3	2000
629	HBF15-00030230	Normal	MIM Alligator	8.5	Two Wire	without	3	2300
630	HBF15-00030260	Normal	MIM Alligator	8.5	Two Wire	without	3	2600
631	HBF15-10118030	Normal	MIM Alligator	4.5	Two Wire	with	1.8	300
632	HBF15-10118050	Normal	MIM Alligator	4.5	Two Wire	with	1.8	500
633	HBF15-10118080	Normal	MIM Alligator	4.5	Two Wire	with	1.8	800
634	HBF15-10118100	Normal	MIM Alligator	4.5	Two Wire	with	1.8	1000
635	HBF15-10118120	Normal	MIM Alligator	4.5	Two Wire	with	1.8	1200
636	HBF15-10118160	Normal	MIM Alligator	4.5	Two Wire	with	1.8	1600
637	HBF15-10118180	Normal	MIM Alligator	4.5	Two Wire	with	1.8	1800
638	HBF15-10118200	Normal	MIM Alligator	4.5	Two Wire	with	1.8	2000
639	HBF15-10118230	Normal	MIM Alligator	4.5	Two Wire	with	1.8	2300
640	HBF15-10118260	Normal	MIM Alligator	4.5	Two Wire	with	1.8	2600
641	HBF15-10123030	Normal	MIM Alligator	6.7	Two Wire	with	2.3	300
642	HBF15-10123050	Normal	MIM Alligator	6.7	Two Wire	with	2.3	500
643	HBF15-10123080	Normal	MIM Alligator	6.7	Two Wire	with	2.3	800

644	HBF15-10123100	Normal	MIM Alligator	6.7	Two Wire	with	2.3	1000
645	HBF15-10123120	Normal	MIM Alligator	6.7	Two Wire	with	2.3	1200
646	HBF15-10123160	Normal	MIM Alligator	6.7	Two Wire	with	2.3	1600
647	HBF15-10123180	Normal	MIM Alligator	6.7	Two Wire	with	2.3	1800
648	HBF15-10123200	Normal	MIM Alligator	6.7	Two Wire	with	2.3	2000
649	HBF15-10123230	Normal	MIM Alligator	6.7	Two Wire	with	2.3	2300
650	HBF15-10123260	Normal	MIM Alligator	6.7	Two Wire	with	2.3	2600
651	HBF15-00130030	Normal	MIM Alligator	8.5	Two Wire	with	3	300
652	HBF15-00130050	Normal	MIM Alligator	8.5	Two Wire	with	3	500
653	HBF15-00130080	Normal	MIM Alligator	8.5	Two Wire	with	3	800
654	HBF15-00130100	Normal	MIM Alligator	8.5	Two Wire	with	3	1000
655	HBF15-00130120	Normal	MIM Alligator	8.5	Two Wire	with	3	1200
656	HBF15-00130160	Normal	MIM Alligator	8.5	Two Wire	with	3	1600
657	HBF15-00130180	Normal	MIM Alligator	8.5	Two Wire	with	3	1800
658	HBF15-00130200	Normal	MIM Alligator	8.5	Two Wire	with	3	2000
659	HBF15-00130230	Normal	MIM Alligator	8.5	Two Wire	with	3	2300
660	HBF15-00130260	Normal	MIM Alligator	8.5	Two Wire	with	3	2600
661	HBF15-11018030	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	300
662	HBF15-11018050	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	500
663	HBF15-11018080	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	800
664	HBF15-11018100	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	1000
665	HBF15-11018120	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	1200
666	HBF15-11018160	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	1600
667	HBF15-11018180	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	1800
668	HBF15-11018200	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	2000
669	HBF15-11018230	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	2300

670	HBF15-11018260	Normal	MIM Alligator	4.5	Four-bar linkage	without	1.8	2600
671	HBF15-11023030	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	300
672	HBF15-11023050	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	500
673	HBF15-11023080	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	800
674	HBF15-11023100	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	1000
675	HBF15-11023120	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	1200
676	HBF15-11023160	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	1600
677	HBF15-11023180	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	1800
678	HBF15-11023200	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	2000
679	HBF15-11023230	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	2300
680	HBF15-11023260	Normal	MIM Alligator	6.7	Four-bar linkage	without	2.3	2600
681	HBF15-01030030	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	300
682	HBF15-01030050	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	500
683	HBF15-01030080	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	800
684	HBF15-01030100	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	1000
685	HBF15-01030120	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	1200
686	HBF15-01030160	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	1600
687	HBF15-01030180	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	1800
688	HBF15-01030200	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	2000
689	HBF15-01030230	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	2300
690	HBF15-01030260	Normal	MIM Alligator	8.5	Four-bar linkage	without	3	2600
691	HBF15-11118030	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	300
692	HBF15-11118050	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	500
693	HBF15-11118080	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	800
694	HBF15-11118100	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	1000
695	HBF15-11118120	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	1200

696	HBF15-11118160	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	1600
697	HBF15-11118180	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	1800
698	HBF15-11118200	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	2000
699	HBF15-11118230	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	2300
700	HBF15-11118260	Normal	MIM Alligator	4.5	Four-bar linkage	with	1.8	2600
701	HBF15-11123030	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	300
702	HBF15-11123050	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	500
703	HBF15-11123080	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	800
704	HBF15-11123100	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	1000
705	HBF15-11123120	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	1200
706	HBF15-11123160	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	1600
707	HBF15-11123180	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	1800
708	HBF15-11123200	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	2000
709	HBF15-11123230	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	2300
710	HBF15-11123260	Normal	MIM Alligator	6.7	Four-bar linkage	with	2.3	2600
711	HBF15-01130030	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	300
712	HBF15-01130050	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	500
713	HBF15-01130080	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	800
714	HBF15-01130100	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	1000
715	HBF15-01130120	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	1200
716	HBF15-01130160	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	1600
717	HBF15-01130180	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	1800
718	HBF15-01130200	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	2000
719	HBF15-01130230	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	2300
720	HBF15-01130260	Normal	MIM Alligator	8.5	Four-bar linkage	with	3	2600
721	HBF55-10018030	Normal	Stamping Oval	4.5	Two Wire	without	1.8	300

722	HBF55-10018050	Normal	Stamping Oval	4.5	Two Wire	without	1.8	500
723	HBF55-10018080	Normal	Stamping Oval	4.5	Two Wire	without	1.8	800
724	HBF55-10018100	Normal	Stamping Oval	4.5	Two Wire	without	1.8	1000
725	HBF55-10018120	Normal	Stamping Oval	4.5	Two Wire	without	1.8	1200
726	HBF55-10018160	Normal	Stamping Oval	4.5	Two Wire	without	1.8	1600
727	HBF55-10018180	Normal	Stamping Oval	4.5	Two Wire	without	1.8	1800
728	HBF55-10018200	Normal	Stamping Oval	4.5	Two Wire	without	1.8	2000
729	HBF55-10018230	Normal	Stamping Oval	4.5	Two Wire	without	1.8	2300
730	HBF55-10018260	Normal	Stamping Oval	4.5	Two Wire	without	1.8	2600
731	HBF55-10023030	Normal	Stamping Oval	6.7	Two Wire	without	2.3	300
732	HBF55-10023050	Normal	Stamping Oval	6.7	Two Wire	without	2.3	500
733	HBF55-10023080	Normal	Stamping Oval	6.7	Two Wire	without	2.3	800
734	HBF55-10023100	Normal	Stamping Oval	6.7	Two Wire	without	2.3	1000
735	HBF55-10023120	Normal	Stamping Oval	6.7	Two Wire	without	2.3	1200
736	HBF55-10023160	Normal	Stamping Oval	6.7	Two Wire	without	2.3	1600
737	HBF55-10023180	Normal	Stamping Oval	6.7	Two Wire	without	2.3	1800
738	HBF55-10023200	Normal	Stamping Oval	6.7	Two Wire	without	2.3	2000
739	HBF55-10023230	Normal	Stamping Oval	6.7	Two Wire	without	2.3	2300
740	HBF55-10023260	Normal	Stamping Oval	6.7	Two Wire	without	2.3	2600
741	HBF55-00030030	Normal	Stamping Oval	8.5	Two Wire	without	3	300
742	HBF55-00030050	Normal	Stamping Oval	8.5	Two Wire	without	3	500
743	HBF55-00030080	Normal	Stamping Oval	8.5	Two Wire	without	3	800
744	HBF55-00030100	Normal	Stamping Oval	8.5	Two Wire	without	3	1000
745	HBF55-00030120	Normal	Stamping Oval	8.5	Two Wire	without	3	1200
746	HBF55-00030160	Normal	Stamping Oval	8.5	Two Wire	without	3	1600
747	HBF55-00030180	Normal	Stamping Oval	8.5	Two Wire	without	3	1800

748	HBF55-00030200	Normal	Stamping Oval	8.5	Two Wire	without	3	2000
749	HBF55-00030230	Normal	Stamping Oval	8.5	Two Wire	without	3	2300
750	HBF55-00030260	Normal	Stamping Oval	8.5	Two Wire	without	3	2600
751	HBF55-10118030	Normal	Stamping Oval	4.5	Two Wire	with	1.8	300
752	HBF55-10118050	Normal	Stamping Oval	4.5	Two Wire	with	1.8	500
753	HBF55-10118080	Normal	Stamping Oval	4.5	Two Wire	with	1.8	800
754	HBF55-10118100	Normal	Stamping Oval	4.5	Two Wire	with	1.8	1000
755	HBF55-10118120	Normal	Stamping Oval	4.5	Two Wire	with	1.8	1200
756	HBF55-10118160	Normal	Stamping Oval	4.5	Two Wire	with	1.8	1600
757	HBF55-10118180	Normal	Stamping Oval	4.5	Two Wire	with	1.8	1800
758	HBF55-10118200	Normal	Stamping Oval	4.5	Two Wire	with	1.8	2000
759	HBF55-10118230	Normal	Stamping Oval	4.5	Two Wire	with	1.8	2300
760	HBF55-10118260	Normal	Stamping Oval	4.5	Two Wire	with	1.8	2600
761	HBF55-10123030	Normal	Stamping Oval	6.7	Two Wire	with	2.3	300
762	HBF55-10123050	Normal	Stamping Oval	6.7	Two Wire	with	2.3	500
763	HBF55-10123080	Normal	Stamping Oval	6.7	Two Wire	with	2.3	800
764	HBF55-10123100	Normal	Stamping Oval	6.7	Two Wire	with	2.3	1000
765	HBF55-10123120	Normal	Stamping Oval	6.7	Two Wire	with	2.3	1200
766	HBF55-10123160	Normal	Stamping Oval	6.7	Two Wire	with	2.3	1600
767	HBF55-10123180	Normal	Stamping Oval	6.7	Two Wire	with	2.3	1800
768	HBF55-10123200	Normal	Stamping Oval	6.7	Two Wire	with	2.3	2000
769	HBF55-10123230	Normal	Stamping Oval	6.7	Two Wire	with	2.3	2300
770	HBF55-10123260	Normal	Stamping Oval	6.7	Two Wire	with	2.3	2600
771	HBF55-00130030	Normal	Stamping Oval	8.5	Two Wire	with	3	300
772	HBF55-00130050	Normal	Stamping Oval	8.5	Two Wire	with	3	500
773	HBF55-00130080	Normal	Stamping Oval	8.5	Two Wire	with	3	800

774	HBF55-00130100	Normal	Stamping Oval	8.5	Two Wire	with	3	1000
775	HBF55-00130120	Normal	Stamping Oval	8.5	Two Wire	with	3	1200
776	HBF55-00130160	Normal	Stamping Oval	8.5	Two Wire	with	3	1600
777	HBF55-00130180	Normal	Stamping Oval	8.5	Two Wire	with	3	1800
778	HBF55-00130200	Normal	Stamping Oval	8.5	Two Wire	with	3	2000
779	HBF55-00130230	Normal	Stamping Oval	8.5	Two Wire	with	3	2300
780	HBF55-00130260	Normal	Stamping Oval	8.5	Two Wire	with	3	2600
781	HBF55-11018030	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	300
782	HBF55-11018050	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	500
783	HBF55-11018080	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	800
784	HBF55-11018100	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	1000
785	HBF55-11018120	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	1200
786	HBF55-11018160	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	1600
787	HBF55-11018180	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	1800
788	HBF55-11018200	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	2000
789	HBF55-11018230	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	2300
790	HBF55-11018260	Normal	Stamping Oval	4.5	Four-bar linkage	without	1.8	2600
791	HBF55-11023030	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	300
792	HBF55-11023050	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	500
793	HBF55-11023080	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	800
794	HBF55-11023100	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	1000
795	HBF55-11023120	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	1200
796	HBF55-11023160	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	1600
797	HBF55-11023180	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	1800
798	HBF55-11023200	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	2000
799	HBF55-11023230	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	2300

800	HBF55-11023260	Normal	Stamping Oval	6.7	Four-bar linkage	without	2.3	2600
801	HBF55-01030030	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	300
802	HBF55-01030050	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	500
803	HBF55-01030080	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	800
804	HBF55-01030100	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	1000
805	HBF55-01030120	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	1200
806	HBF55-01030160	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	1600
807	HBF55-01030180	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	1800
808	HBF55-01030200	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	2000
809	HBF55-01030230	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	2300
810	HBF55-01030260	Normal	Stamping Oval	8.5	Four-bar linkage	without	3	2600
811	HBF55-11118030	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	300
812	HBF55-11118050	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	500
813	HBF55-11118080	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	800
814	HBF55-11118100	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	1000
815	HBF55-11118120	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	1200
816	HBF55-11118160	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	1600
817	HBF55-11118180	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	1800
818	HBF55-11118200	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	2000
819	HBF55-11118230	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	2300
820	HBF55-11118260	Normal	Stamping Oval	4.5	Four-bar linkage	with	1.8	2600
821	HBF55-11123030	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	300
822	HBF55-11123050	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	500
823	HBF55-11123080	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	800
824	HBF55-11123100	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	1000
825	HBF55-11123120	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	1200

826	HBF55-11123160	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	1600
827	HBF55-11123180	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	1800
828	HBF55-11123200	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	2000
829	HBF55-11123230	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	2300
830	HBF55-11123260	Normal	Stamping Oval	6.7	Four-bar linkage	with	2.3	2600
831	HBF55-01130030	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	300
832	HBF55-01130050	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	500
833	HBF55-01130080	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	800
834	HBF55-01130100	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	1000
835	HBF55-01130120	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	1200
836	HBF55-01130160	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	1600
837	HBF55-01130180	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	1800
838	HBF55-01130200	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	2000
839	HBF55-01130230	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	2300
840	HBF55-01130260	Normal	Stamping Oval	8.5	Four-bar linkage	with	3	2600
841	HBF65-10018030	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	300
842	HBF65-10018050	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	500
843	HBF65-10018080	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	800
844	HBF65-10018100	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	1000
845	HBF65-10018120	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	1200
846	HBF65-10018160	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	1600
847	HBF65-10018180	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	1800
848	HBF65-10018200	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	2000
849	HBF65-10018230	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	2300
850	HBF65-10018260	Normal	Stamping Alligator	4.5	Two Wire	without	1.8	2600
851	HBF65-10023030	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	300

852	HBF65-10023050	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	500
853	HBF65-10023080	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	800
854	HBF65-10023100	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	1000
855	HBF65-10023120	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	1200
856	HBF65-10023160	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	1600
857	HBF65-10023180	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	1800
858	HBF65-10023200	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	2000
859	HBF65-10023230	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	2300
860	HBF65-10023260	Normal	Stamping Alligator	6.7	Two Wire	without	2.3	2600
861	HBF65-00030030	Normal	Stamping Alligator	8.5	Two Wire	without	3	300
862	HBF65-00030050	Normal	Stamping Alligator	8.5	Two Wire	without	3	500
863	HBF65-00030080	Normal	Stamping Alligator	8.5	Two Wire	without	3	800
864	HBF65-00030100	Normal	Stamping Alligator	8.5	Two Wire	without	3	1000
865	HBF65-00030120	Normal	Stamping Alligator	8.5	Two Wire	without	3	1200
866	HBF65-00030160	Normal	Stamping Alligator	8.5	Two Wire	without	3	1600
867	HBF65-00030180	Normal	Stamping Alligator	8.5	Two Wire	without	3	1800
868	HBF65-00030200	Normal	Stamping Alligator	8.5	Two Wire	without	3	2000
869	HBF65-00030230	Normal	Stamping Alligator	8.5	Two Wire	without	3	2300
870	HBF65-00030260	Normal	Stamping Alligator	8.5	Two Wire	without	3	2600
871	HBF65-10118030	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	300
872	HBF65-10118050	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	500
873	HBF65-10118080	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	800
874	HBF65-10118100	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	1000
875	HBF65-10118120	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	1200
876	HBF65-10118160	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	1600
877	HBF65-10118180	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	1800

878	HBF65-10118200	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	2000
879	HBF65-10118230	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	2300
880	HBF65-10118260	Normal	Stamping Alligator	4.5	Two Wire	with	1.8	2600
881	HBF65-10123030	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	300
882	HBF65-10123050	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	500
883	HBF65-10123080	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	800
884	HBF65-10123100	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	1000
885	HBF65-10123120	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	1200
886	HBF65-10123160	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	1600
887	HBF65-10123180	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	1800
888	HBF65-10123200	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	2000
889	HBF65-10123230	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	2300
890	HBF65-10123260	Normal	Stamping Alligator	6.7	Two Wire	with	2.3	2600
891	HBF65-00130030	Normal	Stamping Alligator	8.5	Two Wire	with	3	300
892	HBF65-00130050	Normal	Stamping Alligator	8.5	Two Wire	with	3	500
893	HBF65-00130080	Normal	Stamping Alligator	8.5	Two Wire	with	3	800
894	HBF65-00130100	Normal	Stamping Alligator	8.5	Two Wire	with	3	1000
895	HBF65-00130120	Normal	Stamping Alligator	8.5	Two Wire	with	3	1200
896	HBF65-00130160	Normal	Stamping Alligator	8.5	Two Wire	with	3	1600
897	HBF65-00130180	Normal	Stamping Alligator	8.5	Two Wire	with	3	1800
898	HBF65-00130200	Normal	Stamping Alligator	8.5	Two Wire	with	3	2000
899	HBF65-00130230	Normal	Stamping Alligator	8.5	Two Wire	with	3	2300
900	HBF65-00130260	Normal	Stamping Alligator	8.5	Two Wire	with	3	2600
901	HBF65-11018030	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	300
902	HBF65-11018050	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	500
903	HBF65-11018080	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	800

904	HBF65-11018100	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1000
905	HBF65-11018120	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1200
906	HBF65-11018160	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1600
907	HBF65-11018180	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	1800
908	HBF65-11018200	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	2000
909	HBF65-11018230	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	2300
910	HBF65-11018260	Normal	Stamping Alligator	4.5	Four-bar linkage	without	1.8	2600
911	HBF65-11023030	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	300
912	HBF65-11023050	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	500
913	HBF65-11023080	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	800
914	HBF65-11023100	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1000
915	HBF65-11023120	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1200
916	HBF65-11023160	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1600
917	HBF65-11023180	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	1800
918	HBF65-11023200	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	2000
919	HBF65-11023230	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	2300
920	HBF65-11023260	Normal	Stamping Alligator	6.7	Four-bar linkage	without	2.3	2600
921	HBF65-01030030	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	300
922	HBF65-01030050	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	500
923	HBF65-01030080	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	800
924	HBF65-01030100	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	1000
925	HBF65-01030120	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	1200
926	HBF65-01030160	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	1600
927	HBF65-01030180	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	1800
928	HBF65-01030200	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	2000
929	HBF65-01030230	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	2300

930	HBF65-01030260	Normal	Stamping Alligator	8.5	Four-bar linkage	without	3	2600
931	HBF65-11118030	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	300
932	HBF65-11118050	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	500
933	HBF65-11118080	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	800
934	HBF65-11118100	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1000
935	HBF65-11118120	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1200
936	HBF65-11118160	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1600
937	HBF65-11118180	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	1800
938	HBF65-11118200	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	2000
939	HBF65-11118230	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	2300
940	HBF65-11118260	Normal	Stamping Alligator	4.5	Four-bar linkage	with	1.8	2600
941	HBF65-11123030	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	300
942	HBF65-11123050	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	500
943	HBF65-11123080	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	800
944	HBF65-11123100	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1000
945	HBF65-11123120	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1200
946	HBF65-11123160	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1600
947	HBF65-11123180	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	1800
948	HBF65-11123200	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	2000
949	HBF65-11123230	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	2300
950	HBF65-11123260	Normal	Stamping Alligator	6.7	Four-bar linkage	with	2.3	2600
951	HBF65-01130030	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	300
952	HBF65-01130050	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	500
953	HBF65-01130080	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	800
954	HBF65-01130100	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	1000
955	HBF65-01130120	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	1200

956	HBF65-01130160	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	1600
957	HBF65-01130180	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	1800
958	HBF65-01130200	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	2000
959	HBF65-01130230	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	2300
960	HBF65-01130260	Normal	Stamping Alligator	8.5	Four-bar linkage	with	3	2600

EU MDR DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017

Manufacturer's Name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturer's Address	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Manufacturer's SRN	CN-MF-000006950
EU Authorized Representative's Name	Shanghai International Holding Corp. GmbH (Europe)
EU Authorized Representative's Address	Eiffestrasse 80, 20537 Hamburg Germany
EU Authorized Representative SRN	DE-AR-000000001
Product Name	Single-Use Coagulation Forceps
Product Trade Name	Ensure^{TM} Single-Use Coagulation Forceps
Basic UDI-DI	6902284CF58039AJ
Catalogue Number	CF165-A, CF165-B, CF165-C, CF230-A, CF230-B, CF230-C
GMDN Code	58039
EMDN Code	G03080199
Classification and Rule	Class IIb (According to Annex VIII, Rule 9 of MDR 2017/745)
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
Intended Purpose	These instruments have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

The Declaration of Conformity is issued under the sole responsibility of Micro-Tech (Nanjing) Co., Ltd. The device that is covered by the present declaration is in conformity with the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

General applicable Regulation:

REGULATION (EU) 2017/745 of medical device

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

The details, please see Attachment 1.

Notified Body (Name & Address):	BSI Group – The Netherlands B.V Say Building, John M. Keynesplein 9, K1066 EP Amsterdam, The Netherlands
Identification Number:	CE 2797
Certificate Number:	MDR 737205
Certificate Issue Date:	2024-08-02
Certificate Expiry Date:	2026-12-09

Signature: Place and date of issue:

Becky Li ..... Nanjing, PRC, 2024-09-28

Name: Becky Li

Position: Person Responsible for Regulatory Compliance

Attachment 1

- EN ISO 13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- EN ISO 20417:2021 Information supplied by the manufacturer with medical devices
- EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices
- ISO/TR 24971-2020 Medical devices — Guidance on the application of ISO 14971
- EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing
- EN ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-7:2008/A1:2022 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants
- EN ISO 10993-10: 2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- EN ISO 11135:2014/A1:2019 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11737-1:2018/A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products Sterilization of medical devices
- EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2:

Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials
- ASTM F1886/F1886M-16 Standard test method for determining integrity of seals for flexible packaging by visual inspection
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration
- ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices
- EN ISO 8536-4: 2020 Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)
- EN 60601-1:2006/A2:2021 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2: 2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
- EN IEC 60601-2-2: 2018 Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- EN 60601-2-18:2015 Medical electrical equipment Part 2: Particular requirements for the safety of endoscopic equipment
- IEC 62366-1:2015+AMD 1:2020 Medical devices — Part 1: Application of usability engineering to medical devices — Amendment 1
- EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic

safety and essential performance - Collateral standard: Usability

- ISO 8600-1-2015 Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements
- ISO 8600-4-2014 Endoscopes — Medical endoscopes and endotherapy devices — Part 4: Determination of maximum width of insertion portion
- EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness
- EN 17141:2020 Cleanrooms and associated controlled environments — Biocontamination control
- MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI
- MDCG-2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG-2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance
- MDCG 2020-5 Guidance on Clinical Evaluation
- MDCG 2020-6 Guidance on Sufficient Clinical Evaluation
- IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation
- MEDDEV 2.7.1 (Rev. 4) Clinical evaluation: a guide for manufacturers and notified bodies
- MEDDEV 2.12.1 (Rev. 8) Guidelines on a medical devices vigilance system
- MEDDEV 2.12.2 (Rev. 2) Post market clinical follow-up studies a guide for manufacturers and notified bodies
- ISO/TR 20416 Medical devices — post-market surveillance for manufacturers
- (EU) 2021/2226 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices

Revision History

Revision	Date	Description
A/0	2024-09-06	Initial

Declaration of Conformity

Manufacturer	Micro-Tech (Nanjing) Co., Ltd.
Address	NO. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product name	Guidewire Locking Device
Model Number	Please see the Attachment
UMDNS Code	11726
Classification	I sterile (Annex IX, Rule 1 of MDD 93/42/EEC)

Conformity Assessment Route: Annex V of MDD 93/42/EEC amended by directive 2007/47/EC

We herewith declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable Directives:

Medical Device Directive: Council Directive 93/42/EEC concerning medical devices

Standard Applied:

All applicable harmonized Standards (published in the Official Journal of the European Communities)

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 MUnchen, Germany
Identification number:	0123
Certificate Number:	G2S 048850 0048 Rev. 03
Expire date of the certificate:	2028-12-31
Place, Date of Certificate:	Nanjing, 2018-09-27

Signature: Frank Liu **Date**: 2023-07-27

Title: Management Representative

Attachment

Product List of Guidewire Locking Device

No.	REF	Endoscopy	Description
1	MT-RGL-O	Olympus/ Fujinon	The Guidewire Locking Device is mounted at the end of the endoscope. In the ERCP operation used to lock the wire and seal the claw.
2	MT-RGL-P	Pentax	The Guidewire Locking Device is mounted at the end of the endoscope. In the ERCP operation used to lock the wire and seal the claw.

EU MDR DECLARATION OF CONFORMITY

Manufacturer's Name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturer's Address	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
Manufacturer's SRN	CN-MF-000006950
EU Authorized Representative's Name	Shanghai International Holding Corp. GmbH (Europe)
EU Authorized Representative's Address	Eiffestrasse 80, 20537 Hamburg Germany
EU Authorized Representative SRN	DE-AR-000000001
Product Name	Single Use Electrosurgical Knife
Product Trade Name	N/A
Basic UDI-DI	6902284MK58039HV
Catalogue Number	Please refer to Attachment 2
GMDN Code	58039
EMDN Code	K020101
Classification and Rule	Class IIb (According to Annex VIII, Rule 9 of MDR 2017/745)
Conformity Assessment Route	Annex IX (Without chap. II) of MDR 2017/745
Intended Purpose	These devices have been designed to be used with endoscopes and electrosurgical units for marking, dissection, elevation, irrigation and preparation of tissue layers in combination with monopolar cutting and coagulation within the digestive tract.

The Declaration of Conformity is issued under the sole responsibility of Micro-Tech (Nanjing) Co., Ltd. The device that is covered by the present declaration is in conformity with the Regulation (EU) MDR 2017/745 for medical devices.
All supporting documentation is retained at the premises of the manufacturer.

General applicable Regulation:

REGULATION (EU) 2017/745 of medical device

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities), please see Attachment 1.

Notified Body (Name & Address):	BSI Group – The Netherlands B.V Say Building, John M. Keynesplein 9, K1066 EP Amsterdam, The Netherlands
Identification Number:	CE 2797
Certificate Number:	MDR 737205
Certificate Issue Date:	2024-08-02
Certificate Expiry Date:	2026-12-09

Signature: Place and date of issue:

Becky Li ..... Nanjing, PRC, 2024-09-18

Name: Becky Li

Position: Person Responsible for Regulatory Compliance

Attachment 1

- EN ISO 13485:2016/A11:2021 Medical devices – Quality management systems- Requirements for regulatory purposes
- EN ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- EN ISO 20417:2021 Information supplied by the manufacturer with medical devices
- EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices
- ISO TR 24971-2020 Medical devices — Guidance on the application of ISO 14971
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- EN ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-7:2008/A1:2022 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants
- EN ISO 10993-10: 2023 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- EN ISO 11135:2014/A1:2019 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11737-1:2018/A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products Sterilization of medical devices
- EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2:

Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials
- ASTM F1886/F1886M-16 Standard test method for determining integrity of seals for flexible packaging by visual inspection
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration
- ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices
- EN ISO 8536-4: 2020 Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)
- EN 60601-1:2006/A2:2021 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2: 2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
- EN IEC 60601-2-2: 2018 Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- EN 60601-2-18:2015 Medical electrical equipment Part 2: Particular requirements for the safety of endoscopic equipment
- EN 62366-1:2015/A1:2020 Medical devices - Part 1: Application of usability engineering to

medical devices

- EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 8600-1-2015 Endoscopes — Medical endoscopes and endotherapy devices - Part 1: General requirements
- ISO 8600-4-2014 Endoscopes — Medical endoscopes and endotherapy devices - Part 4: Determination of maximum width of insertion portion
- EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness
- EN 17141:2020 Cleanrooms and associated controlled environments - Biocontamination control
- MDCG 2018-1 V4 Guidance on basic UDI-DI and changes to UDI-DI
- MDCG-2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG-2019-7 Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance
- MDCG 2020-5 Clinical Evaluation – Equivalence A guide for manufacturers and notified bodies
- MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
- MEDDEV 2.7.1 (Rev. 4) Clinical evaluation: a guide for manufacturers and notified bodies
- MEDDEV 2.12.1 (Rev. 8) Guidelines on a medical devices vigilance system
- MEDDEV 2.12.2 (Rev. 2) Post market clinical follow-up studies a guide for manufacturers and notified bodies
- ISO/TR 20416 Medical devices — Post-market surveillance for manufacturers
- (EU) 2021/2226 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices

Attachment 2 Catalogue Number

No.	Specification	Cutting Knife Shape	Cutting Knife Length L1	Effective Working Length L	Injection capable or NOT	The maximum diameter of the insertion portion D
1	MK-I-1-165	I	1.5	1650	Yes	<2.7
2	MK-I-1-195	I	1.5	1950	Yes	<2.7
3	MK-I-1-235	I	1.5	2350	Yes	<2.7
4	MK-I-2-165	I	2	1650	Yes	<2.7
5	MK-I-2-195	I	2	1950	Yes	<2.7
6	MK-I-2-235	I	2	2350	Yes	<2.7
7	MK-I-4-165	I	4	1650	Yes	<2.7
8	MK-I-4-195	I	4	1950	Yes	<2.7
9	MK-I-4-235	I	4	2350	Yes	<2.7
10	MK-T-1-165	T	1.5	1650	Yes	<2.7
11	MK-T-1-195	T	1.5	1950	Yes	<2.7
12	MK-T-1-235	T	1.5	2350	Yes	<2.7
13	MK-T-2-165	T	2	1650	Yes	<2.7
14	MK-T-2-195	T	2	1950	Yes	<2.7
15	MK-T-2-235	T	2	2350	Yes	<2.7
16	MK-T-4-165	T	4	1650	Yes	<2.7
17	MK-T-4-195	T	4	1950	Yes	<2.7
18	MK-T-4-235	T	4	2350	Yes	<2.7
19	MK-O-1-165	O	1.5	1650	Yes	<2.7
20	MK-O-1-195	O	1.5	1950	Yes	<2.7
21	MK-O-1-235	O	1.5	2350	Yes	<2.7
22	MK-O-2-165	O	2	1650	Yes	<2.7
23	MK-O-2-195	O	2	1950	Yes	<2.7
24	MK-O-2-235	O	2	2350	Yes	<2.7
25	MK-O-4-165	O	4	1650	Yes	<2.7
26	MK-O-4-195	O	4	1950	Yes	<2.7
27	MK-O-4-235	O	4	2350	Yes	<2.7
28	MK-IT-1-165	IT	1.5	1650	Yes	<2.7
29	MK-IT-1-195	IT	1.5	1950	Yes	<2.7
30	MK-IT-1-235	IT	1.5	2350	Yes	<2.7
31	MK-IT-2-165	IT	2	1650	Yes	<2.7
32	MK-IT-2-195	IT	2	1950	Yes	<2.7

No.	Specification	Cutting Knife Shape	Cutting Knife Length L1	Effective Working Length L	Injection capable or NOT	The maximum diameter of the insertion portion D
33	MK-IT-2-235	IT	2	2350	Yes	<2.7
34	MK-IT-4-165	IT	4	1650	Yes	<2.7
35	MK-IT-4-195	IT	4	1950	Yes	<2.7
36	MK-IT-4-235	IT	4	2350	Yes	<2.7
37	MK-I-1-165-N	I	1.5	1650	No	<2.7
38	MK-I-1-195-N	I	1.5	1950	No	<2.7
39	MK-I-1-235-N	I	1.5	2350	No	<2.7
40	MK-I-2-165-N	I	2	1650	No	<2.7
41	MK-I-2-195-N	I	2	1950	No	<2.7
42	MK-I-2-235-N	I	2	2350	No	<2.7
43	MK-I-4-165-N	I	4	1650	No	<2.7
44	MK-I-4-195-N	I	4	1950	No	<2.7
45	MK-I-4-235-N	I	4	2350	No	<2.7
46	MK-T-1-165-N	T	1.5	1650	No	<2.7
47	MK-T-1-195-N	T	1.5	1950	No	<2.7
48	MK-T-1-235-N	T	1.5	2350	No	<2.7
49	MK-T-2-165-N	T	2	1650	No	<2.7
50	MK-T-2-195-N	T	2	1950	No	<2.7
51	MK-T-2-235-N	T	2	2350	No	<2.7
52	MK-T-4-165-N	T	4	1650	No	<2.7
53	MK-T-4-195-N	T	4	1950	No	<2.7
54	MK-T-4-235-N	T	4	2350	No	<2.7
55	MK-O-1-165-N	O	1.5	1650	No	<2.7
56	MK-O-1-195-N	O	1.5	1950	No	<2.7
57	MK-O-1-235-N	O	1.5	2350	No	<2.7
58	MK-O-2-165-N	O	2	1650	No	<2.7
59	MK-O-2-195-N	O	2	1950	No	<2.7
60	MK-O-2-235-N	O	2	2350	No	<2.7
61	MK-O-4-165-N	O	4	1650	No	<2.7
62	MK-O-4-195-N	O	4	1950	No	<2.7
63	MK-O-4-235-N	O	4	2350	No	<2.7
64	MK-IT-1-165-N	IT	1.5	1650	No	<2.7
65	MK-IT-1-195-N	IT	1.5	1950	No	<2.7

No.	Specification	Cutting Knife Shape	Cutting Knife Length L1	Effective Working Length L	Injection capable or NOT	The maximum diameter of the insertion portion D
66	MK-IT-1-235-N	IT	1.5	2350	No	<2.7
67	MK-IT-2-165-N	IT	2	1650	No	<2.7
68	MK-IT-2-195-N	IT	2	1950	No	<2.7
69	MK-IT-2-235-N	IT	2	2350	No	<2.7
70	MK-IT-4-165-N	IT	4	1650	No	<2.7
71	MK-IT-4-195-N	IT	4	1950	No	<2.7
72	MK-IT-4-235-N	IT	4	2350	No	<2.7

Revision History

Revision	Date	Description
A/0	2024-09-06	Initial

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 080127/01**

Organization:

Olympus Europa SE & Co. KG
Wendenstr. 20
20097 Hamburg
Germany

Site:

c/o **Olympus Europa SE & Co. KG**
Wendenstr. 20
20097 Hamburg
Germany

Scope:

Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid in conjunction with the main certificate 01 100 080127 from 2023-07-16 until 2026-07-15.

2023-07-05

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Traducere din limba engleză

CERTIFICAT

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Standard **ISO 9001:2015**
Nr. inregistrare certificat: 01 100 080127/01

Organizaţia:

Olympus Europa SE & Co. KG
Wendenstr. 20
20097 Hamburg
Germania

Locaţie:

c/o Olympus Europa SE & Co. KG
Wendenstr. 20
20097 Hamburg
Germania

Domeniu:

Marketing, comercializare si service pentru sisteme optice, opto-digitale, electronice si mecanice precum si pentru accesorii asociate si consumabile din domeniul endoscopiei.

S-a facut dovada indeplinirii cerintelor ISO 9001:2015 in urma auditului.

Valabilitate:

Certificatul este valabil impreuna cu certificatul principal 01 100 080127 de la 16-07-2023 pana in 15-07-2026

05-07-2023

(semnatura indescifrabila)
TÜV Rheinland Cert GmbH
Am Grauen Stein – 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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TÜV Rheinland LGA Products GmbH • 51105 Köln

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507
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Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 30, 2024

Notified Body Confirmation Letter
Reference. : OMSC_MDR Application 2024-04-16; order # 150294495

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

OLYMPUS MEDICAL SYSTEMS CORP
2951 Ishikawa-cho, Hachioji-shi
Tokyo, 192-8507
Japan
SRN Number: JP-MF-000008016

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Ning N. C. Chang
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
VIDEO SYSTEM CENTER OLYMPUS CV-170	Class IIa	VIDEO SYSTEM CENTER OLYMPUS CV-170	Certificate # HD 60149405 0001 NB # 0197
Single Use Injector NM-600L-0421, NM-600L-0521, NM-600L-0621, NM-600L-0423, NM-600L-0523, NM-600L-0623, NM-600L-0425, NM-600L-0525, NM-600L-0625, NM-610L-0421, NM-610L-0521, NM-610L-0621, NM-610L-0423, NM-610L-0523, NM-610L-0623, NM-610L-0425, NM-610L-0525, NM-610L-0625, NM-610L-0426, NM-610U-0323, NM-610U-0423, NM-610U-0523, NM-610U-0623, NM-610U-1825, NM-610U-0325, NM-610U-0425, NM-610U-0525, NM-610U-0625, NM-610U-1826, NM-610U-0326, NM-610U-0426	Class IIa	Single Use Injector NM-600L-0421	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Biopsy Forceps FB-215U, FB-216U	Class IIa	Single Use Biopsy Forceps FB-215U	Same as above
MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4	Class IIb	MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4	Same as above
WATER CONTAINER MAJ-901	Class IIa	WATER CONTAINER MAJ-901	Same as above
ENDOCAPSULE SOFTWARE 10 MAJ-2188	Class IIa	ENDOCAPSULE SOFTWARE 10 MAJ-2188	Same as above
ENDOCAPSULE SOFTWARE 10 LIGHT MAJ-2189	Class IIa	ENDOCAPSULE SOFTWARE 10 LIGHT MAJ-2189	Same as above
ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE MAJ-2190	Class IIa	ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE MAJ-2190	Same as above
Single Use Biopsy Forceps FB-456D (EMDN: R070201)	Class IIa	Single Use Biopsy Forceps FB-456D	Same as above
Single Use Biopsy Forceps FB-456D (EMDN: U090301)	Class IIa	Single Use Biopsy Forceps FB-456D	Same as above
ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120108)	Class IIb	ULTRASONIC BIPOLAR GENERATOR USG-410	Same as above
ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120109)	Class IIb	ULTRASONIC BIPOLAR GENERATOR USG-410	Same as above
URETERO-RENO FIBERSCOPE URF-P7	Class IIa	URETERO-RENO FIBERSCOPE URF-P7	Same as above
URETERO-RENO FIBERSCOPE URF-P7R	Class IIa	URETERO-RENO FIBERSCOPE URF-P7R	Same as above
Luer-Split MAJ-2092	Class IIa	Luer-Split MAJ-2092	Same as above
GASTROINTESTINAL VIDEOSCOPE GIF-1100	Class IIa	GASTROINTESTINAL VIDEOSCOPE GIF-1100	Same as above
COLONOVIDEOSCOPE CF-HQ1100DL/I	Class IIa	COLONOVIDEOSCOPE CF-HQ1100DL	Same as above
BRONCHOVIDEO SCOPE BF-1TH1100	Class IIa	BRONCHOVIDEO SCOPE BF-1TH1100	Same as above
SINGLE USE SPLINTING TUBE ST-SB1S	Class IIa	SINGLE USE SPLINTING TUBE ST-SB1S	Same as above
CYSTO-NEPHRO VIDEOSCOPE CYF-VH	Class IIa	CYSTO-NEPHRO VIDEOSCOPE CYF-VH	Same as above
RHINO-LARYNGO VIDEOSCOPE	Class IIa	RHINO-LARYNGO VIDEOSCOPE	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ENF-VT3		ENF-VT3	
BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	Same as above
EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	Class IIa	EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	Same as above
EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-H190	Class IIa	EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-H190	Same as above
EVIS EXERA Ⅲ BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F	Class IIa	EVIS EXERA Ⅲ BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F	Same as above
EVIS LUCERA ELITE BRONCHOFIBERVIDEO SCOPEOLYMPUS BF-MP290F	Class IIa	EVIS LUCERA ELITE BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP290F	Same as above
EVIS EXERA Ⅲ BRONCOVIDEOSCOPE OLYMPUS BF-P190	Class IIa	EVIS EXERA Ⅲ BRONCOVIDEOSCOPE OLYMPUS BF-P190	Same as above
EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-P290	Class IIa	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-P290	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	Same as above
EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	Class IIa	EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	Same as above
EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC190F	Class IIa	EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC190F	Same as above
EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC290F	Class IIa	EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC290F	Same as above
EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-XP190	Class IIa	EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-XP190	Same as above
EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-XP290	Class IIa	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-XP290	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	Same as above
COLONOVIDEOSCOPE	Class IIa	COLONOVIDEOSCOPE	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
OLYMPUS CF-EZ1500DI		OLYMPUS CF-EZ1500DI	
COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-H170I	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-H170I	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-H170L	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-H170L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190L	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290ECI	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290ECI	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290I	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290I	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290L	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190L	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290I	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290I	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290L	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290L	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-XZ1200I	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-XZ1200I	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-XZ1200L	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-XZ1200L	Same as above
EVIS EXERAⅢ XENON LIGHT SOURCE OLYMPUS CLV-190	Class IIa	EVIS EXERAⅢ XENON LIGHT SOURCE OLYMPUS CLV-190	Same as above
EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500	Class IIa	EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5	Class IIa	OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5	Same as above
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5A	Class IIa	OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5A	Same as above
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2	Class IIa	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2	Same as above
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHA	Class IIa	CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHA	Same as above
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR	Class IIa	CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR	Same as above
SINGLE USE POWERSPIRAL TUBE DPST-1	Class IIa	SINGLE USE POWERSPIRAL TUBE DPST-1	Same as above
RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	Class IIa	RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V3	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V3	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 OLYMPUS ENF-V4	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 OLYMPUS ENF-V4	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	Same as above
RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	Class IIa	RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	Same as above
EVIS EXERA Ⅱ ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180	Class IIa	EVIS EXERA Ⅱ ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180	Same as above
EVIS LUCERA ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT260	Class IIa	EVIS LUCERA ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT260	Same as above
EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190	Class IIa	EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE290	Class IIa	EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE290	Same as above
EVIS EXERA Ⅲ GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190	Class IIa	EVIS EXERA Ⅲ GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H170	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H170	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H185	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H185	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190N	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190N	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290EC	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290EC	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290T	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290T	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ190	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ190	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ290	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ290	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP170N	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP170N	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
VIDEOSCOPE OLYMPUS GIF-XP290N		VIDEOSCOPE OLYMPUS GIF-XP290N	
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XZ1200	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XZ1200	Same as above
EVIS LUCERA ELITE PLEURA VIDEOSCOPE OLYMPUS LTF-H290	Class IIa	EVIS LUCERA ELITE PLEURA VIDEOSCOPE OLYMPUS LTF-H290	Same as above
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	Class IIa	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	Same as above
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5	Class IIa	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5	Same as above
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S300-10-3D	Class IIa	ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S300-10-3D	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-GM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-GM2	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-TM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-TM2	Same as above
Lid MAJ-1024	Class IIa	Lid MAJ-1024	Same as above
Lid MAJ-1025	Class IIa	Lid MAJ-1025	Same as above
Container MAJ-1026	Class IIa	Container MAJ-1026	Same as above
O-ring MAJ-1028	Class IIa	O-ring MAJ-1028	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1080	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1080	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1081	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1081	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1082	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1082	Same as above
MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1084	Class IIa	MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1084	Same as above
MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1085	Class IIa	MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1085	Same as above
AIR/WATER VALVE MAJ-1444	Class IIa	AIR/WATER VALVE MAJ-1444	Same as above
PROBE DRIVING UNIT MAJ-1720	Class IIa	PROBE DRIVING UNIT MAJ-1720	Same as above
RESERVOIR TANK MAJ-1727	Class IIa	RESERVOIR TANK MAJ-1727	Same as above
GAS TUBE MAJ-1741	Class IIa	GAS TUBE MAJ-1741	Same as above
LOW FLOW GAS TUBE MAJ-1742	Class IIa	LOW FLOW GAS TUBE MAJ-1742	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EXTRA LOW FLOW GAS TUBE MAJ-1816	Class IIa	EXTRA LOW FLOW GAS TUBE MAJ-1816	Same as above
HAND COIL MAJ-1859	Class IIa	HAND COIL MAJ-1859	Same as above
REFERENCE PLATE MAJ-1860	Class IIa	REFERENCE PLATE MAJ-1860	Same as above
ENDOSCOPE POSITION MARKING PROBE MAJ-1878	Class IIa	ENDOSCOPE POSITION MARKING PROBE MAJ-1878	Same as above
CYLINDER HOSE WITH SWITCH-OVER VALVE (PIN-INDEX) MAJ-1985	Class IIa	CYLINDER HOSE WITH SWITCH-OVER VALVE (PIN-INDEX) MAJ-1985	Same as above
CYLINDER HOSE WITH SWITCH-OVER VALVE (DIN) MAJ-1986	Class IIa	CYLINDER HOSE WITH SWITCH-OVER VALVE (DIN) MAJ-1986	Same as above
GAS/WATER VALVE MAJ-2010	Class IIa	GAS/WATER VALVE MAJ-2010	Same as above
AUXILIARY WATER TUBE MAJ-2021	Class IIa	AUXILIARY WATER TUBE MAJ-2021	Same as above
INSUFFLATION TUBE MAJ-590	Class IIa	INSUFFLATION TUBE MAJ-590	Same as above
AUXILIARY WATER TUBE MAJ-855	Class IIa	AUXILIARY WATER TUBE MAJ-855	Same as above
WATER CONTAINER MAJ-902	Class IIa	WATER CONTAINER MAJ-902	Same as above
Probe/Irrigation Plug MD-807	Class IIa	Probe/Irrigation Plug MD-807	Same as above
AIR/WATER VALVE MH-438	Class IIa	AIR/WATER VALVE MH-438	Same as above
BALLOON CONTROL UNIT OBCU OBCU	Class IIa	BALLOON CONTROL UNIT OBCU OBCU	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DI	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DI	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DL	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DL	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TI	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TI	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290DL	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290DL	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TI	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TI	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TL	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TL	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZI	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZI	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZL	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZL	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190L	Same as above
POWERSPIRAL CONTROL UNIT PSCU	Class IIa	POWERSPIRAL CONTROL UNIT PSCU	Same as above
INTESTINAL VIDEOSCOPE OLYMPUS PSF-1	Class IIa	INTESTINAL VIDEOSCOPE OLYMPUS PSF-1	Same as above
EVIS EXERA III SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H190	Class IIa	EVIS EXERA III SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H190	Same as above
EVIS LUCERA ELITE SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H290S	Class IIa	EVIS LUCERA ELITE SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H290S	Same as above
SINGLE USE SPLINTING TUBE ST-CB1	Class IIa	SINGLE USE SPLINTING TUBE ST-CB1	Same as above
SINGLE USE SPLINTING TUBE ST-SB1	Class IIa	SINGLE USE SPLINTING TUBE ST-SB1	Same as above
EVIS EXERA Ⅱ ULTRASOUND GASTROVIDEOSCOPE OLYMPUS TGF-UC180J	Class IIa	EVIS EXERA Ⅱ ULTRASOUND GASTROVIDEOSCOPE OLYMPUS TGF-UC180J	Same as above
DUODENOVIDEOSCOPE OLYMPUS TJF-Q170V	Class IIa	DUODENOVIDEOSCOPE OLYMPUS TJF-Q170V	Same as above
EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Q190V	Class IIa	EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Q190V	Same as above
EVIS LUCERA ELITE DUODENOVIDEOSCOPE OLYMPUS TJF-Q290V	Class IIa	EVIS LUCERA ELITE DUODENOVIDEOSCOPE OLYMPUS TJF-Q290V	Same as above
ENDOSCOPIC CO2 REGULATION UNIT OLYMPUS UCR	Class IIa	ENDOSCOPIC CO2 REGULATION UNIT OLYMPUS UCR	Same as above
ULTRASONIC PROBE UM-3R	Class IIa	ULTRASONIC PROBE UM-3R	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ULTRASONIC PROBE UM-S20-17S	Class IIa	ULTRASONIC PROBE UM-S20-17S	Same as above
ULTRASONIC PROBE UM-S20-20R	Class IIa	ULTRASONIC PROBE UM-S20-20R	Same as above
ENDOSCOPE POSITION DETECTING UNIT UPD-3	Class IIa	ENDOSCOPE POSITION DETECTING UNIT UPD-3	Same as above
URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3	Class IIa	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3	Same as above
URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3R	Class IIa	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3R	Same as above
HIGH FLOW INSUFFLATION UNIT UHI-4	Class IIa	HIGH FLOW INSUFFLATION UNIT UHI-4	Same as above
SINGLE USE SUCTION VALVE (Sterile) MAJ-209	Class Is	SINGLE USE SUCTION VALVE (Sterile) MAJ-209	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE BIOPSY VALVE MAJ-210	Class Is	SINGLE USE BIOPSY VALVE MAJ-210	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE BIOPSY VALVE MAJ-1555	Class Is	SINGLE USE BIOPSY VALVE MAJ-1555	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE DISTAL COVER MAJ-2315	Class Is	SINGLE USE DISTAL COVER MAJ-2315	Certificate # DD 60144068 0001 NB # 0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/23	OMSC_CL607_CL_2024-01-23	Initial issue
2024/04/25	OMSC_CL607_CL_2024-04-25	Revise the letter to be align with OMSC_PLA0_HZ_20240416_EU 2023_607. − to remove EVIS EUS ENDOSCOPIC ULTRASOUND CENTER EU-ME3, HIGH FLOW INSUFFLATION UNIT UHI-5, HEATABLE INSUFFLATION TUBE MAJ-2464, TUBING SET FOR TRANSANAL SURGERY MAJ-2465 and Table 2. − to add HIGH FLOW INSUFFLATION UNIT UHI-4. − Update device name from Single Use Biopsy Forceps FB-456D to ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120108) and ULTRASONIC

Date	NB internal reference traceable to each version of the letter	Action
		BIPOLAR GENERATOR USG-410 (EMDN: Z120109). − Update legacy device name from Single Use Biopsy Forceps FB-215U, FB-216U to Single Use Biopsy Forceps FB-215U.
2024/04/30	OMSC_CL607_CL_2024-04-30	Correction made on Table 1 in the previous version. − ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120109) − URETERO-RENO FIBERSCOPE URF-P7 − URETERO-RENO FIBERSCOPE URF-P7R

Traducere din limba engleză

Produse din fluxul de producţie Business
Departmentamentul de certificare

TÜVRheinland®
LGA
Precisely Right.

Contact

Tel. +49 911 655-5225
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Data 30 April 2024

TÜV Rheinland LGA Products GmbH • 51105 Köln

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507
Japonia

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Scrisoare de confirmare a organismului notificat
Referinţă: Solicitare OMSC_MDR 16-04-2024; decizie # 150294495

În atenţia persoanelor interesate,

Confirmarea statutului unei solicitări oficiale, a unui acord scris și a unei supravegheri adecvate în cadrul Regulamentului UE 2023/607 de modificare a Regulamentelor (UE) 2017/745 și (UE) 2017/746 în ceea ce privește dispozițiile tranzitorii pentru anumite dispozitive medicale și dispozitive medicale de diagnostic in vitro.

Prezenta scrisoare confirmă faptul că **TÜV Rheinland LGA Products GmbH**, un organism notificat (ON) desemnat conform Regulamentului (UE) 2017/745 (RDM) și identificat prin numărul **0197** pe NANDO, a primit o solicitare oficială în conformitate cu secțiunea 4.3 primul paragraf din anexa VII la RDM și a semnat un acord scris în conformitate cu secțiunea 4.3 al doilea paragraf din anexa VII la RDM cu următorul producător:

OLYMPUS MEDICAL SYSTEMS CORP
2951 Ishikawa-cho, Hachioji-shi
Tokyo, 192-8507
Japonia
Număr SRN: JP-MF-000008016

Dispozitivele vizate de cererea formală și de acordul scris menționat mai sus sunt identificate în tabelele de mai jos. Tabelul 1 identifică dispozitivele pentru care a fost primită o cerere RDM, s-a încheiat un acord scris și pentru care ON este, de asemenea, responsabil pentru supravegherea adecvată în conformitate cu Directiva aplicabilă. Tabelul 2 identifică dispozitivele pentru care a fost primită o solicitare RDM și s-a încheiat un acord scris, dar ON nu și-a asumat încă responsabilitatea pentru supravegherea adecvată a dispozitivelor corespunzătoare conform directivei aplicabile.

În cazul dispozitivelor acoperite de certificate eliberate în temeiul Directivei 90/385/CEE (Directiva privind dispozitivele medicale implantabile active-AIMDD) sau Directivei 93/42/CEE (Directiva privind dispozitivele medicale-MDD) care au expirat după 26 mai 2021 dar înainte de 20 martie 2023 fără a fi fost retrase, prezenta scrisoare, de asemenea confirmă că producătorul fie a semnat acordul scris conform RDM până la data expirării certificatului MDD/AIMDD; sau a furnizat dovezi că o autoritate competentă a unui stat membru a acordat o derogare sau o scutire de la procedura de evaluare a conformității aplicabilă în conformitate cu articolul 59(1) din RDM sau, respectiv, cu articolul 97(1) din RDM, până la 20 martie 2023 pentru dispozitivele relevante.

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Dipl.-Ing.
Thomas Weigand, Spokesman

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Dr. Jörg Schlösser

Nuremberg HRB 26013
Ust.-IdNr. DE 811835490

Președinte al Consiliului de Supraveghere
Dr.-Ing. Michael Fübi

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
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Termenele de tranziție care se aplică dispozitivelor vizate de prezenta scrisoare, sub rezerva respectării în continuare de către producător a celorlalte condiții specificate la articolul 120.3c din RDM (modificat prin (UE) 2023/607), sunt prezentate mai jos:

- 26 mai 2026 pentru dispozitivele implantabile personalizate din Clasa III
- 31 decembrie 2027 pentru dispozitivele din clasa III și dispozitivele implantabile de clasa IIb, cu excepția tehnologiilor consacrate (WET - suturi, capse, obturații dentare, aparate dentare, coroane dentare, șuruburi, pene, plăci, fire, știfturi, cleme și conectori)
- 31 decembrie 2028 pentru alte dispozitive din Clasa IIb, Clasa IIa, Clasa I, dispozitive introduse pe piață în stare sterilă sau au funcție de măsurare
- 31 decembrie 2028 pentru dispozitivele care nu necesită implicarea unui organism notificat în temeiul DDM, dar care o necesită în conformitate cu RDM (de exemplu, dispozitive de clasa I care se califică drept instrumente chirurgicale reutilizabile)

Din partea organismului notificat
(*semnătură indescifrabilă*)

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Ning N. C. Chang
Organismul de certificare

Tabel 1: Dispozitive care fac obiectul prezentei scrisori și pentru care ON este, de asemenea, responsabil pentru supravegherea adecvată a dispozitivelor corespunzătoare conform directivei aplicabile:

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	**Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)**	**Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător**	**Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON**
SISTEM VIDEO CENTRAL OLYMPUS CV-170	Clasa IIa	SISTEM VIDEO CENTRAL OLYMPUS CV-170	Certificat nr. HD 60149405 0001 ON nr. 0197
Injector de unică folosință NM-600L-0421, NM-600L-0521, NM-600L-0621, NM-600L-0423, NM-600L-0523, NM-600L-0623, NM-600L-0425, NM-600L-0525, NM-600L-0625, NM-610L-0421, NM-610L-0521, NM-610L-0621, NM-610L-0423, NM-610L-0523, NM-610L-0623, NM-610L-0425, NM-610L-0525, NM-610L-0625, NM-610L-0426, NM-610U-0323, NM-610U-0423, NM-610U-0523, NM-610U-0623, NM-610U-1825, NM-610U-0325, NM-610U-0425, NM-610U-0525, NM-610U-0625, NM-610U-1826, NM-610U-0326, NM-610U-0426	Clasa IIa	Injector de unică folosință NM-600L-0421	La fel ca mai sus

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Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
Pensă pentru biopsie de unică folosință FB-215U, FB-216U	Clasa IIa	Pensă pentru biopsie de unică folosință FB-215U	La fel ca mai sus
UNITATE MEDICALĂ DE CONTROL PENTRU ENDOCHIRURGIE UCES-4	Clasa IIb	UNITATE MEDICALĂ DE CONTROL PENTRU ENDOCHIRURGIE UCES-4	La fel ca mai sus
RECIPIENT APĂ MAJ-901	Clasa IIa	RECIPIENT APĂ MAJ-901	La fel ca mai sus
SOFTWARE ENDOCAPSULĂ 10 MAJ-2188	Clasa IIa	SOFTWARE ENDOCAPSULĂ 10 MAJ-2188	La fel ca mai sus
SOFTWARE ENDOCAPSULĂ 10 LIGHT MAJ-2189	Clasa IIa	SOFTWARE ENDOCAPSULĂ 10 LIGHT MAJ-2189	La fel ca mai sus
SOFTWARE ENDOCAPSULĂ 10 PACHET UPGRADE MAJ-2190	Clasa IIa	SOFTWARE ENDOCAPSULĂ 10 PACHET UPGRADE MAJ-2190	La fel ca mai sus
Pensă pentru biopsie de unică folosință FB-456D (EMDN: R070201)	Clasa IIa	Pensă pentru biopsie de unică folosință FB-456D	La fel ca mai sus
Pensă pentru biopsie de unică folosință FB-456D (EMDN: U090301)	Clasa IIa	Pensă pentru biopsie de unică folosință FB-456D	La fel ca mai sus
GENERATOR BIPOLAR ULTRASONIC USG-410 (EMDN: Z120108)	Clasa IIb	GENERATOR BIPOLAR ULTRASONIC USG-410	La fel ca mai sus
GENERATOR BIPOLAR ULTRASONIC USG-410 (EMDN: Z120109)	Clasa IIb	GENERATOR BIPOLAR ULTRASONIC USG-410	La fel ca mai sus
FIBRO URETRORENOSCOP URF-P7	Clasa IIa	FIBRO URETRORENOSCOP URF-P7	La fel ca mai sus
FIBRO URETRORENOSCOP URF-P7R	Clasa IIa	FIBRO URETRORENOSCOP URF-P7R	La fel ca mai sus
Adaptor Luer-Split MAJ-2092	Clasa IIa	Adaptor Luer-Split MAJ-2092	La fel ca mai sus
VIDEOSCOP GASTROINTESTINAL GIF-1100	Clasa IIa	VIDEOSCOP GASTROINTESTINAL GIF-1100	La fel ca mai sus
COLONOVIDEOSCOP CF-HQ1100DL/I	Clasa IIa	COLONOVIDEOSCOP CF-HQ1100DL	La fel ca mai sus
BRONCHOVIDEOSCOP BF-1TH1100	Clasa IIa	BRONCHOVIDEOSCOP BF-1TH1100	La fel ca mai sus
TUB DESPICARE DE UNICĂ FOLOSINŢĂ ST-SB1S	Clasa IIa	TUB DESPICARE DE UNICĂ FOLOSINŢĂ ST-SB1S	La fel ca mai sus
VIDEO CISTONEFROSCOP CYF-VH	Clasa IIa	VIDEO CISTONEFROSCOP CYF-VH	La fel ca mai sus
VIDEO RINOLARINGOSCOP	Clasa IIa	VIDEO RINOLARINGOSCOP	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
ENF-VT3		ENF-VT3	
VIDEO BRONHOSCOP OLYMPUS BF-1TH1200	Clasa IIa	VIDEO BRONHOSCOP OLYMPUS BF-1TH1200	La fel ca mai sus
EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-1TH190	Clasa IIa	EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-1TH190	La fel ca mai sus
VIDEO BRONHOSCOP OLYMPUS BF-1TQ170	Clasa IIa	VIDEO BRONHOSCOP OLYMPUS BF-1TQ170	La fel ca mai sus
VIDEO BRONHOSCOP OLYMPUS BF-H1100	Clasa IIa	VIDEO BRONHOSCOP OLYMPUS BF-H1100	La fel ca mai sus
VIDEO BRONHOSCOP OLYMPUS BF-H1200	Clasa IIa	VIDEO BRONHOSCOP OLYMPUS BF-H1200	La fel ca mai sus
EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-H190	Clasa IIa	EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-H190	La fel ca mai sus
EVIS EXERA Ⅲ VIDEO BRONHOFIBROSCOP OLYMPUS BF-MP190F	Clasa IIa	EVIS EXERA Ⅲ VIDEO BRONHOFIBROSCOP OLYMPUS BF- MP190F	La fel ca mai sus
EVIS LUCERA ELITE VIDEO BRONHOFIBROSCOP OLYMPUS BF-MP290F	Clasa IIa	EVIS LUCERA ELITE VIDEO BRONHOFIBROSCOP OLYMPUS BF-MP290F	La fel ca mai sus
EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-P190	Clasa IIa	EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-P190	La fel ca mai sus
EVIS LUCERA ELITE VIDEO BRONHOSCOP OLYMPUS BF-P290	Clasa IIa	EVIS LUCERA ELITE VIDEO BRONHOSCOP OLYMPUS BF-P290	La fel ca mai sus
VIDEO BRONHOSCOP OLYMPUS BF-Q170	Clasa IIa	VIDEO BRONHOSCOP OLYMPUS BF-Q170	La fel ca mai sus
EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-Q190	Clasa IIa	EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-Q190	La fel ca mai sus
EVIS EUS VIDEO BRONHOFIBROSCOP CU ULTRASUNETE OLYMPUS BF-UC190F	Clasa IIa	EVIS EUS VIDEO BRONHOFIBROSCOP CU ULTRASUNETE OLYMPUS BF-UC190F	La fel ca mai sus
EVIS EUS VIDEO BRONHOFIBROSCOP CU ULTRASUNETE OLYMPUS BF-UC290F	Clasa IIa	EVIS EUS VIDEO BRONHOFIBROSCOP CU ULTRASUNETE OLYMPUS BF-UC290F	La fel ca mai sus
EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-XP190	Clasa IIa	EVIS EXERA Ⅲ VIDEO BRONHOSCOP OLYMPUS BF-XP190	La fel ca mai sus
EVIS LUCERA ELITE VIDEO BRONHOSCOP OLYMPUS BF-XP290	Clasa IIa	EVIS LUCERA ELITE VIDEO BRONHOSCOP OLYMPUS BF-XP290	La fel ca mai sus
EVIS EXERA III VIDEO BRONHOSCOP OLYMPUS BF-XT190	Clasa IIa	EVIS EXERA III VIDEO BRONHOSCOP OLYMPUS BF-XT190	La fel ca mai sus
VIDEO COLONOSCOP	Clasa IIa	VIDEO COLONOSCOP	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
OLYMPUS CF-EZ1500DI		OLYMPUS CF-EZ1500DI	
VIDEO COLONOSCOP OLYMPUS CF-EZ1500DL	Clasa IIa	VIDEO COLONOSCOP OLYMPUS CF-EZ1500DL	La fel ca mai sus
VIDEO COLONOSCOP OLYMPUS CF-H170I	Clasa IIa	VIDEO COLONOSCOP OLYMPUS CF-H170I	La fel ca mai sus
VIDEO COLONOSCOP OLYMPUS CF-H170L	Clasa IIa	VIDEO COLONOSCOP OLYMPUS CF-H170L	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H185I	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H185I	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H185L	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H185L	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H190I	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H190I	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H190L	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-H190L	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-H290ECI	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-H290ECI	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-H290I	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-H290I	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-H290L	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-H290L	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-HQ190I	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-HQ190I	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-HQ190L	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS CF-HQ190L	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-HQ290I	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-HQ290I	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-HQ290L	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS CF-HQ290L	La fel ca mai sus
VIDEO COLONOSCOP OLYMPUS CF-XZ1200I	Clasa IIa	VIDEO COLONOSCOP OLYMPUS CF-XZ1200I	La fel ca mai sus
VIDEO COLONOSCOP OLYMPUS CF-XZ1200L	Clasa IIa	VIDEO COLONOSCOP OLYMPUS CF-XZ1200L	La fel ca mai sus
EVIS EXERA Ⅲ SURSA DE LUMINA XENON OLYMPUS CLV-190	Clasa IIa	EVIS EXERA Ⅲ SURSA DE LUMINA XENON OLYMPUS CLV-190	La fel ca mai sus
EVIS X1 SISTEM VIDEO CENTRAL OLYMPUS CV-1500	Clasa IIa	EVIS X1 SISTEM VIDEO CENTRAL OLYMPUS CV-1500	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
OES CISTO-NEFRO-FIBROSCOP OLYMPUS CYF-5	Clasa IIa	OES CISTO-NEFRO-FIBROSCOP OLYMPUS CYF-5	La fel ca mai sus
OES CISTO-NEFRO-FIBROSCOP OLYMPUS CYF-5A	Clasa IIa	OES CISTO-NEFRO-FIBROSCOP OLYMPUS CYF-5A	La fel ca mai sus
VISERA VIDEO CISTO-NEFROSCOP OLYMPUS CYF TYPE V2	Clasa IIa	VISERA VIDEO CISTO-NEFROSCOP OLYMPUS CYF TYPE V2	La fel ca mai sus
VIDEO CISTO-NEFROSCOP OLYMPUS CYF- VHA	Clasa IIa	VIDEO CISTO-NEFROSCOP OLYMPUS CYF-VHA	La fel ca mai sus
VIDEO CISTO-NEFROSCOP OLYMPUS CYF-VHR	Clasa IIa	VIDEO CISTO-NEFROSCOP OLYMPUS CYF-VHR	La fel ca mai sus
TUB POWERSPIRAL DE UNICĂ FOLOSINŢĂ DPST-1	Clasa IIa	TUB POWERSPIRAL DE UNICĂ FOLOSINŢĂ DPST-1	La fel ca mai sus
RINO-LARINGO FIBROSCOP OLYMPUS ENF-GP2	Clasa IIa	RINO-LARINGO FIBROSCOP OLYMPUS ENF-GP2	La fel ca mai sus
VIDEO RINO-LARINGOSCOP OLYMPUS ENF-V3	Clasa IIa	VIDEO RINO-LARINGOSCOP OLYMPUS ENF-V3	La fel ca mai sus
VIDEO RINO-LARINGOSCOP OLYMPUS ENF-V4 OLYMPUS ENF-V4	Clasa IIa	VIDEO RINO-LARINGOSCOP OLYMPUS ENF-V4 OLYMPUS ENF-V4	La fel ca mai sus
VIDEO RINO-LARINGOSCOP OLYMPUS ENF-VH	Clasa IIa	VIDEO RINO-LARINGOSCOP OLYMPUS ENF-VH	La fel ca mai sus
VIDEO RINO-LARINGOSCOP OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	Clasa IIa	VIDEO RINO-LARINGOSCOP OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	La fel ca mai sus
RINO-LARINGO FIBROSCOP OLYMPUS ENF TYPE XP	Clasa IIa	RINO-LARINGO FIBROSCOP OLYMPUS ENF TYPE XP	La fel ca mai sus
EVIS EXERA Ⅱ VIDEO GASTROSCOP CU ULTRASUNETE OLYMPUS TIP GF UCT180	Clasa IIa	EVIS EXERA Ⅱ VIDEO GASTROSCOP CU ULTRASUNETE OLYMPUS TIP GF UCT180	La fel ca mai sus
EVIS LUCERA VIDEO GASTROSCOP CU ULTRASUNETE OLYMPUS TIP GF UCT260	Clasa IIa	EVIS LUCERA VIDEO GASTROSCOP CU ULTRASUNETE OLYMPUS TIP GF UCT260	La fel ca mai sus
EVIS EUS VIDEOSCOP GASTROINTESTINAL CU ULTRASUNETE OLYMPUS GF-UE190	Clasa IIa	EVIS EUS VIDEOSCOP GASTROINTESTINAL CU ULTRASUNET OLYMPUS GF-UE190	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
EVIS EUS VIDEOSCOP GASTROINTESTINAL CU ULTRASUNETE OLYMPUS GF-UE290	Clasa IIa	EVIS EUS VIDEOSCOP GASTROINTESTINAL CU ULTRASUNET OLYMPUS GF-UE290	La fel ca mai sus
EVIS EXERA Ⅲ VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-1TH190	Clasa IIa	EVIS EXERA Ⅲ VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-1TH190	La fel ca mai sus
VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-EZ1500	Clasa IIa	VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-EZ1500	La fel ca mai sus
VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H170	Clasa IIa	VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H170	La fel ca mai sus
EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H185	Clasa IIa	EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H185	La fel ca mai sus
EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H190	Clasa IIa	EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H190	La fel ca mai sus
EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H190N	Clasa IIa	EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H190N	La fel ca mai sus
EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF- H290	Clasa IIa	EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H290	La fel ca mai sus
EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF- H290EC	Clasa IIa	EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H290EC	La fel ca mai sus
EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H290T	Clasa IIa	EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-H290T	La fel ca mai sus
EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF- HQ190	Clasa IIa	EVIS EXERA III VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-HQ190	La fel ca mai sus
EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-HQ290	Clasa IIa	EVIS LUCERA ELITE VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-HQ290	La fel ca mai sus
VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-XP170N	Clasa IIa	VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-XP170N	La fel ca mai sus
EVIS LUCERA ELITE VIDEOSCOP	Clasa IIa	EVIS LUCERA ELITE VIDEOSCOP	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
GASTROINTESTINAL OLYMPUS GIF- XP290N		GASTROINTESTINAL OLYMPUS GIF-XP290N	
VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-XZ1200	Clasa IIa	VIDEOSCOP GASTROINTESTINAL OLYMPUS GIF-XZ1200	La fel ca mai sus
EVIS LUCERA ELITE VIDEO PLEOROSCOP OLYMPUS LTF-H290	Clasa IIa	EVIS LUCERA ELITE VIDEO PLEUROSCOP OLYMPUS LTF-H290	La fel ca mai sus
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	Clasa IIa	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	La fel ca mai sus
ENDOEYE FLEX VIDEOSCOP DEFLECTABIL OLYMPUS LTF-S190-5	Clasa IIa	ENDOEYE FLEX VIDEOSCOP DEFLECTABIL OLYMPUS LTF-S190-5	La fel ca mai sus
ENDOEYE FLEX 3D VIDEOSCOP DEFLECTABIL OLYMPUS LTF-S300-10-3D	Clasa IIa	ENDOEYE FLEX 3D VIDEOSCOP DEFLECTABIL OLYMPUS LTF-S300-10-3D	La fel ca mai sus
AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	Clasa IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	La fel ca mai sus
ENDOSCOP MOBIL PENTRU CĂILE RESPIRATORII OLYMPUS MAF-GM2	Clasa IIa	ENDOSCOP MOBIL PENTRU CĂILE RESPIRATORII OLYMPUS MAF-GM2	La fel ca mai sus
ENDOSCOP MOBIL PENTRU CĂILE RESPIRATORII OLYMPUS MAF-TM2	Clasa IIa	ENDOSCOP MOBIL PENTRU CĂILE RESPIRATORII OLYMPUS MAF-TM2	La fel ca mai sus
Capac MAJ-1024	Clasa IIa	Capac MAJ-1024	La fel ca mai sus
Capac MAJ-1025	Clasa IIa	Capac MAJ-1025	La fel ca mai sus
Recipient MAJ-1026	Clasa IIa	Recipient MAJ-1026	La fel ca mai sus
Inel-O MAJ-1028	Clasa IIa	Inel-O MAJ-1028	La fel ca mai sus
FURTUN BUTELIE PENTRU UHI-3 MAJ-1080	Clasa IIa	FURTUN BUTELIE PENTRU UHI-3 MAJ-1080	La fel ca mai sus
FURTUN BUTELIE PENTRU UHI-3 MAJ-1081	Clasa IIa	FURTUN BUTELIE PENTRU UHI-3 MAJ-1081	La fel ca mai sus
FURTUN BUTELIE PENTRU UHI-3 MAJ-1082	Clasa IIa	FURTUN BUTELIE PENTRU UHI-3 MAJ-1082	La fel ca mai sus
ADAPTATOR CONDUCTA DE GAZ MEDICAL PENTRU UHI-3 MAJ-1084	Clasa IIa	ADAPTATOR CONDUCTA DE GAZ MEDICAL PENTRU UHI-3 MAJ-1084	La fel ca mai sus
ADAPTATOR CONDUCTA DE GAZ MEDICAL PENTRU UHI-3 MAJ-1085	Clasa IIa	ADAPTATOR CONDUCTA DE GAZ MEDICAL PENTRU UHI-3 MAJ-1085	La fel ca mai sus
SUPAPĂ AER/APĂ MAJ-1444	Clasa IIa	SUPAPĂ AER/APĂ MAJ-1444	La fel ca mai sus
UNITATE ACŢIONARE SONDĂ MAJ- 1720	Clasa IIa	UNITATE ACŢIONARE SONDĂ MAJ-1720	La fel ca mai sus
REZERVOR MAJ-1727	Clasa IIa	REZERVOR MAJ-1727	La fel ca mai sus
TUB GAZ MAJ-1741	Clasa IIa	TUB GAZ MAJ-1741	La fel ca mai sus
TUB GAZ DEBIT MIC MAJ-1742	Clasa IIa	TUB GAZ DEBIT MIC MAJ-1742	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
TUB GAZ DEBIT FOARTE MIC MAJ-1816	Clasa IIa	TUB GAZ DEBIT FOARTE MIC MAJ-1816	La fel ca mai sus
BOBINĂ DE MÂNĂ MAJ-1859	Clasa IIa	BOBINĂ DE MÂNĂ MAJ-1859	La fel ca mai sus
PLACĂ DE REFERINŢĂ MAJ- 1860	Clasa IIa	PLACĂ DE REFERINŢĂ MAJ-1860	La fel ca mai sus
SONDĂ GHIDAJ ENDOSCOP MAJ-1878	Clasa IIa	SONDĂ GHIDAJ ENDOSCOP MAJ- 1878	La fel ca mai sus
FURTUN BUTELIE CU SUPAPĂ COMUTATOR (PIN- INDEX) MAJ-1985	Clasa IIa	FURTUN BUTELIE CU SUPAPĂ COMUTATOR (PIN-INDEX) MAJ-1985	La fel ca mai sus
FURTUN BUTELIE CU SUPAPĂ COMUTATOR (DIN) MAJ-1986	Clasa IIa	FURTUN BUTELIE CU SUPAPĂ COMUTATOR (DIN) MAJ-1986	La fel ca mai sus
SUPAPĂ GAZ/APĂ MAJ-2010	Clasa IIa	SUPAPĂ GAZ/APĂ MAJ-2010	La fel ca mai sus
TUB AUXILIAR APĂ MAJ-2021	Clasa IIa	TUB AUXILIAR APĂ MAJ-2021	La fel ca mai sus
TUB INSUFLARE MAJ-590	Clasa IIa	TUB INSUFLARE MAJ-590	La fel ca mai sus
TUB AUXILIAR APĂ MAJ-855	Clasa IIa	TUB AUXILIAR APĂ MAJ-855	La fel ca mai sus
RECIPIENT APĂ MAJ-902	Clasa IIa	RECIPIENT APĂ MAJ-902	La fel ca mai sus
DOP SONDĂ/IRIGARE MD-807	Clasa IIa	DOP SONDĂ/IRIGARE MD-807	La fel ca mai sus
SUPAPĂ AER/APĂ MH-438	Clasa IIa	SUPAPĂ AER/APĂ MH-438	La fel ca mai sus
UNITATEA CONTROL BALON OBCU OBCU	Clasa IIa	UNITATEA CONTROL BALON OBCU OBCU	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-H190DI	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-H190DI	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-H190DL	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-H190DL	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-H190TI	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-H190TI	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP E OLYMPUS PCF-H190TL	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-H190TL	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290DL	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290DL	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290TI	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290TI	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290TL	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290TL	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290ZI	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290ZI	La fel ca mai sus
EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290ZL	Clasa IIa	EVIS LUCERA ELITE VIDEO COLONOSCOP OLYMPUS PCF-H290ZL	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-HQ190I	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-HQ190I	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-HQ190L	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-HQ190L	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-PH190I	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-PH190I	La fel ca mai sus
EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-PH190L	Clasa IIa	EVIS EXERA III VIDEO COLONOSCOP OLYMPUS PCF-PH190L	La fel ca mai sus
UNITATE CONTROL POWERSPIRAL PSCU	Clasa IIa	UNITATE CONTROL POWERSPIRAL PSCU	La fel ca mai sus
VIDEOSCOP INTESTINAL OLYMPUS PSF-1	Clasa IIa	VIDEOSCOP INTESTINAL OLYMPUS PSF-1	La fel ca mai sus
EVIS EXERA III SMALL VIDEOSCOP INTESTINAL OLYMPUS SIF-H190	Clasa IIa	EVIS EXERA III SMALL VIDEOSCOP INTESTINAL OLYMPUS SIF-H190	La fel ca mai sus
EVIS LUCERA ELITE SMALL VIDEOSCOP INTESTINAL OLYMPUS SIF-H290S	Clasa IIa	EVIS LUCERA ELITE SMALL VIDEOSCOP INTESTINAL OLYMPUS SIF-H290S	La fel ca mai sus
TUB DESPICARE DE UNICĂ FOLOSINŢĂST-CB1	Clasa IIa	TUB DESPICARE DE UNICĂ FOLOSINŢĂ ST-CB1	La fel ca mai sus
TUB DESPICARE DE UNICĂ FOLOSINŢĂ ST-SB1	Clasa IIa	TUB DESPICARE DE UNICĂ FOLOSINŢĂ ST-SB1	La fel ca mai sus
EVIS EXERA Ⅱ VIDEO GSTROSCOP CU ULTRASUNETE OLYMPUS TGF-UC180J	Clasa IIa	EVIS EXERA Ⅱ VIDEO GSTROSCOP CU ULTRASUNETE OLYMPUS TGF-UC180J	La fel ca mai sus
VIDEO DUODENOSCOP OLYMPUS TJF-Q170V	Clasa IIa	VIDEO DUODENOSCOP OLYMPUS TJF-Q170V	La fel ca mai sus
EVIS EXERA III VIDEO DUODENOSCOP OLYMPUS TJF-Q190V	Clasa IIa	EVIS EXERA III VIDEO DUODENOSCOP OLYMPUS TJF-Q190V	La fel ca mai sus
EVIS LUCERA ELITE VIDEO DUODENOSCOP OLYMPUS TJF-Q290V	Clasa IIa	EVIS LUCERA ELITE VIDEO DUODENOSCOP OLYMPUS TJF-Q290V	La fel ca mai sus
UNITATE DE REGLARE CO2 ENDOSCOPIC OLYMPUS UCR	Clasa IIa	UNITATE DE REGLARE CO2 ENDOSCOPIC OLYMPUS UCR	La fel ca mai sus
SONDĂ CU ULTRASUNETE UM-3R	Clasa IIa	SONDĂ CU ULTRASUNETE UM-3R	La fel ca mai sus

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
SONDĂ CU ULTRASUNETE UM- S20-17S	Clasa IIa	SONDĂ CU ULTRASUNETE UM-S20-17S	La fel ca mai sus
SONDĂ CU ULTRASUNETE UM-S20-20R	Clasa IIa	SONDĂ CU ULTRASUNETE UM-S20-20R	La fel ca mai sus
UNITATE DE DETECȚIE A POZIȚIEI ENDOSCOPULUI UPD-3	Clasa IIa	UNITATE DE DETECȚIE A POZIȚIEI ENDOSCOPULUI UPD-3	La fel ca mai sus
VIDEO URETERO-RENOSCOP OLYMPUS URF-V3	Clasa IIa	VIDEO URETERO-RENOSCOP OLYMPUS URF-V3	La fel ca mai sus
VIDEO URETERO-RENOSCOP OLYMPUS URF-V3R	Clasa IIa	VIDEO URETERO-RENOSCOP OLYMPUS URF-V3R	La fel ca mai sus
UNITATE DE INSUFLARE DEBIT MARE UHI-4	Clasa IIa	UNITATE DE INSUFLARE DEBIT MARE UHI- 4	La fel ca mai sus
SUPAPĂ DE ASPIRARE DE UNICĂ FOLOSINŢĂ (Sterilă) MAJ-209	Clasa Is	SUPAPĂ DE ASPIRARE DE UNICĂ FOLOSINŢĂ (Sterilă) MAJ-209	Certificat nr. DD 60144068 0001 ON nr. 0197
SUPAPĂ BIOPSIE DE UNICĂ FOLOSINŢĂ MAJ-210	Clasa Is	SUPAPĂ BIOPSIE DE UNICĂ FOLOSINŢĂ MAJ-210	Certificat nr. DD 60144068 0001 ON nr. 0197
SUPAPĂ BIOPSIE DE UNICĂ FOLOSINŢĂ MAJ-1555	Clasa Is	SUPAPĂ BIOPSIE DE UNICĂ FOLOSINŢĂ MAJ-1555	Certificat nr. DD 60144068 0001 ON nr. 0197
CARCASĂ DISTALĂ DE UNICĂ FOLOSINŢĂ MAJ-210MAJ-2315	Clasa Is	CARCASĂ DISTALĂ DE UNICĂ FOLOSINŢĂ MAJ-2315	Certificat nr. DD 60144068 0001 ON nr. 0197

Istoricul revizuirilor scrisorii de confirmare

Data	Referinţă internă a ON care poate fi urmărită la fiecare versiune a scrisorii	Acţiune
23/01/2024	OMSC_CL607_CL_2024-01-23	Emiterea iniţială
25/04/2024	OMSC_CL607_CL_2024-04-25	Revizuire scrisoarea pentru a fi aliniată la OMSC_PLA0_HZ_20240416_EU 2023_607. – pentru eliminarea EVIS EUS CENTRU DE ECOGRAFIE ENDOSCOPIC EU-ME3, UNITATE DE INSUFLARE DEBIT MARE UHI-5, TUB DE INSUFLAȚIE CU ÎNCĂLZIRE MAJ-2464, SET DE TUBURI PENTRU CHIRURGIE TRANSANALĂ MAJ-2465 şi Tabel 2. – pentru adăugarea UNITATE DE INSUFLARE DEBIT MARE UHI-4. – Actualizare denumire dispozitiv din Pensă pentru biopsie de unică folosinţă FB-456D în GENERATOR BIPOLAR ULTRASONIC USG-410 (EMDN: Z120108) şi GENERATOR BIPOLAR ULTRASONIC

Data	Referință internă a ON care poate fi urmărită la fiecare versiune a scrisorii	Acţiune
		USG-410 (EMDN: Z120109). – Actualizare denumire dispozitiv anterior de la Pensă pentru biopsie de unică folosință FB-215U, FB-216U la Pensă pentru biopsie de unică folosință FB-215U.
30/04/2024	OMSC_CL607_CL_2024-04-30	Corectare făcută pe Tabelul 1 în versiunea anterioară. – GENERATOR BIPOLAR ULTRASONIC USG-410 (EMDN: Z120109) – URETERO-RENO-FIBROSCOP URF-P7 – URETERO-RENO-FIBROSCOP URF-P7R

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MINA FANEA-IVANOVICI
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Medicines & Healthcare products Regulatory Agency

EU MDR Article 120 extension confirmation

Manufacturer Name ('Manufacturer')	Manufacturer Address	MHRA Account Number
Olympus Medical Systems Corp.	2951, Ishikawa-cho Tokyo Hachioji-shi 192-8507, Japan	0000014720
UKRP/Northern Ireland Authorised Representative Name (if applicable)	**UKRP/NI Authorised Representative Address**	**MHRA Account Number**
KeyMed (Medical & Industrial Equipment) Ltd.	KeyMed House, Stock Road, Southend-on-Sea, Essex, SS2 5QH, United Kingdom	0000009451

I/we declare that:

- the CE certificate(s) listed below were issued under the EU Medical Devices Directive (93/42/EEC) or under the EU Active Implantable Medical Devices Directive (90/385/EEC) on or after 25 May 2017 and were still valid on 26 May 2021 **AND**

- the conditions for extension of the validity of the CE certificate(s) (under the EU Medical Devices Regulation (2017/745) (EU MDR) Article 120) set out below have been met in relation to the CE certificates as listed in the table below

[Complete the relevant table below]

	CE Certificate number/s	Notified Body that issued the CE certificate	Expiry date/s	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
a) That, in the case of a certificate that **expired before 20 March 2023** I/we/the manufacturer has a signed contract with a notified body that pre-dates the original expiry of the certificate	N/A	N/A	N/A	N/A	N/A	N/A

	CE Certificate number/s	Notified Body that issued CE certificate	Expiry date/s	Derogation Reference Number & issuing Competent Authority (if any)	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
b) That, in the case of a certificate that **expired before 20 March 2023,** no such contract (set out in (a) above) was signed before the date of certificate expiry, and the Manufacturer was granted in respect of the device: - a derogation from the conformity assessment procedures under EU MDR Article 59 **OR** - a period of time to carry out conformity assessment in accordance with EU MDR Article 97	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	CE Certificate number/s	Notified Body that issued the certificate	Expiry date/s	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
c) The CE certificate(s) **was due to expire on or after 20 March 2023**, and remains valid by virtue of EU MDR Article 120(2).	HD 60149405 0001	TÜV Rheinland LGA Products GmbH No. 0197	2024-05-26	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	2028-06-30
	DD 60144068 0001	TÜV Rheinland LGA Products GmbH No. 0197	2024-05-26	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	2028-06-30

Signed by Manufacturer:

Masaharu Hirose	**Vice President of Customer Quality & Management Representative**	14/05/2024
Name of Signatory	**Position of Signatory**	**Date**

Signed by UK Responsible Person/Northern Ireland Authorised Representative (if applicable):

Shaleenah Ramjan	**Head of RA – UI / MEA**	
Name of Signatory	**Position of Signatory**	**Date**

OMSC - EU_MDR_Article_120_extension_confirmation

Interim Agreement Report 2024-05-14

Created:	2024-05-13
By:	Alexander Madell (alexander.madell@olympus.com)
Status:	Out for Signature
Transaction ID:	CBJCHBCAABAAb5EOLG1GNQ994lu0M-0ZC0qfDQ6eRcX-

Agreement History

Agreement history is the list of the events that have impacted the status of the agreement prior to the final signature. A final audit report will be generated when the agreement is complete.

"OMSC - EU_MDR_Article_120_extension_confirmation" History

Document created by Alexander Madell (alexander.madell@olympus.com)
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Document emailed to Masaharu Hirose (masaharu.hirose@olympus.com) for signature
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2024-05-14 - 05:38:08 GMT

Document e-signed by Masaharu Hirose (masaharu.hirose@olympus.com)
Signature Date: 2024-05-14 - 05:42:08 GMT - Time Source: server

RDM UE articolul 120 confirmare extindere

Denumire producător ('Producător')	**Adresă producător**	**Număr cont MHRA**
Olympus Medical Systems Corp.	2951, Ishikawa-cho Tokyo Hachioji-shi 192-8507, Japan	0000014720
Deumire reprezentant autorizat UKRP/Irlanda de Nord (dacă este cazul)	**Adresă reprezentant autorizat UKRP/IN**	**Număr cont MHRA**
KeyMed (Medical & Industrial Equipment) Ltd.	KeyMed House, Stock Road, Southend-on-Sea, Essex, SS2 5QH, Regatul Unit	0000009451

Declar(ăm) următoarele:

- certificatul(ele) CE enumerate mai jos au fost emise în conformitate cu Directiva UE privind dispozitivele medicale (93/42/CEE) sau conform Directivei UE privind dispozitivele medicale implantabile active (90/385/CEE) la data sau după 25 mai 2017 și erau încă valabile la 26 mai 2021 **ȘI**

- au fost îndeplinite condițiile de prelungire a valabilității certificatului(lor) CE (în conformitate cu Regulamentul UE privind dispozitivele medicale (2017/745) (UE RDM) Articolul 120) stabilite mai jos în legătură cu certificatele CE enumerate în tabelul de mai jos

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471456

ROMÂNIA
MINISTERUL JUSTIȚIEI
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AUT. NR. 22069
TEL.: 0745471456

[Se va completa tabelul relevant de mai jos]

	Număr (Numere) certificat(e) CE	**Organismul notificat care a emis certificatele**	**Data (date) de expirare**	**Organismul notificat responsabil în prezent pentru supraveghere**	**Data (date) de valabilitate extinsă pentru piața din IN**	**Data (date) de valabilitate extinsă pentru piața din Regatul Unit**
a) Că, în cazul unui certificat care **a expirat înainte de 20 martie 2023**, eu/noi/producătorul avem un contract semnat cu un organism notificat care este anterior expirării inițiale a certificatului	Nu este cazul	Nu este cazul	Nu este cazul	Nu este cazul	Nu este cazul	Nu este cazul

	Număr (Numere) certificat(e) CE	**Organismul notificat care a emis certificatele**	**Data (date) de expirare**	**Numărul de referință al derogării și autoritatea competentă emitentă (dacă există)**	**Organismul notificat responsabil în prezent pentru supraveghere**	**Data (date) de valabilitate extinsă pentru piața din IN**	**Data (date) de valabilitate extinsă pentru piața din Regatul Unit**
b) Că, în cazul unui certificat care **a expirat înainte de 20 martie 2023**, niciun astfel de contract (prevăzut la litera (a) de mai sus) nu a fost semnat înainte de data expirării certificatului, iar Producătorului i s-a acordat pentru dispozitiv: - o derogare de la procedurile de evaluare a conformității în conformitate cu articolul 59 din RDM UE **SAU** o perioadă de timp pentru a efectua evaluarea conformității în conformitate cu articolul 97 din RDM UE	Nu este cazul	Nu este cazul	Nu este cazul	Nu este cazul	Nu este cazul	Nu este cazul	Nu este cazul

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	Număr (Numere) certificat(e) CE	Organismul notificat care a emis certificatele	Data (date) de expirare	Organismul notificat responsabil în prezent pentru supraveghere	Data (date) de valabilitate extinsă pentru piața din IN	Data (date) de valabilitate extinsă pentru piața din Regatul Unit
c) Certificatul (certificatele) CE **urma(u) să expire la data sau după 20 martie 2023** și rămâne valabil în temeiul articolului 120 (2) din RDM UE.	HD 60149405 0001	TÜV Rheinland LGA Products GmbH No. 0197	26-05-2024	TÜV Rheinland LGA Products GmbH No. 0197	31-12-2028	30-06-2028
	DD 60144068 0001	TÜV Rheinland LGA Products GmbH No. 0197	26-05-2024	TÜV Rheinland LGA Products GmbH No. 0197	31-12-2028	30-06-2028

Semnat de producator:

(semnătură indescifrabilă)

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TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
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Masaharu Hirose	**Vicepreşedinte calitate şi reprezentant management**	14/05/2024
Nume semnatar	**Funcţie semnatar**	**Data**

Semnat de persoana responsabilă pentru Marea Britanie / Reprezentant autorizat pentru Irlanda de Nord (daca este cazul):

Shaleenah Ramjan	**Director RA – UI / MEA**	
Nume semnatar	**Funcţie semnatar**	**Data**

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AUT. NR. 22069
TEL.: 0745471452

OMSC - EU_MDR_Article_120_extension_confirmation

Raport de acord interimar 14-05-2024

Creat:	13-05-2024
By:	Alexander Madell (alexander.madell@olympus.com)
Statut:	Eliberat pentru semnare
ID operaţiune:	CBJCHBCAABAAb5EOLG1GNQ994lu0M-0ZC0qfDQ6eRcX-

Istoric acord

Istoricul acordului este lista evenimentelor care au afectat statutul acordului înainte de semnarea finală. Un raport de audit final va fi generat la încheierea acordului.

Istoric "OMSC - EU_MDR_Article_120_extension_confirmation"

Document creat de Alexander Madell (alexander.madell@olympus.com)
2024-05-13 - 12:43:37 GMT

Document trimis pe email lui Masaharu Hirose (masaharu.hirose@olympus.com) pentru semnare
2024-05-13 - 12:43:42 GMT

Document trimis pe email lui Shaleenah Ramjan (shaleenah.ramjan@olympus.com) pentru semnare
2024-05-13 - 12:43:42 GMT

Email citit de Masaharu Hirose (masaharu.hirose@olympus.com)
2024-05-14 - 05:38:08 GMT

Document semnat digital de Masaharu Hirose (masaharu.hirose@olympus.com)
Data semnării: 2024-05-14 - 05:42:08 GMT – Sursa timpului: server

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TEL.: 0745471452

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 24, 2024

Notified Body Confirmation Letter
Reference: OSTE_MDR Application 2024-04-16; order # 1159799

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany
SRN Number (if available): DE-MF-000006729

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Digital unterschrieben
von Karsten Kluge
Datum: 2024.04.24
13:21:37 +02'00'

i.V. Dr. Karsten Kluge
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
40427611102852	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611105657	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611105759	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611106252	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611106354	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611102954	IIa	N/A	HD 60151129 0001 #0197
40427611107459	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611106456	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611106558	IIb non-implantable	N/A	HD 60151129 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4042761110024G	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110034J	IIa	N/A	HD 60151129 0001 #0197
40427611112755	IIa	A22091A A42091A	HD 60151129 0001 #0197
40427611112959	IIa	N/A	HD 60151129 0001 #0197
4042761111304S	IIa	N/A	HD 60151129 0001 #0197
4042761111314U	IIa	N/A	HD 60151129 0001 #0197
4042761111324W	IIa	N/A	HD 60151129 0001 #0197
4042761111334Y	IIa	N/A	HD 60151129 0001 #0197
40427611113452	IIa	N/A	HD 60151129 0001 #0197
40427611113554	IIa	N/A	HD 60151129 0001 #0197
40427611113656	IIa	N/A	HD 60151129 0001 #0197
4042761111395C	IIa	N/A	HD 60151129 0001 #0197
4042761111404V	IIa	N/A	HD 60151129 0001 #0197
4042761111414X	IIa	A37025A	HD 60151129 0001 #0197
4042761111424Z	IIa	A20919A A20918A	HD 60151129 0001 #0197
40427611114557	IIa	A4760 A47610A A4761 A4770 A4771 A4772 A4773 A4775 A4776	HD 60151129 0001 #0197
40427611114659	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111475B	Is	N/A	HD 60151129 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4042761111485D	IIa	A37022A A37025A WA33038A WA33037A	HD 60151129 0001 #0197
4042761111504Y	IIa	N/A	HD 60151129 0001 #0197
40427611115152	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611115254	IIb non-implantable	A6294 A6292 A6299 A6293	HD 60151129 0001 #0197
40427611115356	IIb non-implantable	WA90004W WA90004C WA90004J	HD 60151129 0001 #0197
4042761111575E	Is	N/A	HD 60151129 0001 #0197
4042761111585G	IIa	O0102.1	HD 60151129 0001 #0197
40427611116053	IIa	N/A	HD 60151129 0001 #0197
40427611116257	IIa	WA22810A WA22850A	HD 60151129 0001 #0197
40427611116359	IIa	A70950A A70970A WA70990A WA70992A A70951A A70971A WA70991A WA70993A	HD 60151129 0001 #0197
4042761111645B	IIa	A70951A A70950A A70971A A70970A WA70991A WA70990A WA70993A WA70992A	HD 60151129 0001 #0197
4042761111675H	Ir	N/A	HD 60151129 0001 #0197
4042761111685K	Ir	N/A	HD 60151129 0001 #0197
4042761111695M	IIb non-implantable	N/A	HD 60151129 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
40427611117158	Ir	N/A	HD 60151129 0001 #0197
4042761111765J	IIa	A3551 A3552	HD 60151129 0001 #0197
4042761111775L	Ir	N/A	HD 60151129 0001 #0197
4042761111775L	IIa	N/A	HD 60151129 0001 #0197
40427681108589	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042768110868B	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042768111017E	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042768111027G	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110044L	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110184X	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110274Y	IIa	N/A	HD 60151129 0001 #0197
4042761110304M	Ir	N/A	HD 60151129 0001 #0197
4042761110314P	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110334T	Ir	N/A	HD 60151129 0001 #0197
4042761110344V	Ir	N/A	HD 60151129 0001 #0197
40427611103855	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611103957	Ir	N/A	HD 60151129 0001 #0197
4042761110404Q	IIa	N/A	HD 60151129 0001 #0197
4042761110414S	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110424U	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110434W	IIa	N/A	HD 60151129 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4042761110444Y	IIa	N/A	HD 60151129 0001 #0197
4042761111234V	IIa	N/A	HD 60151129 0001 #0197
40427611114353	IIa	N/A	HD 60151129 0001 #0197
40427611104552	IIa	N/A	HD 60151129 0001 #0197
4042761110495A	IIa	N/A	HD 60151129 0001 #0197
4042761110504T	IIa	N/A	HD 60151129 0001 #0197
4042761110514V	IIa	N/A	HD 60151129 0001 #0197
4042761110524X	IIa	N/A	HD 60151129 0001 #0197
4042761110534Z	IIa	N/A	HD 60151129 0001 #0197
40427611105453	IIa	N/A	HD 60151129 0001 #0197
4042761110585B	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110595D	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110604W	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110614Y	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110675C	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611107255	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611107357	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110755B	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110845C	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110875J	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110925B	IIb non-implantable	N/A	HD 60151129 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4042761110935D	IIa	N/A	HD 60151129 0001 #0197
4042761110945F	IIa	N/A	HD 60151129 0001 #0197
4042761110965K	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110975M	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761110985P	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611111854	IIa	N/A	HD 60151129 0001 #0197
4042761110995R	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111004H	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111034P	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111044R	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111054T	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111074X	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111084Z	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611110953	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111104L	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111114N	Ir	N/A	HD 60151129 0001 #0197
4042761111124Q	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111134S	IIb non-implantable	N/A	HD 60151129 0001 #0197
4042761111144U	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611111752	IIb non-implantable	N/A	HD 60151129 0001 #0197
40427611111956	IIa	N/A	HD 60151129 0001 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4042761111204P	IIa	N/A	HD 60151129 0001 #0197
4042761111224T	IIa	WA22018A WA22019A A22021A A22022A A22023A A22026A A22027A A42021A	HD 60151129 0001 #0197
40427611112653	IIa	A22051A A22053A A22054A	HD 60151129 0001 #0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
40427611114353	IIa	WA33039A	Notified body involvement not required pursuant to MDD
40427611114455	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111495F	IIa	N/A	Notified body involvement not required pursuant to MDD
40427611115458	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111555A	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111565C	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111595J	IIa	N/A	Notified body involvement not required pursuant to MDD
40427611116155	IIa	N/A	Notified body involvement not

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			required pursuant to MDD
4042761111655D	Ir	N/A	Notified body involvement not required pursuant to MDD
40427611117056	Ir	N/A	Notified body involvement not required pursuant to MDD
4042761111725A	Ir	N/A	Notified body involvement not required pursuant to MDD
4042761111745E	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111755G	Ir	N/A	Notified body involvement not required pursuant to MDD
4042761111785N	IIa	A02908A	Notified body involvement not required pursuant to MDD
4042761110354X	Ir	N/A	Notified body involvement not required pursuant to MDD
4042761110364Z	Ir	N/A	Notified body involvement not required pursuant to MDD
40427611103753	Ir	N/A	Notified body involvement not required pursuant to MDD
40427611111854	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111234V	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111254Z	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761111244X	IIa	N/A	Notified body involvement not required pursuant to MDD
4042761110324R	Ir	N/A	Notified body involvement not required pursuant to MDD
4042761111214R	IIa	N/A	Notified body involvement not required pursuant to MDD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4042761111665F	Ir	N/A	Notified body involvement not required pursuant to MDD

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/18	OSTE_CL607_2024-04-18.pdf	Initial issue
2024/04/24	OSTE_CL607_2024-04-24.pdf	Correction of MDR device classification of 40427611114659 to class IIb non-implantable Correction of the substitute device of 4042761111485D (A37025A) Adding of a MDR device class IIa to 4042761111775L Adding the devices 40427611114353, 4042761111234V under a MDD Certificate Change that the device 4042761111595J required not a Notified body Change that the device 40427611111854 referred to a MDD certificate
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list

Traducere din limba engleză

Produse din fluxul de producţie Business
Departmentamentul de certificare

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germania

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Data 24 Aprilie 2024

Scrisoare de confirmare a organismului notificat
Referinţă: Solicitare OSTE_MDR 16-04-2024; decizie # 1159799

În atenţia persoanelor interesate,

Confirmarea statutului unei solicitări oficiale, a unui acord scris și a unei supravegheri adecvate în cadrul Regulamentului UE 2023/607 de modificare a Regulamentelor (UE) 2017/745 și (UE) 2017/746 în ceea ce privește dispozițiile tranzitorii pentru anumite dispozitive medicale și dispozitive medicale de diagnostic in vitro.

Prezenta scrisoare confirmă faptul că **TÜV Rheinland LGA Products GmbH**, un organism notificat (ON) desemnat conform Regulamentului (UE) 2017/745 (RDM) și identificat prin numărul **0197** pe NANDO, a primit o solicitare oficială în conformitate cu secțiunea 4.3 primul paragraf din anexa VII la RDM și a semnat un acord scris în conformitate cu secțiunea 4.3 al doilea paragraf din anexa VII la RDM cu următorul producător:

Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germania
Număr SRN (daca este cazul): DE-MF-000006729

Dispozitivele vizate de cererea formală și de acordul scris menționat mai sus sunt identificate în tabelele de mai jos. Tabelul 1 identifică dispozitivele pentru care a fost primită o cerere RDM, s-a încheiat un acord scris și pentru care ON este, de asemenea, responsabil pentru supravegherea adecvată în conformitate cu Directiva aplicabilă. Tabelul 2 identifică dispozitivele pentru care a fost primită o solicitare RDM și s-a încheiat un acord scris, dar ON nu și-a asumat încă responsabilitatea pentru supravegherea adecvată a dispozitivelor corespunzătoare conform directivei aplicabile.

În cazul dispozitivelor acoperite de certificate eliberate în temeiul Directivei 90/385/CEE (Directiva privind dispozitivele medicale implantabile active-AIMDD) sau Directivei 93/42/CEE (Directiva privind dispozitivele medicale-MDD) care au expirat după 26 mai 2021 dar înainte de 20 martie 2023 fără a fi fost retrase, prezenta scrisoare, de asemenea confirmă că producătorul fie a semnat acordul scris conform RDM până la data expirării certificatului MDD/AIMDD; sau a furnizat dovezi că o autoritate competentă a unui stat membru a acordat o derogare sau o scutire de la procedura de evaluare a conformității aplicabilă în conformitate cu articolul 59(1) din RDM sau, respectiv, cu articolul 97(1) din RDM, până la 20 martie 2023 pentru dispozitivele relevante.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germania

Sediu

Tillystraße 2
90431 Nuremberg

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ROMÂNIA MINISTERUL JUSTIȚIEI MINA FANEA-IVANOVICI TRADUCĂTOR AUTORIZAT ENGLEZĂ * FRANCEZĂ AUT. NR. 2069 TEL.: 0745471459

Termenele de tranziție care se aplică dispozitivelor vizate de prezenta scrisoare, sub rezerva respectării în continuare de către producător a celorlalte condiții specificate la articolul 120.3c din RDM (modificat prin (UE) 2023/607), sunt prezentate mai jos:

- 26 mai 2026 pentru dispozitivele implantabile personalizate din Clasa III
- 31 decembrie 2027 pentru dispozitivele din clasa III și dispozitivele implantabile de clasa IIb, cu excepția tehnologiilor consacrate (WET - suturi, capse, obturații dentare, aparate dentare, coroane dentare, șuruburi, pene, plăci, fire, știfturi, cleme și conectori)
- 31 decembrie 2028 pentru alte dispozitive din Clasa IIb, Clasa IIa, Clasa I, dispozitive introduse pe piață în stare sterilă sau au funcție de măsurare
- 31 decembrie 2028 pentru dispozitivele care nu necesită implicarea unui organism notificat în temeiul DDM, dar care o necesită în conformitate cu RDM (de exemplu, dispozitive de clasa I care se califică drept instrumente chirurgicale reutilizabile)

Din partea organismului notificat
(*semnătură indescifrabilă*)

Digital unterschrieben
von Karsten Kluge
Datum: 2024.04.24
13:21:37 +02'00'

i.V. Dr. Karsten Kluge
Organismul de certificare

Tabel 1: Dispozitive care fac obiectul prezentei scrisori și pentru care ON este, de asemenea, responsabil pentru supravegherea adecvată a dispozitivelor corespunzătoare conform directivei aplicabile:

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
40427611102852	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611105657	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611105759	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611106252	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611106354	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611102954	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611107459	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611106456	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611106558	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
4042761110024G	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110034J	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611112755	IIa	A22091A A42091A	HD 60151129 0001 #0197
40427611112959	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111304S	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111314U	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111324W	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111334Y	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611113452	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611113554	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611113656	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111395C	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111404V	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111414X	IIa	A37025A	HD 60151129 0001 #0197
4042761111424Z	IIa	A20919A A20918A	HD 60151129 0001 #0197
40427611114557	IIa	A4760 A47610A A4761 A4770 A4771 A4772 A4773 A4775 A4776	HD 60151129 0001 #0197
40427611114659	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111475B	Is	Nu este cazul	HD 60151129 0001 #0197

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
4042761111485D	IIa	A37022A A37025A WA33038A WA33037A	HD 60151129 0001 #0197
4042761111504Y	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611115152	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611115254	IIb neimplantabile	A6294 A6292 A6299 A6293	HD 60151129 0001 #0197
40427611115356	IIb neimplantabile	WA90004W WA90004C WA90004J	HD 60151129 0001 #0197
4042761111575E	Is	Nu este cazul	HD 60151129 0001 #0197
4042761111585G	IIa	O0102.1	HD 60151129 0001 #0197
40427611116053	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611116257	IIa	WA22810A WA22850A	HD 60151129 0001 #0197
40427611116359	IIa	A70950A A70970A WA70990A WA70992A A70951A A70971A WA70991A WA70993A	HD 60151129 0001 #0197
4042761111645B	IIa	A70951A A70950A A70971A A70970A WA70991A WA70990A WA70993A WA70992A	HD 60151129 0001 #0197
4042761111675H	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761111685K	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761111695M	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
40427611117158	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761111765J	IIa	A3551 A3552	HD 60151129 0001 #0197
4042761111775L	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761111775L	IIa	Nu este cazul	HD 60151129 0001 #0197
40427681108589	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042768110868B	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042768111017E	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042768111027G	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110044L	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110184X	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110274Y	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110304M	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761110314P	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110334T	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761110344V	Ir	Nu este cazul	HD 60151129 0001 #0197
40427611103855	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611103957	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761110404Q	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110414S	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110424U	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110434W	IIa	Nu este cazul	HD 60151129 0001 #0197

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
4042761110444Y	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111234V	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611114353	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611104552	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110495A	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110504T	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110514V	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110524X	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110534Z	IIa	Nu este cazul	HD 60151129 0001 #0197
40427611105453	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110585B	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110595D	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110604W	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110614Y	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110675C	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611107255	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611107357	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110755B	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110845C	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110875J	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110925B	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197

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Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
4042761110935D	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110945F	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110965K	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110975M	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761110985P	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611111854	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761110995R	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111004H	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111034P	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111044R	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111054T	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111074X	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111084Z	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611110953	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111104L	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111114N	Ir	Nu este cazul	HD 60151129 0001 #0197
4042761111124Q	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111134S	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
4042761111144U	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611111752	IIb neimplantabile	Nu este cazul	HD 60151129 0001 #0197
40427611111956	IIa	Nu este cazul	HD 60151129 0001 #0197

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
4042761111204P	IIa	Nu este cazul	HD 60151129 0001 #0197
4042761111224T	IIa	WA22018A WA22019A A22021A A22022A A22023A A22026A A22027A A42021A	HD 60151129 0001 #0197
40427611112653	IIa	A22051A A22053A A22054A	HD 60151129 0001 #0197

Tabel 2: Dispozitivele vizate de prezenta scrisoare și pentru care ON NU este responsabil pentru supravegherea adecvată a dispozitivelor corespunzătoare conform directivei aplicabile:

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
40427611114353	IIa	WA33039A	Implicarea organismului notificat nu este necesară în conformitate cu MDD
40427611114455	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111495F	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
40427611115458	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111555A	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111565C	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111595J	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
40427611116155	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
4042761111655D	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
40427611117056	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111725A	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111745E	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111755G	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111785N	IIa	A02908A	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761110354X	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761110364Z	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
40427611103753	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
40427611111854	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111234V	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111254Z	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111244X	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761110324R	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD
4042761111214R	IIa	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD

Denumire dispozitiv sau UDI-DI de bază (supus aplicării RDM)	Clasificarea dispozitivului RDM (așa cum este propusă de producător și verificată în etapa pre-solicitare)	Dacă dispozitivul RDM este un dispozitiv de înlocuire, identificarea dispozitivului MDD/AIMDD corespunzător	Referințele certificatului MDD/AIMDDC ale dispozitivelor supuse aplicării RDM și identificarea ON
4042761111665F	Ir	Nu este cazul	Implicarea organismului notificat nu este necesară în conformitate cu MDD

Istoricul revizuirilor scrisorii de confirmare

Data	Referință internă a ON care poate fi urmărită la fiecare versiune a scrisorii	Acțiune
18/04/2024	OSTE_CL607_2024-04-18.pdf	Emiterea inițială
24/04/2024	OSTE_CL607_2024-04-24.pdf	Corectarea clasificării dispozitivului RDM la 40427611114659 la clasa IIb neimplantabil Corectarea dispozitivului de înlocuire la 4042761111485D (A37025A) Adăugarea unui dispozitiv RDM clasa IIa la 4042761111775L Adăugarea dispozitivelor 40427611114353, 4042761111234V în baza unui Certificat MDD S-a modificat fapt că dispozitivul 4042761111595J nu necesita un organism notificat S-a modificat faptul că dispozitivul 40427611111854 se referă la un certificat MDD
ZZ/LL/AAAA	XXXXXXXXX	Eliminarea dispozitivului XYZ din listă

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60149405 0001

Report No.: 12018179 053

Manufacturer:
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products:
Design and Development, Manufacture of Medical Endoscopy Systems, Diagnostic, Operation and Treatment Products

(see attachments for products included)

Replaces Approval, Registration No.: HD 60144066 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-12

Date: 2020-05-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Notified Body

M.Aihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60149405 0001
Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products included:

Medical Endoscopy Systems:
-Endoscopes
-Endotherapy Devices
-Imaging Processors
-Pumps for Endoscopy
-Light Sources
-Position Detecting Units
-Electrothermal Cautery Units
-Integrated Endosurgery Systems
-Endoscopic Regulation/Control Units
Electrosurgical Equipment
Probes and Transducers for Ultrasonic Lithotriptors
Laparoscopic Insufflators
Ultrasound Surgical Equipment
Ultrasonic Surgical System generator
Ultrasonic Surgical System transducer
Hard-tissue ultrasonic surgical system holder/tip
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-05-12

M.Aihara

M.Sc. M. Aihara

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Traducere din limba engleza

TÜVRheinland®

CERTIFICAT CE
Directiva CE 93/42/CEE Anexa II, excluzând Secţiunea 4
Sistem complet de asigurare a calităţii
Echipamente medicale

Nr. Înregistrare: HD 60149405 0001
Nr. Raport: 12018179 053

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Proiectare şi dezvoltare, producţie de sisteme de endoscopie medicală, produse de diagnostic, operaţie şi tratament.
(a se vedea atasamentele pentru produsele incluse)
Înlocuieşte Aprobarea cu nr. de înregistrare: HD 60144066 0001

Data expirarii: 26.05.2024

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei II, excluzând secţiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa II, secţiunea 5 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate du Anexa II, secţiunea 4.

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data intrării în vigoare: 12-05-2020

Data: 12.05.2020

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜVRheinland

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat

Nr. Înregistrare: HD 60149405 0001
Nr. Raport: 12018179 053

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse incluse:

- Sisteme medicale de endoscopie:
  - -Endoscoape
  - -Echipamente endoterapie
  - -Procesoare de imagine
  - -Pompe pentru endoscopie
  - -Surse de lumină
  - -Unităţi de detectare poziţie
  - -Unităţi de cauterizare electrotermică
  - -Sisteme endochirurgicale integrate
  - - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde şi traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Generator sistem chirurgical cu ultrasunete
- Traductor sistem chirurgical cu ultrasunete
- Suport/varf sistem chirurgical cu ultrasunete pentru tesut tare
- Unitati de sterilizare
- Sisteme şi endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data: 12.05.2020

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60151129 0001

Report No.: 21232416 020

Manufacturer:
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products: medical endoscopy, surgical, diagnostic, and treatment systems

(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60104211 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-08-12

Date: 2020-08-12

Notified Body

Roland Gruber

TÜVRheinland LGA Products GmbH

TÜVRheinland

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/3, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products included:

- Telescopes, Videoscopes and Fiberscopes
- Electrosurgical Instruments
- Electrosurgical Forceps
- Electrosurgical Hand Pieces
- Electrosurgical Units
- Electrosurgical Electrodes
- Electrosurgical Cables and Adapters, Active Cords
- Peristaltic Pump Units
- Peristaltic Tubing Sets
- Invasive Access Devices
  (which would encompass obturators, sheaths, trocars, bridges and irrigation ports)
- Endoscopy Instruments
  (which would encompass cannulas, injection needles, ballon dilators, adaptors, tubes and non-active instruments)

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜVRheinland®

Doc. 2/3, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products included:

- Working Elements and Inserts
- Bladder Syringes
- Washer-Disinfectors
- Adaptors for Washer-Disinfectors
- Fluid Management Systems used in Endoscopy
- Light Sources

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- sterile Caps

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜVRheinland®

Doc. 3/3, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Sites included:

Olympus Winter & Ibe GmbH
Rheinstr. 8
14513 Teltow
Germany

- Design and development, manufacturing of medical devices for electrosurgery and for endoscopic applications

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜVRheinland

Traducere din limba engleză

Certificat CE

Directiva 93/42/CEE Anexa II, excluzând Secţiunea 4
Sistem complet de asigurare a calităţii
Dispozitive medicale

Nr. de înregistrare: HD 60151129 0001
Raport nr.: 21232416 020

Producător: **Olympus Winter & Ibe GmbH**
Kuehnstr. 61
22045 Hamburg
Germania

Produse: sisteme de endoscopie medicală, chirurgicală, diagnostic şi tratament
(vezi anexa pentru produsele şi locaţiile incluse)
Înlocuieşte Aprobarea, nr. de înregistrare: HD 60104211 0001

Data expirării: 26.05.2024

Organismul notificat declară prin prezenta că cerinţele Anexei II, excluzând secţiunea 4 din Directiva 93/42/CEE au fost îndeplinite pentru produsele enumerate. Producătorul menţionat mai sus a stabilit şi aplică un sistem de asigurare a calităţii, care face obiectul supravegherii periodice, definite prin Anexa II, secţiunea 5 din directiva menţionată mai sus. Pentru punerea pe piaţă a dispozitivelor din clasa III, acoperite de acest certificat, este necesar un certificat CE de examinare a designului, conform Anexei II, secţiunea 4.

Data intrării în vigoare: 12.08.2020

Data: 12.08.2020

Organism notificat,
Ştampilă oficială
Semnătură indescifrabilă
Roland Gruber

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg

TÜV Rheinland LGA Products GmbH este un organism notificat conform Directivei 93/42/CEE privind dispozitivele medicale cu numărul de identificare 0197.

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜVRheinland

Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2 – 90431 Nürnberg

Anexă la certificatul cu
Nr. de înregistrare: HD 60151129 0001
Raport nr.: 21232416 020

Producător: **Olympus Winter & Ibe GmbH**
Kuehnstr. 61
22045 Hamburg
Germania

Produse incluse:

- Telescoape, videoscoape şi fibroscoape
- Instrumente electrochirurgicale
- Pensă electrochirurgicală
- Piese de mână electrochirurgicale
- Unităţi electrochirurgicale
- Electrozi electrochirurgicali
- Cabluri şi adaptoare, cabluri active electrochirurgicale
- Unităţi pompe peristaltice
- Seturi tubulatură peristaltică
- Dispozitive de acces invaziv (care ar include obturatoare, teci, trocare, punţi şi porturi de irigare)
- Instrumente endoscopice (care ar include canule, ace de injecţie, dilatatoare cu balon, adaptoare, tuburi şi instrumente inactive)

Data: 12.08.2020

Organism notificat,
Ştampilă oficială
Semnătură indescifrabilă
Roland Gruber

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2 – 90431 Nürnberg

Anexă la certificatul cu
Nr. de înregistrare: HD 60151129 0001
Raport nr.: 21232416 020

Producător: **Olympus Winter & Ibe GmbH**
Kuehnstr. 61
22045 Hamburg
Germania

Produse incluse:

- Elemente de lucru şi inserţii
- Seringi pentru vezică
- Dispozitive de spălat – dezinfectat
- Adaptoare pentru dispozitive de spălat-dezinfectat
- Sisteme de management al fluidelor utilizate în endoscopie
- Surse de lumină

Pentru următoarele dispozitive medicale, aparatul optic acoperă doar aspectele producătorului privind siguranţa şi menţinerea condiţiilor sterile:

- Capace sterile

Data: 12.08.2020

Organism notificat,
Ştampilă oficială
Semnătură indescifrabilă
Roland Gruber

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2 – 90431 Nürnberg

Anexă la certificatul cu
Nr. de înregistrare: HD 60151129 0001
Raport nr.: 21232416 020

Producător: **Olympus Winter & Ibe GmbH**
Kuehnstr. 61
22045 Hamburg
Germania

Locaţii incluse:

Olympus Winter & Ibe GmbH
Rheinstr. 8
14513 Teltow
Germania

- Designul şi dezvoltarea, fabricarea dispozitivelor medicale pentru electrochirurgie şi pentru aplicaţiile endoscopice

Data: 12.08.2020

Organism notificat,
Ştampilă oficială
Semnătură indescifrabilă
Roland Gruber

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2158445-1
Certificate Holder:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan
Scope:	Design and Development, Manufacture, Distribution, Service, Quality Assurance, Regulatory Affairs of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units, Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump, Surgical Microscope

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	150293386-301
Effective date:	2024-07-27
Expiry date:	2027-07-26
Issue date:	2024-07-04

Replaces certificate SX 2158445-1 issued 2024-02-29

This certificate can be validated on https://www.certipedia.com

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2158445-1

Certificate Holder: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o OLYMPUS MEDICAL SYSTEMS CORP. Ishikawa Facility 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan	Design and Development, Service, Administration, Quality Assurance, Regulatory Affairs
/02	c/o OLYMPUS MEDICAL SYSTEMS CORP. Utsuki Facility 2-3, Kuboyama-cho, Hachioji-shi, Tokyo 192-8512 Japan	Design and Development of Endoscopes, Light Sources, Imaging Processors
/03	c/o OLYMPUS MEDICAL SYSTEMS CORP. Tatsuno Facility 6789 Inatomi, Tatsuno-machi, Kamiina-gun, Nagano 399-0428 Japan	Design and Development of Endoscopes
/04	c/o Olympus Medical Systems Corp. Hinode Facility 34-3 Hirai, Hinode-machi Nishitama-gun, Tokyo 190-0182 Japan	Design and Development and Quality Assurance of Endoscopes, Endotherapy devices, Imaging Processors, Endoscopic Regulation/Control Units, Camera Heads, Capsule Endoscopy Systems, Ultrasound Diagnostic Imaging Systems, Surgical Microscope, Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Endoscopes and Sterile Non Active Instrument used in conjunction with Endoscopes, and Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems, IT Products used in conjunction with Medical Endoscopy Systems

Report No.: 150293386-301

Effective date: 2024-07-27

Expiry date: 2027-07-26

Issue date: 2024-07-04

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2158445-1

Certificate Holder: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

The scope of certification also covers the following sites:

/05	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shirakawa Facility 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061 Japan	Design and Development and Quality Assurance of Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/Recorders for Endoscopy, Electrosurgical Equipment, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Ultrasound Surgical Equipment and Endoscopes, Probes and Transducers for Ultrasonic Lithotriptors, Ultrasonic Lithotriptors, Capsule Endoscopes, Printed wiring boards for medical devices
/06	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aizu Facility 3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520 Japan	Design and Development and Quality Assurance of Medical Endoscopes and Disinfecting Units, Probe for Endoscope Position Detecting Units
/07	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aomori Facility 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357 Japan	Design and Development and Quality Assurance of Endotherapy devices, Ultrasound Surgical Equipment, Sterile Non Active Instruments used in conjunction with Endoscopes and Ultrasound Imaging Systems, and Sterile Endotherapy Devices used in conjunction with Endoscopes

Report No.: 150293386-301

Effective date: 2024-07-27

Expiry date: 2027-07-26

Issue date: 2024-07-04

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

Traducere din limba engleză

Certificat

Sistemul de management al calităţii
EN ISO 13485:2016

Nr. înregistrare: SX 2158445-1
Organizaţie: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japonia

Domeniu de aplicabilitate : Proiectare şi dezvoltare, producţie, distribuţie, service, asigurarea calităţii, aspecte reglementare pentru endoscoape, echipamente endoterapie, surse de lumină, procesoare de imagine, unităţi de detectare a poziţiei endoscopului, unităţi de cauterizare electrotermică, sisteme endochirurgicale integrate, unităţi de control/reglare endoscopice, capete cameră/pompe/sisteme monitorizare/sisteme înregistrare pentru endoscopie, echipamente electrochirurgicale, endoscoape capsulă şi sisteme, insuflatoare laparoscopice, sisteme de imagistică pentru diagnostic ecografic, unităţi dezinfectare, echipamente chirurgicale cu ultrasunete, sonde şi traductoare pentru litotriptoare ultrasonice, instrumente sterile inactive utilizate împreună cu endoscoape, echipamente sterile pentru endoterapie utilizate împreună cu endoscoape, echipamente sterile inactive utilizate împreună cu sisteme medicale de imagistică pentru diagnostic ecografic şi recipiente apă, tuburi alimentare apă, supape apă şi întrerupătoare de picior pentru pompă, microscop chirurgical.

Organismul de certificare al TÜV Rheinland LGA Products GmbH certifică prin prezenta faptul că organizaţia a implementat şi aplică un sistem de management al calităţii pentru dispozitive medicale.
S-a furnizat dovada faptului ca au fost îndeplinite cerinţele specificate în standardul menţionat mai sus.
Sistemul de management al calităţii este supus unei supravegheri anuale.

Nr. raport: 150293386-301
Data intrării în vigoare: 27.07.2024
Data expirării: 26.07.2027
Data emiterii: 04.07.2024

Înlocuieşte certificatul SX 2158445-1 emis la 29.02.2024

Certificatul poate fi validat pe https://www.certipedia.com

Atsushi Kato
Semnătură indescifrabilă
TÜV Rheinland LGA Products GmbH)
Tillystraße 2 – 90431 Nuernberg – Germania

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Certificat

Sistemul de management al calităţii
EN ISO 13485:2016

Nr. înregistrare: SX 2158445-1
Organizaţie: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japonia

Domeniul de aplicabilitate al certificării acoperă de asemenea următoarele locaţii:

Nr.	Unitate	Domeniu de aplicabilitate
/01	c/o OLYMPUS MEDICAL SYSTEMS CORP. Unitatea Ishikawa 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japonia	Proiectare şi dezvoltare, service, administrare, asigurarea calităţii, aspecte reglementare
/02	c/o OLYMPUS MEDICAL SYSTEMS CORP. Unitatea Utsuki 2-3, Kuboyama-cho, Hachioji-shi, Tokyo 192-8512 Japonia	Proiectarea şi dezvoltarea endoscoapelor, surselor de lumină, procesoarelor de imagini
/03	c/o OLYMPUS MEDICAL SYSTEMS CORP. Unitatea Tatsuno 6789 Inatomi, Tatsuno-machi, Kamiina-gun, Nagano 399-0428 Japonia	Proiectarea şi dezvoltarea endoscoapelor
/04	c/o Olympus Medical Systems Corp. Unitatea Hinode 34-3 Hirai, Hinode-machi Nishitama-gun, Tokyo 190-0182 Japonia	Proiectarea și dezvoltarea și asigurarea calității endoscoapelor, dispozitivelor endoterapeutice, procesoarelor de imagini, unități de reglare/control endoscopic, capete de cameră, sisteme de endoscopie cu capsulă, sisteme de imagistică pentru diagnosticare cu ultrasunete, microscop chirurgical, recipient cu apă, tub de alimentare cu apă, supapă de alimentare cu apă și comutator de picior pentru endoscoape și instrument steril inactiv utilizat împreună cu endoscoape și dispozitive sterile inactive utilizate în combinație cu sisteme medicale de diagnosticare cu ultrasunete, produse IT utilizate împreună cu sisteme medicale de endoscopie

Nr. raport: 150293386-301
Data intrării în vigoare: 27.07.2024
Data expirării: 26.07.2027
Data emiterii: 04.07.2024

Certificatul poate fi validat pe https://www.certipedia.com

Atsushi Kato
Semnătură indescifrabilă
TÜV Rheinland LGA Products GmbH)
Tillystraße 2 – 90431 Nuernberg – Germania

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

ROMÂNIA MINISTERUL JUSTIȚIEI ANA-MARIA IVANOVICI TRADUCĂTOR AUTORIZAT ENGLEZĂ * FRANCEZĂ AUT. NR. 22069 TEL.: 0745471459

Certificat

Sistemul de management al calităţii
EN ISO 13485:2016

Nr. înregistrare: SX 2158445-1
Organizaţie: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japonia

Domeniul de aplicabilitate al certificării acoperă de asemenea următoarele locaţii:

Nr.	Centru de producţie	Domeniu de aplicabilitate
05/	c/o OLYMPUS MEDICAL SYSTEMS CORP. Unitatea Shirakawa 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061 Japonia	Proiectarea și dezvoltarea și asigurarea calității surselor de lumină, procesoarelor de imagini, unităților de detectare a poziției endoscopului, unități de cauterizare electrotermică, sisteme integrate de endochirurgie, unități de reglare/control endoscopice, capete de cameră/pompe/monitoare/aparate de înregistrat pentru endoscopie, echipamente electrochirurgicale, insuflatoare laparoscopice, sisteme de diagnosticare imagistică cu ultrasunete, echipamente chirurgicale cu ultrasunete și endoscoape, sonde și traductoare pentru litotriptoare cu ultrasunete, litotriptoare cu ultrasunete, endoscoape cu capsule, circuite imprimate pentru dispozitive medicale
/06	c/o OLYMPUS MEDICAL SYSTEMS CORP. Ishikawa Office Aizu Facility 3-1-1 Niiderakita Aizuwakamatsu-shi, Fukushima 965-8520 Japonia	Proiectarea și dezvoltarea și asigurarea calității endoscoapelor medicale și a unităților de dezinfectare, sondă pentru unitățile de detectare a poziției endoscopului
/07	c/o OLYMPUS MEDICAL SYSTEMS CORP. Ishikawa Office Aomori Facility 2-248-1 Okkonoki Kuroishi-shi, Aomori 036-0357 Japonia	Proiectarea și dezvoltarea și asigurarea calității dispozitivelor de endoterapie, echipamentelor chirurgicale cu ultrasunete, instrumentelor sterile inactive utilizate împreună cu endoscoape și sisteme de imagistică cu ultrasunete și dispozitive sterile de endoterapie utilizate împreună cu endoscoape

Nr. raport: 150293386-301
Data intrării în vigoare: 27.07.2024
Data expirării: 26.07.2027
Data emiterii: 04.07.2024

Certificatul poate fi validat pe https://www.certipedia.com

Atsushi Kato
Semnătură indescifrabilă
TÜV Rheinland LGA Products GmbH)
Tillystraße 2 – 90431 Nuernberg – Germania

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

ROMÂNIA MINISTERUL JUSTIȚIEI MIHAI IANCU IVANOVICI TRADUCĂTOR AUTORIZAT ENGLEZĂ * FRANCEZĂ AUT. NR. 22069 TEL.: 0745471459

Certificate

Certificate No.:	MD 1845129-1-1
Manufacturer:	**Olympus Winter & Ibe GmbH** Kuehnstr. 61 22045 Hamburg Germany
REPs Facility ID:	F001098
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	1156361-140
Issue Date:	2024-07-10
Effective Date:	2024-07-12
Expiry Date:	2027-07-11

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1845129-1-1

Manufacturer:

Olympus Winter & Ibe GmbH

Kuehnstr. 61
22045 Hamburg
Germany

Scope:

Design and development, manufacture, distribution, and service of medical endoscopy, diagnostic, surgical, and treatment systems

Products included:
- Telescopes, Videoscopes and Fiberscopes
- Electrosurgical Instruments
- Electrosurgical Forceps
- Electrosurgical Hand Pieces
- Electrosurgical Units
- Electrosurgical Cables and Adapters, Active Cords
- Electrosurgical Electrodes
- Peristaltic Pump Units
- Peristaltic Tubing Sets
- Invasive Access devices
  (which would encompass obturators, sheaths, trocars, bridges and irrigation ports)
- Endoscopy Instruments
  (which would encompass cannulas, injection needles, balloon dilators, adaptors, tubes and non-active instruments)
- Intra bronchial valve systems
  (Spiration® Valve System)
- Working Elements and Inserts
- Bladder Syringes
- Washer-Disinfectors
- Adaptors for Washer-Disinfectors
- Fluid Management Systems used in Endoscopy
- Light Sources
- LG-Cables
- Sterile Caps

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1845129-1-1

Manufacturer: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germany

The scope of certification also covers the following sites:

No.	Location	Scope
/01	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg Germany REPs Facility ID: F001098	Design and development, manufacture, distribution, and service of medical endoscopy, diagnostic, surgical, and treatment systems
/02	Olympus Winter & Ibe GmbH Building 01, 02, 03, 04, 05, 06, 07, 10 Kuehnstr. 61 22045 Hamburg Germany REPs Facility ID: F001098	Manufacture and service
/03	Olympus Winter & Ibe GmbH Building HA, HB, HD Kuehnstr. 71 22045 Hamburg Germany REPs Facility ID: F001098	Administration
/04	Olympus Winter & Ibe GmbH Building 11 Albert-Schweitzer-Ring 16 22045 Hamburg Germany REPs Facility ID: F001098	Administration

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1845129-1-1

Manufacturer: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germany

The scope of certification also covers the following sites:

No.	Location	Scope
/05	Olympus Winter & Ibe GmbH Building HK Kuehnstr. 65 22045 Hamburg Germany REPs Facility ID: F001098	Design and development
/06	Olympus Winter & Ibe GmbH Building 20 Albert-Schweitzer-Ring 9-11 22045 Hamburg Germany REPs Facility ID: F001098	Design and development, manufacture
/07	Olympus Winter & Ibe GmbH Building 22 Rahlau 38 22045 Hamburg Germany REPs Facility ID: F001098	Design and development, manufacture
/08	Olympus Winter & Ibe GmbH Building H4 Albert-Schweitzer-Ring 22 22045 Hamburg Germany REPs Facility ID: F001098	Administration

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1845129-1-1

Manufacturer: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germany

The scope of certification also covers the following sites:

No.	Location	Scope
/09	Olympus Winter & Ibe GmbH Building 21 Rahlau 40 22045 Hamburg Germany REPs Facility ID: F001098	Warehouse
/10	Olympus Winter & Ibe GmbH Building 30 Albert-Schweitzer-Ring 24-26 22045 Hamburg Germany REPs Facility ID: F001098	Manufacture and service
/11	Olympus Winter & Ibe GmbH Building 09 Albert-Schweitzer-Ring 14 22045 Hamburg Germany REPs Facility ID: F001098	Administration
/12	Olympus Winter & Ibe GmbH Building H5 Albert-Schweitzer-Ring 23 22045 Hamburg Germany REPs Facility ID: F001098	Administration

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1845129-1-1

Manufacturer: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germany

The scope of certification also covers the following sites:

No.	Location	Scope
/13	Olympus Winter & Ibe GmbH Building 31 Albert-Schweitzer-Ring 35 22045 Hamburg Germany REPs Facility ID: F001098	Service
/14	Olympus Winter & Ibe GmbH Rheinstr. 8 14513 Teltow Germany REPs Facility ID: F002022	Design and development, manufacture

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificat

Nr. certificat:	MD 1845129-1-1
Producător:	**Olympus Winter & Ibe GmbH** Kuehnstr. 61 22045 Hamburg Germania
Cod unitate REPs:	F001098
Criterii de certificare:	ISO 13485:2016 Regulamentul australian pentru produse terapeutice (dispozitive medicale), 2002, Anexa 3 Partea 1 (excluzând Partea 1.6) – Procedura de asigurare completă a calității Brazilia RDC ANVISA nr. 665/2022, DRC ANVISA nr. 551/2021, DRC ANVISA nr. 67/2009 Reglementările privind dispozitivele medicale din Canada – Partea 1 – SOR 98/282 Japonia Ordonanța ministerială MHLW 169, de la Articolul 4 până la Articolul 68, Legea PMD Statele Unite ale Americii 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subpărțile de la A la D

TUV Rheinland of North America, Inc., o organizație de audit recunoscută de MDSAP, certifică că sistemul de management al calității Producătorului a fost auditat și s-a constatat că este conform cu criteriile de certificare pentru domeniul de aplicare conținut în acest certificat. Sistemul de management al calității este supus auditului/auditurilor anuale de supraveghere.

Nr. proiect:	1156361-140
Data emiterii:	10.07.2024
Data intrării în vigoare:	12.07.2024
Data expirării:	11.07.2027

Semnătură indescifrabilă

Ofiţer certificare: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Valabilitatea certificatului poate fi verificată pe: https://www.certipedia.com
sau sunând la 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, SUA
Tel: (925) 249-9123, Fax: (925) 249-9124

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. [illegible]
TEL.: 0745471459

Certificat

Nr. certificat: MD 1845129-1-1

Producător: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germania

Scop: Proiectarea și dezvoltarea, fabricarea, distribuția și service-ul pentru sistemele endoscopice medicale, sistemele de diagnosticare, chirurgicale și de tratament

Produse incluse:

- Telescoape, videoscoape și fibroscoape
- Instrumente electrochirurgicale
- Pense electrochirurgicale
- Piese de mână electrochirurgicale
- Unităţi electrochirurgicale
- Cabluri și adaptoare electrochirurgicale, cabluri active
- Electrozi electrochirurgicali
- Unități de pompe peristaltice
- Seturi de tuburi peristaltice
- Dispozitive de acces invaziv

(care ar cuprinde obturatoarele, tecile, trocarele, punţile și porturile de irigare)

- Instrumente de endoscopie
- (care ar cuprinde canule, ace de injectare, dilatatoare cu baloane, adaptoare, tuburi și instrumente inactive)
- Sisteme de valve intra-bronhiale (Sistem de valve Spiration®)
- Elemente de lucru și inserții
- Seringi pentru vezica urinara
- Mașini de spălat-dezinfectat
- Adaptoare pentru mașini de spălat-dezinfectat
- Sisteme de management al fluidelor utilizate în Endoscopie
- Surse de lumină
- Cabluri LG
- Capace sterile

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Valabilitatea certificatului poate fi verificată pe: https://www.certipedia.com
sau sunând la 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, SUA
Tel: (925) 249-9123, Fax: (925) 249-9124

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 20220
TEL.: 0745471459

Certificat

Nr. certificat: MD 1845129-1-1

Producător: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germania

Scopul certificării acoperă, de asemenea, următoarele locaţii:

Nr.	Locaţie	Scop
/01	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg Germania Cod unitate REPs: F001098	Proiectarea și dezvoltarea, fabricarea, distribuția și service-ul sistemelor endoscopice medicale, sistemelor de diagnosticare, chirurgicale și de tratament
/02	Olympus Winter & Ibe GmbH Building 01, 02, 03, 04, 05, 06, 07, 10 Kuehnstr. 61 22045 Hamburg Germania Cod unitate REPs: F001098	Fabricare şi service
/03	Olympus Winter & Ibe GmbH Building HA, HB, HD Kuehnstr. 71 22045 Hamburg Germania Cod unitate REPs: F001098	Administrare
/04	Olympus Winter & Ibe GmbH Building 11 Albert-Schweitzer-Ring 16 22045 Hamburg Germania Cod unitate REPs: F001098	Administrare

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Valabilitatea certificatului poate fi verificată pe: https://www.certipedia.com
sau sunând la 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, SUA
Tel: (925) 249-9123, Fax: (925) 249-9124

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 20339
TEL.: 0745471459

Certificat

Nr. certificat: MD 1845129-1-1

Producător: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germania

Scopul certificării acoperă, de asemenea, următoarele locaţii:

Nr.	Locaţie	Scop
/05	Olympus Winter & Ibe GmbH Building HK Kuehnstr. 65 22045 Hamburg Germania Cod unitate REPs: F001098	Proiectare şi dezvoltare
/06	Olympus Winter & Ibe GmbH Building 20 Albert-Schweitzer-Ring 9-11 22045 Hamburg Germania Cod unitate REPs: F001098	Proiectare şi dezvoltare, fabricare
/07	Olympus Winter & Ibe GmbH Building 22 Rahlau 38 22045 Hamburg Germania Cod unitate REPs: F001098	Proiectare şi dezvoltare, manufacture
/08	Olympus Winter & Ibe GmbH Building H4 Albert-Schweitzer-Ring 22 22045 Hamburg Germania Cod unitate REPs: F001098	Administrare

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Valabilitatea certificatului poate fi verificată pe: https://www.certipedia.com
sau sunând la 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, SUA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificat

Nr. certificat: MD 1845129-1-1

Producător: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germania

Scopul certificării acoperă, de asemenea, următoarele locaţii:

Nr.	Locaţie	Scop
/09	Olympus Winter & Ibe GmbH Building 21 Rahlau 40 22045 Hamburg Germania Cod unitate REPs: F001098	Depozitare
/10	Olympus Winter & Ibe GmbH Building 30 Albert-Schweitzer-Ring 24-26 22045 Hamburg Germania Cod unitate REPs: F001098	Fabricare şi service
/11	Olympus Winter & Ibe GmbH Building 09 Albert-Schweitzer-Ring 14 22045 Hamburg Germania Cod unitate REPs: F001098	Administrare
/12	Olympus Winter & Ibe GmbH Building H5 Albert-Schweitzer-Ring 23 22045 Hamburg Germania Cod unitate REPs: F001098	Administrare

Valabilitatea certificatului poate fi verificată pe: https://www.certipedia.com
sau sunând la 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, SUA
Tel: (925) 249-9123, Fax: (925) 249-9124

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 20239
TEL.: 0745471459

Certificat

Nr. certificat: MD 1845129-1-1

Producător: **Olympus Winter & Ibe GmbH**

Kuehnstr. 61
22045 Hamburg
Germania

Scopul certificării acoperă, de asemenea, următoarele locaţii:

Nr.	Locaţie	Scop
/13	Olympus Winter & Ibe GmbH Building 31 Albert-Schweitzer-Ring 35 22045 Hamburg Germania Cod unitate REPs: F001098	Service
/14	Olympus Winter & Ibe GmbH Rheinstr. 8 14513 Teltow Germania Cod unitate REPs: F002022	Proiectare şi dezvoltare, fabricare

Valabilitatea certificatului poate fi verificată pe: https://www.certipedia.com
sau sunând la 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, SUA
Tel: (925) 249-9123, Fax: (925) 249-9124

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 20220
TEL.: 0745471459

Bureau Veritas Certification

Certificate

awarded to

Olympus Winter & Ibe GmbH

Kuehnstr. 61
22045 Hamburg, Germany

Bureau Veritas Certification certifies that the Management System of the above organisation has been assessed and found to be in accordance with the requirements of the standards detailed below.

Standard

DIN EN ISO 14001:2015

Scope of application

Development, manufacturing, distribution and service of medical endoscope-, diagnosis-, surgery-, and therapy systems.

Certification cycle start date: **01. June 2022**

Subject to the continual satisfactory operation of the organisation's Management System, this certificate expires on: **31. May 2025**

Certificate n° : **DE012761-1**

Date: **31. May 2022**

Certification Manager (A. Sterl)

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-16024-01-00

Certification body address: Bureau Veritas Certification Germany GmbH, Veritaskai 1, 21079 Hamburg

To check this certificate validity you may contact Bureau Veritas Certification. Further clarifications regarding the scope of this certificate and the applicability of the Management Systems requirements may be obtained by consulting the organisation.

BUREAU VERITAS

Bureau Veritas Certification

Annex to the Certificate N° DE012761-1

awarded to

Olympus Winter & Ibe GmbH

Kuehnstr. 61
22045 Hamburg, Germany

Bureau Veritas Certification has issued this annex to the Management Certificate of the above mentioned company.

Standard

DIN EN ISO 14001:2015

Site	Scope of application
Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg, Germany	Development, manufacturing, distribution and service of medical endoscope-, diagnosis-, surgery-, and therapy systems.
Olympus Winter & Ibe GmbH Rheinstr. 8 14513 Teltow, Germany	

Date: **31. May 2022**

Certificate n° : **DE012761-1**

Valid until: **31. May 2025**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16024-01-00

Certification body address: Bureau Veritas Certification Germany GmbH, Veritaskai 1, 21079 Hamburg

To check this certificate validity you may contact Bureau Veritas Certification. Further clarifications regarding the scope of this certificate and the applicability of the Management Systems requirements may be obtained by consulting the organisation.

Traducere din limba engleză

Bureau Veritas Certification

Certificat

Conferit

Olympus Winter & Ibe GmbH

Kuehnstr. 61

22045 Hamburg, Germania

Bureau Veritas Certification certifică faptul că Sistemul de management al organizaţiei de mai sus a fost evaluat şi s-a constatat că este în conformitate cu cerinţele standardelor detaliate mai jos.

Standardul

DIN EN ISO 14001:2015

Domeniul de aplicare

Dezvoltarea, fabricarea, distribuţia şi service-ul sistemelor medicale endoscopice, de diagnosticare, chirurgicale şi terapeutice.

Data începerii ciclului de certificare: **01 iunie 2022**

Făcând obiectul operării continue satisfăcătoare a sistemului de management al organizaţiei, acest certificat expiră la data: **31 mai 2025**

Nr. certificat: **DE012761-1**

Data: **31 mai 2022**

Semnătură indescifrabilă

Director Certificare (A. Sterl)

DAkkS Deutsche Akkreditierungsstelle D-ZM-16024-01-00

Pagina: 1 din 2

Adresă organism de certificare: Bureau Veritas Certification Germany GmbH, Veritaskai 1, 21079 Hamburg

Pentru a verifica valabilitatea acestui certificat, puteţi contacta Bureau Veritas Certification. Mai multe clarificări cu privire la domeniul de aplicare al acestui certificat şi aplicabilitatea cerinţelor Sistemelor de management pot fi obţinute prin consultarea organizaţiei.

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Anexă la Certificatul nr. DE012761-1

conferit

Conferit

Olympus Winter & Ibe GmbH

Kuehnstr. 61

22045 Hamburg, Germania

Bureau Veritas Certification a emis această anexă la Certificatul de management al companiei menţionate mai sus.

Standard

Unitate	Domeniul de aplicare
Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg, Germania	Dezvoltarea, fabricarea, distribuţia şi service-ul sistemelor medicale endoscopice, de diagnosticare, chirurgicale şi terapeutice.
Olympus Winter & Ibe GmbH Rheinstr. 8 14513 Teltow, Germania	

Data: **31 mai 2022**

Pagina: 2 din 2

Certificat nr.: **DE012761-1**

Valabil până la: **31 mai 2025**

DAkkS Deutsche Akkreditierungsstelle D-ZM-16024-01-00

Adresă organism de certificare: Bureau Veritas Certification Germany GmbH, Veritaskai 1, 21079 Hamburg

Pentru a verifica valabilitatea acestui certificat, puteţi contacta Bureau Veritas Certification. Mai multe clarificări cu privire la domeniul de aplicare al acestui certificat şi aplicabilitatea cerinţelor Sistemelor de management pot fi obţinute prin consultarea organizației.

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1627783-1

Organization: Olympus Europa SE & Co. KG
Wendenstr. 20
20097 Hamburg
Germany

Scope: Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1126841-150
Effective date: 2023-06-21
Expiry date: 2026-06-20
Issue date: 2023-06-05

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Traducere din limba engleză

Certificat

Sistemul de management al calităţii
EN ISO 13485:2016

Nr. înregistrare:	SX 1627783-1
Organizaţie:	Olympus Europa SE & Co. KG Wendenstr. 20 20097 Hamburg Germania
Scop:	Marketing-ul, vânzările şi service-ul pentru sistemele optice, opto-digitale, electronice şi mecanice, precum şi accesoriile şi consumabilele asociate din domeniul endoscopiei

Organismul de certificare al TÜV Rheinland LGA Products GmbH certifică prin prezenta faptul că organizaţia a implementat şi aplică un sistem de management al calităţii pentru dispozitive medicale.
S-a furnizat dovada faptului ca au fost îndeplinite cerinţele specificate în standardul menţionat mai sus. Sistemul de management al calităţii este supus unei supravegheri anuale.

Nr. raport:	1126841-150
Data intrării în vigoare:	21.06.2023
Data expirării:	20.06.2026
Data emiterii:	05.06.2023

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Dipl.-Ing.(FH) D. Wiedemuth
(Semnătură indescifrabilă şi ştampilă)
TÜV Rheinland LGA Products GmbH
Tillystraße 2 – 90431 Nuernberg – Germania

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Certificate JP19/071613.00

The management system of

Olympus Group

Olympus Corporation Ishikawa Facility 2951 Ishikawa-machi, Hachioji-shi, Tokyo Japan

has been assessed and certified as meeting the requirements of

ISO 14001:2015

For the following activities
Medical business: Design, development, manufacture, and incidental services (repair, maintenance and customer training) for gastrointestinal endoscopes, surgical endoscopes, endoscopic instruments, ultrasonic endoscopes and accessories
Biomaterials business: Design, development and manufacture of artificial bone and accessories

This certificate is valid from 19 August 2023 until 19 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 16 December 2019
Multiple certificates have been issued for this scope, the main certificate is numbered JP19/071613.00
Certified activities performed by additional sites are listed on subsequent pages.

Organization certified since 15 February 1998 and first certified by SGS on 16 December 2019.

Jonathan H. Hall

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

Olympus Group

ISO 14001:2015

Issue 8
Sites
Olympus Corporation Ishikawa Facility 2951 Ishikawa-machi, Hachioji-shi, Tokyo Japan Promotion of environmental management in Olympus Group Research, development, related engineering supports and marketing of medical endoscopy systems and related products
Olympus Medical Systems Corporation Ishikawa Facility 2951 Ishikawa-machi, Hachioji-shi, Tokyo Japan Research, development, related engineering supports and marketing of medical endoscopy systems and related products
Olympus Corporation Utsugi Facility 2-3 Kuboyama-cho, Hachioji-shi, Tokyo Japan Research, development and related engineering supports of medical endoscopy systems and related products
Olympus Medical Systems Corporation Utsugi Facility 2-3 Kuboyama-cho, Hachioji-shi, Tokyo Japan Research, development and related engineering supports of medical endoscopy systems and related products

Olympus Group

ISO 14001:2015

Olympus Corporation Nagano Facility Tatsuno 6666 Inatomi, Ooaza, Tatsuno-machi, Kamiina-gun, Nagano-ken Japan Design, development, manufacture and repair of medical devices
Nagano Olympus Co., Ltd. Main Office 6666 Inatomi, Ooaza, Tatsuno-machi, Kamiina-gun, Nagano-ken Japan Design, development, manufacture and repair of medical devices
Olympus Medical systems Corporation Nagano Facility Tatsuno 6666 Inatomi, Ooaza, Tatsuno-machi, Kamiina-gun, Nagano-ken Japan Technology development for distal end of endoscope
Olympus Corporation Nagano Facility Ina-site 5128 Nishi-machi, Ina-shi, Nagano-ken Japan Management of medical endoscopes parts accepted to be repaired
Nagano Olympus Co., Ltd. Ina Office 5128 Nishi-machi, Ina-shi, Nagano-ken Japan Repair and inspection of medical endoscopes

Olympus Group

ISO 14001:2015

Shirakawa Olympus Co., Ltd 3-1 Okamiyama, Odakura, Nishigou-mura, Nishi-Shirakawa-gun, Fukushima-ken Japan Design and development, manufacture and servicing of medical endoscopy systems and related products; Contracted manufacture of printed circuit board units
Shirakawa Olympus Co., Ltd Repair Department 3-1 Okamiyama, Odakura, Nishigou-mura, Nishi-Shirakawa-gun, Fukushima-ken Japan Repair of medical endoscopy systems and related products Inspection for demo/loaners of medical endoscopy systems and related products
Olympus Corporation CPC Shirakawa 3-1 Okamiyama, Odakura, Nishigou-mura, Nishi-Shirakawa-gun, Fukushima-ken Japan Procurement, quality control, logistics of parts used in products and repair

Olympus Group

ISO 14001:2015

Aizu Olympus Co., Ltd. Aizu Factory 3-1-1 Niidera-kita, Aizuwakamatsu-shi, Fukushima-ken Japan Design and manufacture of medical endoscopy systems and related products
Aizu Olympus Co., Ltd. Kita Aizu Factory 1-95 Mamiyashinmachikita, Aizuwakamatsu-shi, Fukushima-ken Japan Design and manufacture of medical endoscopy systems and related products
Olympus Corporation Procurement : Aizu 3-1-1 Niidera-kita, Aizuwakamatsu-shi, Fukushima-ken Japan Production startup management and quality control of new parts used in medical endoscopy systems

Olympus Group

ISO 14001:2015

Aomori-Olympus Corporation Aomori-plant 2-248-1 Okkonoki, Kuroishi-shi, Aomori-ken Japan Design, development and manufacture of medical endoscopy systems related products
Olympus Corporation Procurement : Aomori 2-248-1 Okkonoki, Kuroishi-shi, Aomori-ken Japan Production startup management and quality control of new parts used in medical endoscopy systems related products
Aomori-Olympus Corporation Hirosaki-Operation 1-1-5 Ohgi-machi, Hirosaki-shi, Aomori-ken Japan Logistics of medical endoscopy systems related products
Olympus Corporation Procurement : Hirosaki 1-1-5 Ohgi-machi, Hirosaki-shi, Aomori-ken Japan Procurement, quality control, logistics of production parts used in medical endoscopy systems related products

Certificate JP19/071613.00, continued

Olympus Group

ISO 14001:2015

Olympus Medical Systems Corporation
Hinode Plant
34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo Japan

Manufacture, design and development of production technology of medical endoscopy systems and related products

Certificate JP19/071613.00, continued

Olympus Group

ISO 14001:2015

Olympus Terumo-Bio Material corporation Mishima-plant 454-1 Higashino, Nagaizumi-cho, Suntou-gun, Shizuoka-ken Japan Manufacture, design and development of biomaterials
Olympus Terumo-Bio Material corporation R&D Center 1002-1 Shimonagakubo, Nagaizumi-cho, Suntou-gun, Shizuoka-ken Japan Design and development of biomaterials

Olympus Group

ISO 14001:2015

Olympus Vietnam Co., Ltd.
Vietnam Plant
8 Street, Long Thanh Industrial Zone, Tam An Commune, Long Thanh District, Dong Nai Province, Vietnam

Manufacture of Accessories for Medical Endoscopy and Medical Parts

Olympus Group

ISO 14001:2015

OLYMPUS Trading (ShangHai) Co.,Ltd. GuangZhou Branch No. 3 Panshan Building, No.537 Northern Panyu Avenue, Panyu District, Guangzhou, 511400 Guangdong Province, China Manufacture of Loading Equipment for Medical Use, Repair of Endoscopes and Peripherals for Medical Use
Olympus Trading (Shanghai) Limited Head-office Unit E, F, G,3F, & Unit B, 1F 185 Taigu Rd., Pilot F.T.Z., Shanghai 200131, China Logistics, import and export trading and service of medical equipment
Olympus Trading (Shanghai) Limited Warehouse Part AB, 2nd Floor, Building B, No. 5-6, Lane 251, Shendong Road, Pudong New District, Shanghai, China Logistics of medical equipment
Olympus Trading (Shanghai) Limited Jinqiao Branch 1F zone A, 2F,4F zone A, 5-8F, Building 3, No.778, Jinji Road, Pudong New Area, Shanghai, China Repair of medical equipment

COPIE

Certificat JP19/071613.00

Sistemul de management al

Grupul Olympus

Traducere din limba engleză

Olympus Corporation Unitatea Ishikawa Facility 2951 Ishikawa-machi, Hachioji-shi, Tokyo Japonia a fost evaluată și certificată ca îndeplinind cerințele
ISO 14001:2015

Pentru următoarele activități
Domeniul medical: Proiectarea, dezvoltarea, producția și serviciile ocazionale (reparațiile, întreținerea și instruirea clienților) pentru endoscoape gastrointestinale, endoscoape chirurgicale, instrumente endoscopice, endoscoape ecografice și accesorii.
Domeniul biomaterialelor: Proiectarea, dezvoltarea și fabricarea oaselor artificiale și accesoriilor

Prezentul certificat este valabil începând cu data de 19 august 2023 până la data de 19 august 2026 și rămâne valabil sub rezerva unor audituri de supraveghere satisfăcătoare.

Versiunea 8. Certificat din 16 decembrie 2019
Au fost emise mai multe certificate în acest scop, certificatul principal având numărul JP19/071613.00
Activitățile certificate efectuate de unităţi suplimentare sunt enumerate în paginile următoare.

Organizație certificată din 15 februarie 1998 și certificată pentru prima dată de SGS pe 16 decembrie 2019.

Semnătură indescifrabilă
Autorizat de
Jonathan Hall
Director Global - Servicii de certificare

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, Marea Britanie
T +44 (0)151 350-6666- www.sgs.com

Cod de bare

ROMÂNIA
MINISTERUL JUSTIȚIEI
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Certificat JP19/071613.00, continuare

Sistemul de management al

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ISO 14001:2015

Versiunea 8
Unităţi
Olympus Corporation Unitatea Ishikawa 2951 Ishikawa-machi, Hachioji-shi, Tokyo Japonia Promovarea managementului mediului în Grupul Olympus Cercetarea, dezvoltarea, suporturi aferente ingineriei şi marketing pentru sistemele endoscopice medicale şi produselor aferente
Olympus Medical Systems Corporation Unitatea Ishikawa 2951 Ishikawa-machi, Hachioji-shi, Tokyo Japonia Cercetarea, dezvoltarea, suporturi aferente ingineriei şi marketing pentru sistemele endoscopice medicale şi produselor aferente
Olympus Corporation Unitatea Utsugi 2-3 Kuboyama-cho, Hachioji-shi, Tokyo, Japonia Cercetarea, dezvoltarea, suporturi aferente ingineriei şi marketing pentru sistemele endoscopice medicale şi produselor aferente
Olympus Medical Systems Corporation Unitatea Utsugi 2-3 Kuboyama-cho, Hachioji-shi, Tokyo, Japonia Cercetarea, dezvoltarea, suporturi aferente ingineriei şi marketing pentru sistemele endoscopice medicale şi produselor aferente

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Sistemul de management al

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ISO 14001:2015

Olympus Corporation Nagano Unitatea Tatsuno 6666 Inatomi, Ooaza, Tatsuno-machi, Kamiina-gun, Nagano-ken, Japonia Proiectarea, dezvoltarea, fabricarea şi repararea dispozitivelor medicale
Nagano Olympus Co., Ltd. Sediu principal 6666 Inatomi, Ooaza, Tatsuno-machi, Kamiina-gun, Nagano-ken, Japonia Proiectarea, dezvoltarea, fabricarea şi repararea dispozitivelor medicale
Olympus Medical Systems Corporation Nagano Unitatea Tatsuno 6666 Inatomi, Ooaza, Tatsuno-machi, Kamiina-gun, Nagano-ken, Japonia Dezvoltarea tehnologiei pentru capătul distal al endoscopului
Olympus Corporation Nagano Unitatea Ina-site 5128 Nishi-machi, Ina-shi, Nagano-ken Japonia Managementul pieselor endoscoapelor medicale acceptate pentru reparaţii
Nagano Olympus Co., Ltd. Sediul Ina 5128 Nishi-machi, Ina-shi, Nagano-ken Japonia Repararea şi inspecţia endoscoapelor medicale

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Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigou-mura, Nishi-Shirakawa-gun, Fukushima-ken Japonia Proiectarea şi dezvoltarea, fabricarea şi întreţinerea sistemelor endoscopice medicale şi a produselor aferente; fabricarea contractată a unităţilor de plăci de circuite imprimat
Shirakawa Olympus Co., Ltd. Departamentul Reparaţii 3-1 Okamiyama, Odakura, Nishigou-mura, Nishi-Shirakawa-gun, Fukushima-ken Japonia Repararea sistemelor endoscopice medicale şi a produselor aferente Inspecţia pentru demo/produselor înlocuitoare pe perioada reparaţiei sistemelor endoscopice medicale şi produselor aferente
Olympus Corporation CPC Shirakawa 3-1 Okamiyama, Odakura, Nishigou-mura, Nishi-Shirakawa-gun, Fukushima-ken Japonia Achiziţia, controlul calităţii, logistica părţilor uzate ale produselor şi repararea

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Aizu Olympus Co., Ltd. Fabrica Aizu 3-1-1 Niidera-kita, Aizuwakamatsu-shi, Fukushima-ken Japonia Proiectarea şi fabricarea sistemelor endoscopice medicale şi a produselor aferente
Aizu Olympus Co., Ltd. Kita Fabrica Aizu 1-95 Mamiyashimachikita, Aizuwakamatsu-shi, Fukushima-ken Japonia Proiectarea şi fabricarea sistemelor endoscopice medicale şi a produselor aferente
Olympus Corporation Achiziţii: Aizu 3-1-1 Niidera-kita, Aizuwakamatsu-shi, Fukushima-ken Japonia Managementul începerii producţiei şi controlul calităţii pentru noile piese utilizate în sistemele endoscopice medicale

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ISO 14001:2015

Aomori-Olympus Corporation Fabrica Aomori 2-248-1 Okkonoki, Kuroishi-shi, Aomori-ken Japonia Proiectarea şi fabricarea sistemelor endoscopice medicale şi a produselor aferente
Olympus Corporation Achiziţii: Aomori 2-248-1 Okkonoki, Kuroishi-shi, Aomori-ken Japonia Managementul începerii producţiei şi controlul calităţii pentru noile piese utilizate în sistemele endoscopice medicale
Aomori-Olympus Corporation Hirosaki-Operare 1-1-5 Ohgi-machi, Hirosaki-shi, Aomori-ken Japonia Logistica produselor aferente sistemelor endoscopice medicale
Olympus Corporation Achiziţii: Hirosaki 1-1-5 Ohgi-machi, Hirosaki-shi, Aomori-ken Japonia Achiziţia, controlul calităţii, logistica pieselor din producţie utilizate în produsele aferente sistemelor endoscopice medicale

Cod de bare

ISO 14001:2015

Olympus Medical Systems Corporation
Fabrica Hinode
34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo Japonia

Fabricarea, proiectarea şi dezvoltarea tehnologiei producţiei sistemelor endoscopice medicale şi a produselor aferente

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Certificat JP19/071613.00, continuare

Sistemul de management al

Grupul Olympus

ISO 14001:2015

Olympus Terumo-Bio Material Corporation Fabrica Mishima 454-1 Higashino, Nagaizumi-cho, Suntou-gun, Shizuoka-ken Japonia Fabricarea, proiectarea şi dezvoltarea biomaterialelor
Olympus Terumo-Bio Material Corporation Centrul R&D 1002-1 Shimonagakubo, Nagaizumi-cho, Suntou-gun, Shizuoka-ken Japonia Proiectarea şi dezvoltarea biomaterialelor

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Sistemul de management al

Grupul Olympus

ISO 14001:2015

Olympus Vietnam Co., Ltd. Fabrica Vietnam 8 Street, Long Thanh Zona Industrială, Comuna Tam An, Districtul Long Thanh, Provincia Dong Nai, Vietnam Fabricarea accesoriilor pentru endoscopie medicală şi piese medicale

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Sistemul de management al

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ISO 14001:2015

Olympus Trading (ShangHai) Co., Ltd. Sucursala GuangZhou Nr. 3 Clădirea Panshan, nr. 537, Atrada Northern Panyu, Districtul Panyu, Guangzhou, 511400, Provincia Guangdong, China Fabricarea echipamentelor de încărcare pentru uz medical, repararea endoscoapelor şi perifericelor de uz medical
Olympus Trading (Shanghai) Limited Sediu social Unitatea E, F, G, 3F, & Unitatea B, 1F 185 Taigu Rd., Pilot F.T.Z., Shanghai 200131, China Logistică, comerţ import şi export şi service pentru echipamente medicale
Olympus Trading (Shanghai) Limited Depozit Partea AB, etaj 2, clădirea B. nr. 5-6, Lane 251, Shendong Road, Pudong New District, Shanghai, China Logistica echipamentelor medicale
Olympus Trading (Shanghai) Limited Sucursala Jinquiao 1F zona A, 2F, 4F zona A, 5-8F, Clădirea 3, nr. 778, Jinji Road, Pudong New Area, Shanghai, China Repararea echipamentelor medicale

Cod de bare

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737637 R000

Manufacturer: KeyMed (Medical and Industrial Equipment) Ltd

Address:
KeyMed House
Stock Road
Southend-on-Sea
SS2 5QH
United Kingdom

Single Registration Number: GB-MF-000035162

EU Authorised Representative: Olympus Europa SE & CO. KG

Address:
Wendenstrasse 14-20
Hamburg
20097
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-11-29**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-11-28**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737637 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Disinfection systems	The Olympus Manual Disinfector TD-20 has been designed to facilitate the cleaning and disinfection of compatible Olympus endoscopes and their accessories in accordance with their instructions for use

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Surgical irrigators	Class IIa
Surgical aspirators	Class IIa
Tubing accessories	Class IIa
Endocuff Vision	Class Is

First Issue Date: **2021-11-29**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-11-28**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737637 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-29	3308074	Issued
2023-04-13	3793914	Supplemented – addition of device categories: Surgical irrigators, Surgical aspirators, Tubing accessories
Current	30000962	Supplemented – Addition of Endocuff Vision device.

First Issue Date: **2021-11-29**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-11-28**

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Certificat UE pentru Sistem de Management al Calității

Regulamentul (UE) 2017/745, anexa IX capitolul I și III

MDR 737637 R000

Producător: KeyMed (Echipamente medicale şi industriale) Ltd

Adresa:
KeyMed House
Stock Road
Southend-on-Sea
SS2 5QH
Marea Britanie

Număr unic de înregistrare: GB-MF-000035162

Reprezentant autorizat UE: Olympus Europa SE & CO. KG

Adresa:
Wendenstrasse 14-20
Hamburg
20097
Germania

Domeniul de aplicabilitate: Consultați atașamentul **Listă dispozitive**
Pe baza examinării noastre a sistemului calității în conformitate cu Regulamentul (UE) 2017/745, Anexa IX Capitolul I și III, sistemul calității îndeplinește cerințele Regulamentului. Pentru introducerea pe piață a dispozitivelor din clasa III și a dispozitivelor implantabile din clasa IIb care nu sunt considerate tehnologii bine stabilite, conform articolului 52(4), este necesar un certificat suplimentar din anexa IX capitolul II.

Pentru și în numele BSI, un organism notificat pentru regulamentul de mai sus (organism notificat numărul 2797):

Graeme Tunbridge, Vicepreședinte executiv Dispozitive medicale

Data primei emiteri: **29-11-2021**

Data emiterii curente: **05-06-2023**

Data de start a valabilităţii: **05-06-2023**

Data de expirare: **28-11-2026**

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Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate al producătorului conform cerințelor regulamentului, așa cum este demonstrat prin activitățile de supraveghere necesare ale organismului notificat.
Acest certificat a fost eliberat electronic și este supus condițiilor contractului.

Contact organism notificat: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Ţările de Jos. Tel: + 31 (0) 20 346 07 80
Contact corporatist: BSI Group Assurance Limited, înregistrată în Anglia sub numărul 05435540 la 389 Chiswick High Road, Londra, W4 4AL, MB.
Membră a grupului de companii BSI

Certificat UE pentru Sistem de Management al Calității

Regulamentul (UE) 2017/745, anexa IX capitolul I și III

MDR 737637 R000

Listă dispozitive: Dispozitive Clasa III şi Clasa IIb

Clasa IIb	Scopul vizat
Sisteme de dezinfecție	Olympus Manual Disinfector TD-20 a fost proiectat pentru a facilita curățarea și dezinfectarea endoscoapelor Olympus compatibile și a accesoriilor acestora, în conformitate cu instrucțiunile de utilizare ale acestora.

Listă dispozitive: Clasa IIa, Dispozitive personalizate și alte dispozitive

Dispozitiv(e)	Clasa de risc
Irigatoare chirurgicale	Clasa IIa
Aspiratoare chirurgicale	Clasa IIa
Accesorii tubulaturi	Clasa IIa
Endocuff Vision	Clasa Is

Data primei emiteri: **29-11-2021**

Data emiterii curente: **05-06-2023**

Data de start a valabilităţii: **05-06-2023**

Data de expirare: **28-11-2026**

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Certificat UE pentru Sistem de Management al Calității

Regulamentul (UE) 2017/745, anexa IX capitolul I și III

MDR 737637 R000

Istoric Certificat

(Referințele la specificațiile comune aplicabile, standardele armonizate respectate și rapoartele relevante de testare și audit care susțin oricare dintre modificările de mai jos ale certificatului pot fi solicitate de la Certificate.Verification@bsigroup.com)

Data	Număr referinţă	Acţiune
29-11-2021	3308074	Emitere
13-04-2023	3793914	Suplimentare – adaugarea categoriilor de aparate: Irigatoare chirurgicale, Aspiratoare chirurgicale, Accesorii tubulaturi
Actual	30000962	Suplimentare – adăugarea echipamentului Endocuff Vision.

Data primei emiteri: **29-11-2021**

Data de start a valabilităţii: **05-06-2023**

Data emiterii curente: **05-06-2023**

Data de expirare: **28-11-2026**

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bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

KeyMed (Medical and Industrial Equipment) Ltd
KeyMed House
Stock Road
Southend-on-Sea
SS2 5QH
United Kingdom

Facility ID Number: F000254

Holds Certificate No: **MDSAP 689076**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture, distribution, servicing, and installation of flushing pumps, workstation carts, endoscope disinfection systems and accessories including sterile accessories, used in endoscopic applications.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-10-26 Effective Date: 2024-03-25 Expiry Date: 2027-03-24

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 689076**

Location	Registered Activities
KeyMed (Medical and Industrial Equipment) Ltd KeyMed House Stock Road Southend-on-Sea SS2 5QH United Kingdom Facility ID Number: F000254	Administrative activities, HR, customer service, QARA and control of outsourced processes.
KeyMed (Medical & Industrial Equipment) Ltd Medical Device Manufacture Centre Journeymans Way Temple Farm Industrial Estate Southend on Sea Essex SS2 5TF United Kingdom Facility ID Number: F000254	Design, development, manufacture, control of distribution, service, repair and installation of flushing pumps, workstation carts, endoscope disinfection systems and accessories used in endoscopic applications.
KeyMed (Medical & Industrial Equipment) KeyMed KLM Building The Cordwainers Temple Farm Industrial Estate Southend-on-Sea Essex SS2 5RU United Kingdom Facility ID Number: F000254	Design, development, control of distribution, service, repair and installation of flushing pumps, workstation carts, endoscope disinfection systems and accessories used in endoscopic applications.

Original Registration Date: 2018-10-26 Effective Date: 2024-03-25 Expiry Date: 2027-03-24

Traducere din limba engleză

Logo:bsi. *Blazon*
By Royal Charter

Certificat de înregistrare

SISTEMUL DE MANAGEMENT AL CALITĂŢII – ISO 13485:2016

Prin prezentul document se certifică faptul că:

KeyMed (Medical and Industrial Equipment) Ltd
KeyMed House
Stock Road
Southend-on-Sea
SS2 5QH
Marea Britanie

Număr identificare facilitate de producţie: F000254

Deţine certificatul numărul: **MDSAP 689076**

Compania menţionată pe acest certificat a fost auditată şi s-a constatat că este conformă cu ISO 13485: 2016, inclusiv cu cerinţele specifice din următoarele ţări:
Australia : Regulamentul privind Produsele terapeutice (Dispozitive medicale), 2002, Anexa 3, Partea 1 (fără Partea 1.6) – Procedura Completă de Asigurare a Calităţii;
Brazilia : RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 – Bune practici privind producţia, RDC ANVISA n. 551/2021;
Canada : Regulamentul privind dispozitivele medicale – Partea 1-SOR 98/282;
Japonia – MHLW Ordonanţa Ministerială nr. 169 (2004) modificată prin MHLW Ordonanţa Ministerială nr 60 (2021), Legea PMD
SUA : 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subpărţile de la A la D

Proiectarea, dezvoltarea, fabricarea, distribuția, întreținerea și instalarea pompelor de spălare, cărucioarelor pentru stații de lucru, sistemelor și accesoriilor de dezinfecție a endoscoapelor, inclusiv accesorii sterile, utilizate în aplicații endoscopice.

Pentru şi în numele BSI: *Semnătură indescifrabilă*
Graeme Tunbridge, Vicepreşedinte senior – Dispozitive Medicale

Data înregistrării iniţiale: 26.10.2018 Data intrării în vigoare: 25-03-2024
Data expirării: 24.03.2027

Logo: bsi.
Logo: MDSAP ...making from excellence a habit™
PROGRAM DE AUDIT UNIC PENTRU DISPOZITIVE MEDICALE
BSI Group America Inc. este o organizaţie de audit autorizată MDSAP

Prezentul certificat rămâne proprietatea BSI şi va fi returnat imediat la cerere.
Un certificat electronic poate fi autentificat online. Copiile tipărite pot fi validate la www.bsigroup.com/ClientDirectory
A se citi împreună cu domeniul de aplicabilitate de mai sus sau anexa ataşată.

Sediul central America: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 SUA
Membru al Grupului de Companii BSI.

Certificat nr.: **MDSAP 689076**

Locaţie	Activităţi înregistrate
KeyMed (Medical and Industrial Equipment) Ltd KeyMed House Stock Road Southend-on-Sea SS2 5QH Marea Britanie Număr identificare facilitate de producţie: F000254	Activităţi administrative, resurse umane, serviciu pentru clienți, QARA (Asigurarea calității și afaceri de reglementare) și controlul proceselor externalizate.
KeyMed (Medical and Industrial Equipment) Ltd Centrul de Fabricare a Dispozitivelor Medicale Journeyman's Way Temple Farm Industrial Estate Southend on Sea Essex SS2 5TF Marea Britanie Număr identificare facilitate de producţie: F000254	Proiectarea, dezvoltarea, producţia, controlul distribuţiei, întreţinerea, repararea şi instalarea pompelor de spălare, cărucioarelor pentru stații de lucru, sistemelor și accesoriilor de dezinfecție a endoscoapelor.
KeyMed (Medical and Industrial Equipment) KeyMed KLM Building The Cordwainers Temple Farm Industrial Estate Southend-on-Sea Essex SS2 5RU Număr identificare locaţie producţie: F000254	Proiectarea, dezvoltarea, controlul distribuţiei, întreţinerea, repararea şi instalarea pompelor de spălare, cărucioarelor pentru stații de lucru, sistemelor și accesoriilor de dezinfecție a endoscoapelor.

Data înregistrării iniţiale: 26.10.2018 Data intrării în vigoare: 25-03-2024
Data expirării: 24.03.2027

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 011634 0208 Rev. 02

Certificate Holder: medela

Medela AG
Lättichstrasse 4b
6340 Baar
SWITZERLAND

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution and Service of Breast Pump Systems, Breastfeeding Products, Body Fluid and Vacuum Aspirator Systems and Vacuum Assisted Wound Closure Systems**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001274**

Effective Date: **2022-01-20**

Expiry Date: **2025-01-03**

Date of Issue: 2022-01-26

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 011634 0208 Rev. 02

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Medela AG
Lättichstrasse 4b, 6340 Baar, SWITZERLAND

Medela AG
Sennweidstrasse 30, 6312 Steinhausen, SWITZERLAND

Medela AG
Turmstrasse 30, 6312 Steinhausen, SWITZERLAND

Medela AG
Lättichstrasse 7, 6340 Baar, SWITZERLAND

Date of Issue: 2022-01-26

Michael Ogunleye

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 011634 0208 Rev. 02

Facility Scopes:

Medela AG
Lättichstrasse 4b, 6340 Baar, SWITZERLAND

Headquarters (Administration, Resource Management) Quality Management Department (CAPA, Document Control, Change Control, Regulatory, Post Market Surveillance), Design and Development
REPs Facility ID: F001274

Medela AG
Sennweidstrasse 30, 6312 Steinhausen, SWITZERLAND

Manufacturing Site; Incoming Inspection, Packaging, Warehouse Components and Finished Goods, Logistic
REPs Facility ID: F002183

Medela AG
Turmstrasse 30, 6312 Steinhausen, SWITZERLAND

Manufacturing Site; Assembly of Health Care and Breastfeeding Devices and Assembly of Accessories Kits
REPs Facility ID: F002183

Medela AG
Lättichstrasse 7, 6340 Baar, SWITZERLAND

Purchasing, Supplier Quality, Customer Service including Service/ Repair
REPs Facility ID: F001274

Date of Issue: 2022-01-26

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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Traducere din limba engleză

America

CERTIFICAT

Nr. QS6 011634 0208 Rev.02

Deţinătorul certificatului: **MEDELA AG**
Lättichstrasse 4b
6340 Baar
ELVEȚIA

Marca certificatului:

Domeniul de aplicabilitate al certificatului: Proiectare si dezvoltare, producţie, distribuţie si service de sisteme pompe sân, produse de alăptare, sisteme de aspirare cu vacuum a fluidelor din corp şi sisteme de închidere asistată cu vacuum a plăgilor

Standarde: EN ISO 13485: 2016

Autorităţi de reglementare: Australia TGA, Brazilia ANVISA, Health Canada, SUA FDA, MHLW / PMDA. A se vedea anexa pentru enumerarea cerinţelor specifice de reglementare

Organismul de certificare al TUV SUD America Inc. certifică faptul că sistemul de management al calităţii al producătorului mai sus menţionat a fost auditat conform criteriilor enunţate şi s-a constatat că este conform cu aceste criterii pentru domeniul de aplicabilitate al certificării enunţate. Valabilitatea acestui certificat poate fi obţinută vizitând site-ul web https://www.tuvsud.com/ps-cert

TUV SUD America Inc. este o organizaţie de audit recunoscută MDSAP.

ID unitate RESp: F001274
Valabil de la: 20.01.2022
Valabil până la: 03.01.2025

(semnătură indescifrabilă)
(Michael Ogunleye)
Manager, Organism Certificare SUA
Servicii medicale şi de sănătate

Data emiterii: 26.01.2022

TUV SUD America Inc.-401 Edgewater Place Suite #500 – Wakefield – MA 01880 - SUA - www.tuvsud.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TUV SUD America

CERTIFICAT

Nr. QS6 011634 0208 Rev.02

Cerinţe de reglementare: **Criterii de audit/certificare**

Australia

Regulamentul privind Produsele terapeutice (Dispozitive medicale), 2002, Anexa 3, Partea 1 (Excluzând Partea 1.6) – Procedura Asigurării Complete a Calităţii

Brazilia

-RDC ANVISA n. 16/2013
-RDC ANVISA n. 23/2012
-RDC ANVISA n. 67/2009

Canada

- Regulamentul privind dispozitivele medicale SOR 98/282, Partea 1

Japonia

- MHLW Ordonanţa Ministerială 169, de la Articolul 4 la Articolul 68
- Legea PMD

Statele Unite

-21 CFR Partea 803
-21 CFR Partea 806
-21 CFR Partea 807 – Sub-părţile de la A la D
-21 CFR Partea 820

Facilităţi de producţie:

MedelaAG
Lattichstrasse 4b, 6340 Baar, ELVEŢIA
MedelaAG
Sennweidstrasse 30, 6312 Steinhausen, ELVEŢIA
MedelaAG
Turmstrasse 30, 6312 Steinhausen, ELVEŢIA
MedelaAG
Lattichstrasse 7, 6340 Baar, ELVEŢIA

(semnătură indescifrabilă)
(Michael Ogunleye)
Manager, Organism Certificare SUA
Servicii medicale şi de sănătate

Data emiterii: 26.01.2022

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICAT

Nr. QS6 011634 0208 Rev.02

Domeniul de aplicabilitate pentru facilităţile de producţie:	**Medela AG** Lattichstrasse 4b, 6340 Baar, ELVEŢIA Sediul central (administraţie, gestionarea resurselor) Departamentul de management al calităţii (CAPA, controlul documentelor, controlul modificărilor, reglementare, supraveghere post-vânzare), proiectare şi dezvoltare ID unitate RESp: F001274
	Medela AG Sennweidstrasse 30, 6312 Steinhausen, ELVEŢIA Locaţie de producţie; Inspecţie intrare, ambalare, componente de depozit şi produse finite, logistică ID unitate RESp: F002183
	Medela AG Turmstrasse 30, 6312 Steinhausen, ELVEŢIA Locaţie de producţie; asamblare dispozitive medicale şi de alăptare, asamblare kituri accesorii ID unitate RESp: F002183
	Medela AG Lattichstrasse 7, 6340 Baar, ELVEŢIA Achiziţii, calitate furnizori, relaţii clienţi, inclusiv service/reparaţii ID unitate RESp: F001274

Data emiterii: 26.01.2022

(semnătură indescifrabilă)
(Michael Ogunleye)
Manager, Organism Certificare SUA
Servicii medicale şi de sănătate

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 011634 0235 Rev. 00

Manufacturer:

Medela AG
Lättichstrasse 4b
6340 Baar
SWITZERLAND

SRN Manufacturer: CH-MF-000018913

Authorized Representative:

Medela Medizintechnik GmbH & Co. Handels KG
Georg-Kollmannsbergerstrasse 2, 85386 Eching, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 011634 0235 Rev. 00

Report No.: 713181494

Valid from: 2022-01-17
Valid until: 2027-01-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-01-17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 011634 0235 Rev. 00

Classification:	IIa
Device Group:	Z12080303 - BREAST PUMPS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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BS-MDR-099

Traducere din limba engleză

Product Service

Certificat sistem de management al calităţii UE (MDR)

Conform Reglementării (EU) 2017/745 privind Dispozitivele Medicale, Anexa IX
Capitolele I şi III (Dispozitive din Clasa IIa şi Clasa IIb)

Nr. G10 011634 0235 Rev. 00

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

Producător: **Medela AG**
Lättichstrasse 4b
6340 Baar
ELVEŢIA

SRN Producător: CH-MF-000018913

Reprezentant autorizat: Medela Medizintechnik GmbH & Co. Handels KG
Georg-Kollmannsbergerstrasse 2, 85386 Eching, GERMANIA

Organismul de certificare al TÜV SÜD Product Service GmbH certifică faptul că producătorul a stabilit, documentat şi implementat un sistem de management al calităţii aşa cum este descris în Articolul 10 (9) din Reglementarea (UE) 2017/745 privind dispozitivele medicale. Detaliile privind categoriile de dispozitive acoperite de sistemul de management al calităţii sunt descrise pe următoarea(ele) pagină(i).
Raportul menţionat mai jos rezumă rezultatul evaluării şi include referinţa la standardele CS, armonizate relevante şi rapoartele de testare. Evaluarea conformităţii a fost efectuată conform Anexei IX Capitolul I şi III din această reglementare cu un rezultat pozitiv.
Evaluarea sistemului de management al calităţii a fost însoţită de evaluarea documentaţiei tehnice pentru dispozitivele selectate pe bază reprezentativă.
Sistemul de management al calităţii certificat face obiectul supravegherii periodice de către TÜV SÜD Product Service GmbH. Evaluarea supravegherii va include şi o evaluare a documentaţiei tehnice pentru dispozitivul sau dispozitivele în cauză pe baza eşantioanelor reprezentative viitoare.
Toate cerinţele aplicabile ale reglementării privind testarea şi certificarea Grupului TÜV SÜD trebuie respectate.
Pentru detalii şi validitatea certificatului vezi: www.tuvsud.com/ps-cert?q=cert:G10 011634 0235 Rev. 00

Nr. raport: 713181494

Valabil de la: 2022-01-17
Până la: 2027-01-16

Christoph Dicks
Directorul Departamentului de Certificare/ Organism Notificat

Data emiterii:2022-01-17

TÜV SÜD Product Service GmbH este organism notificat cu nr. de identificare 0123
TÜV SÜD Product Service GmbH • Organism de certificare • Ridlerstraße 65 • 80339 Munchen • Germania

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www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

Certificat sistem de management al calităţii UE (MDR)

Conform Reglementării (EU) 2017/745 privind Dispozitivele Medicale, Anexa IX Capitolele I şi III (Dispozitive din Clasa IIa şi Clasa IIb)

Nr. G10 011634 0235 Rev. 00

Clasificare:	IIa
Grup dispozitive:	Z12080303 - POMPE DE SÂN
Scopul utilizării:	-
Valabilitatea acestui certificat depinde de condiţiile şi/sau este limitată la următoarele:	- niciuna -

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV SÜD Product Service GmbH este organism notificat cu nr. de identificare. 0123

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TÜV®

Number: 6082015CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone
210032 Nanjing, Jiangsu Province
P. R. China
SRN ID.: CN-MF-000006950

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 6082014CN

Additional certificate: 6126407TD01

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße, 80 20537 Hamburg, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **16 September 2022** Date: **1 August 2023** Expiry date**: 1 September 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 6082015CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Active non-implantable imaging devices utilising non-ionizing radiation (MDA0202, class IIa)
Device name: - Single-Use Video Bronchoscopes - Digital Controllers - Single-Use Video Pancreaticobiliary Scopes - PB Digital Controllers

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN 1203, class IIa)
Device name: - Sterile Biliary Stone Retrieval Balloon Catheter (including Retrieval Balloon / short-wire compatible) - Biliary Plastic Stent Introducer (Biliary Plastic Stent Introducer, Biliary Plastic Stent Introducer/ short-wire compatible) - Dilation Balloon - Disposable Multistage Dilation Balloon Catheter - Non Vascular Sterile Hydro Slide Guidewire

Non-active non-implantable instruments (MDN 1208, class IIa)
Device name: - Extraction Basket (including Extraction Basket/short-wire compatible) - Nitinol Spiral Extraction Basket (including Nitinol Spiral Extraction Basket/short-wire compatible) - Injection Needle - Single-Use SD Biopsy Forceps - Single-Use Biopsy Forceps

First Issued: **16 September 2022** Date: **1 August 2023** Expiry date**: 1 September 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 6082015CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

SPHINCTEROTOMES (G030402, class IIb)	
Device name: - Sphincterotome / short-wire compatible - Sphincterotome	*Intended Purpose: The device is intended to be used with endoscope and guidewire for selective cannulation of the biliary ducts and monopolar cutting in sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi using high-frequency current. The device can also be used to inject contrast medium.*

Esophageal Prostheses-Other (P050199, class IIb implantable)	
Device name: - Esophageal Stent	*Intended Purpose: The Esophageal Stent implant is indicated for use in the palliative treatment of esophageal stricture caused by malignant neoplasms, cardia stricture, anastomotic stoma stricture, and the esophageal fistula occluding.*

Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	16 September 2022	6082014CN02	First issue
1	20 April 2023	6082014CN04	Revised
2	18 July 2023	6082014CN06	Revised
3	24 July 2023	6082014CN07	Revised
4	1 August 2023	6082014CN08	Revised

First Issued: **16 September 2022** Date: **1 August 2023** Expiry date**: 1 September 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

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T +31 88 96 83000 www.dekra.nl Company registration 09085396

Specification list of Biopsy Forceps MTN-0020914 A/6

NO.	REF	Configuration Type	Diameter Of Jaws (unit: mm)	Minimum diameter of working channel (unit: mm)	Opening width of cup jaws (unit: mm）	Classification of jaws	Configuration Needle	Spring sheathType	Classification of spring tube	Woking length (unit: mm）	Description
1	BF01-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
2	BF01-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
3	BF01-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
4	BF01-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
5	BF01-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1200 mm
6	BF01-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1600 mm
7	BF01-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1800 mm
8	BF01-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*2300 mm
9	BF03-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
10	BF03-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
11	BF03-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
12	BF03-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
13	BF03-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1200 mm
14	BF03-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1600 mm
15	BF03-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1800 mm
16	BF03-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*2300 mm
17	BF01-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
18	BF01-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
19	BF01-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
20	BF01-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*1600 mm
21	BF01-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*1800 mm
22	BF01-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*2300 mm
23	BF03-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
24	BF03-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
25	BF03-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
26	BF03-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1600 mm
27	BF03-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1800 mm
28	BF03-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*2300 mm
29	BF01-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
30	BF01-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
31	BF01-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
32	BF03-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
33	BF03-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
34	BF03-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
35	BF11-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
36	BF11-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
37	BF11-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
38	BF11-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
39	BF11-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1200 mm
40	BF11-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1600 mm
41	BF11-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1800 mm
42	BF11-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*2300 mm
43	BF13-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
44	BF13-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
45	BF13-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
46	BF13-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
47	BF13-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1200 mm
48	BF13-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1600 mm
49	BF13-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1800 mm
50	BF13-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*2300 mm
51	BF11-11023160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
52	BF11-11023180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
53	BF11-11023230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
54	BF11-11123160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*1600 mm
55	BF11-11123180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*1800 mm
56	BF11-11123230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*2300 mm
57	BF13-11023160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
58	BF13-11023180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
59	BF13-11023230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
60	BF13-11123160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*1600 mm
61	BF13-11123180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*1800 mm
62	BF13-11123230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*2300 mm
63	BF11-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
64	BF11-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
65	BF11-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
66	BF13-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
67	BF13-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm

NO.	REF	Configuration Type	Diameter Of Jaws (unit: mm)	Minimum diameter of working channel (unit: mm)	Opening width of cup jaws (unit: mm）	Classification of jaws	Configuration Needle	Spring sheathType	Classification of spring tube	Woking length (unit: mm）	Description
68	BF13-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
69	BF51-11018120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
70	BF51-11018160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
71	BF51-11018180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
72	BF51-11018230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
73	BF51-11118120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1200 mm
74	BF51-11118160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1600 mm
75	BF51-11118180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1800 mm
76	BF51-11118230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*2300 mm
77	BF53-11018120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
78	BF53-11018160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
79	BF53-11018180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
80	BF53-11018230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
81	BF53-11118120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1200 mm
82	BF53-11118160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1600 mm
83	BF53-11118180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1800 mm
84	BF53-11118230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*2300 mm
85	EBF01-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
86	EBF01-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
87	EBF01-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
88	EBF01-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
89	EBF01-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1200 mm
90	EBF01-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1600 mm
91	EBF01-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1800 mm
92	EBF01-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*2300 mm
93	EBF03-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
94	EBF03-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
95	EBF03-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
96	EBF03-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
97	EBF03-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1200 mm
98	EBF03-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1600 mm
99	EBF03-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1800 mm
100	EBF03-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*2300 mm
101	EBF01-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
102	EBF01-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
103	EBF01-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
104	EBF03-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
105	EBF03-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
106	EBF03-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
107	EBF01-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*1200 mm
108	EBF01-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*1600 mm
109	EBF01-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*1800 mm
110	EBF01-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*2300 mm
111	EBF03-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*1200 mm
112	EBF03-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*1600 mm
113	EBF03-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*1800 mm
114	EBF03-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*2300 mm
115	EBF01-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*1200 mm
116	EBF01-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*1600 mm
117	EBF01-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*1800 mm
118	EBF01-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*2300 mm
119	EBF03-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*1200 mm
120	EBF03-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*1600 mm
121	EBF03-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*1800 mm
122	EBF03-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*2300 mm
123	EBF11-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
124	EBF11-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
125	EBF11-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
126	EBF11-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
127	EBF11-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1200 mm
128	EBF11-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1600 mm
129	EBF11-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1800 mm
130	EBF11-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*2300 mm
131	EBF13-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
132	EBF13-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
133	EBF13-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
134	EBF13-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
135	EBF13-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1200 mm
136	EBF13-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1600 mm
137	EBF13-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1800 mm

NO.	REF	Configuration Type	Diameter Of Jaws (unit: mm)	Minimum diameter of working channel (unit: mm)	Opening width of cup jaws (unit: mm）	Classification of jaws	Configuration Needle	Spring sheathType	Classification of spring tube	Woking length (unit: mm）	Description
138	EBF13-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*2300 mm
139	EBF11-11023160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
140	EBF11-11023180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
141	EBF11-11023230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
142	EBF11-11123160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*1600 mm
143	EBF11-11123180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*1800 mm
144	EBF11-11123230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*2300 mm
145	EBF13-11023160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
146	EBF13-11023180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
147	EBF13-11023230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
148	EBF13-11123160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*1600 mm
149	EBF13-11123180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*1800 mm
150	EBF13-11123230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*2300 mm
151	EBF11-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
152	EBF11-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
153	EBF11-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
154	EBF13-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
155	EBF13-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
156	EBF13-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
157	EBF11-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*1200 mm
158	EBF11-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*1600 mm
159	EBF11-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*1800 mm
160	EBF11-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*2300 mm
161	EBF13-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*1200 mm
162	EBF13-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*1600 mm
163	EBF13-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*1800 mm
164	EBF13-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*2300 mm
165	EBF11-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*1200 mm
166	EBF11-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*1600 mm
167	EBF11-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*1800 mm
168	EBF11-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*2300 mm
169	EBF13-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*1200 mm
170	EBF13-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*1600 mm
171	EBF13-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*1800 mm
172	EBF13-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*2300 mm
173	EBF51-11018120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
174	EBF51-11018160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
175	EBF51-11018180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
176	EBF51-11018230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
177	EBF51-11118120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1200 mm
178	EBF51-11118160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1600 mm
179	EBF51-11118180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1800 mm
180	EBF51-11118230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*2300 mm
181	EBF53-11018120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
182	EBF53-11018160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
183	EBF53-11018180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
184	EBF53-11018230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
185	EBF53-11118120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1200 mm
186	EBF53-11118160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1600 mm
187	EBF53-11118180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1800 mm
188	EBF53-11118230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*2300 mm
189	EBF61-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
190	EBF61-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
191	EBF61-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
192	EBF61-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,uncoated, 2.3*1600 mm
193	EBF61-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,uncoated, 2.3*1800 mm
194	EBF61-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,uncoated, 2.3*2300 mm
195	EBF63-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
196	EBF63-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
197	EBF63-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
198	EBF63-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.3*1600 mm
199	EBF63-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.3*1800 mm
200	EBF63-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.3*2300 mm
201	NBF01-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
202	NBF01-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
203	NBF01-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
204	NBF01-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
205	NBF01-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1200 mm
206	NBF01-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1600 mm
207	NBF01-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*1800 mm

NO.	REF	Configuration Type	Diameter Of Jaws (unit: mm)	Minimum diameter of working channel (unit: mm)	Opening width of cup jaws (unit: mm）	Classification of jaws	Configuration Needle	Spring sheathType	Classification of spring tube	Woking length (unit: mm）	Description
208	NBF01-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 1.8*2300 mm
209	NBF03-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
210	NBF03-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
211	NBF03-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
212	NBF03-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
213	NBF03-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1200 mm
214	NBF03-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1600 mm
215	NBF03-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*1800 mm
216	NBF03-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*2300 mm
217	NBF01-11023120	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*1200 mm
218	NBF01-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
219	NBF01-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
220	NBF01-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
221	NBF01-11123120	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*1200 mm
222	NBF01-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*1600 mm
223	NBF01-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*1800 mm
224	NBF01-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*2300 mm
225	NBF03-11023120	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1200 mm
226	NBF03-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
227	NBF03-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
228	NBF03-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
229	NBF03-11123120	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1200 mm
230	NBF03-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1600 mm
231	NBF03-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1800 mm
232	NBF03-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*2300 mm
233	NBF01-01023120	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*1200 mm
234	NBF01-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
235	NBF01-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
236	NBF01-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
237	NBF03-01023120	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*1200 mm
238	NBF03-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
239	NBF03-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
240	NBF03-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 5.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
241	NBF01-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*1200 mm
242	NBF01-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*1600 mm
243	NBF01-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*1800 mm
244	NBF01-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,uncoated, 3*2300 mm
245	NBF03-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*1200 mm
246	NBF03-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*1600 mm
247	NBF03-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*1800 mm
248	NBF03-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 3*2300 mm
249	NBF01-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*1200 mm
250	NBF01-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*1600 mm
251	NBF01-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*1800 mm
252	NBF01-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,uncoated, 3*2300 mm
253	NBF03-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*1200 mm
254	NBF03-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*1600 mm
255	NBF03-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*1800 mm
256	NBF03-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 3*2300 mm
257	NBF11-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
258	NBF11-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
259	NBF11-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
260	NBF11-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
261	NBF11-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1200 mm
262	NBF11-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1600 mm
263	NBF11-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*1800 mm
264	NBF11-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 1.8*2300 mm
265	NBF13-11018120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
266	NBF13-11018160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
267	NBF13-11018180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
268	NBF13-11018230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
269	NBF13-11118120	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1200 mm
270	NBF13-11118160	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1600 mm
271	NBF13-11118180	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*1800 mm
272	NBF13-11118230	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*2300 mm
273	NBF11-11023120	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1200 mm
274	NBF11-11023160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
275	NBF11-11023180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
276	NBF11-11023230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
277	NBF11-11123120	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	1200	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*1200 mm

NO.	REF	Configuration Type	Diameter Of Jaws (unit: mm)	Minimum diameter of working channel (unit: mm)	Opening width of cup jaws (unit: mm）	Classification of jaws	Configuration Needle	Spring sheathType	Classification of spring tube	Woking length (unit: mm）	Description
278	NBF11-11123160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*1600 mm
279	NBF11-11123180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*1800 mm
280	NBF11-11123230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 2.3*2300 mm
281	NBF13-11023120	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1200 mm
282	NBF13-11023160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
283	NBF13-11023180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
284	NBF13-11023230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
285	NBF13-11123120	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	1200	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*1200 mm
286	NBF13-11123160	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*1600 mm
287	NBF13-11123180	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*1800 mm
288	NBF13-11123230	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*2300 mm
289	NBF11-01023120	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1200 mm
290	NBF11-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
291	NBF11-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
292	NBF11-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
293	NBF13-01023120	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1200 mm
294	NBF13-01023160	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
295	NBF13-01023180	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
296	NBF13-01023230	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
297	NBF11-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*1200 mm
298	NBF11-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*1600 mm
299	NBF11-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*1800 mm
300	NBF11-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,uncoated, 3*2300 mm
301	NBF13-01030120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*1200 mm
302	NBF13-01030160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*1600 mm
303	NBF13-01030180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*1800 mm
304	NBF13-01030230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 3*2300 mm
305	NBF11-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*1200 mm
306	NBF11-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*1600 mm
307	NBF11-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*1800 mm
308	NBF11-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,uncoated, 3*2300 mm
309	NBF13-01130120	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	1200	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*1200 mm
310	NBF13-01130160	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*1600 mm
311	NBF13-01130180	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*1800 mm
312	NBF13-01130230	Four-bar linkage	3.0	3.2	8.5	MIM Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 8.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 3*2300 mm
313	NBF51-11018120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1200 mm
314	NBF51-11018160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1600 mm
315	NBF51-11018180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*1800 mm
316	NBF51-11018230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 1.8*2300 mm
317	NBF51-11118120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1200 mm
318	NBF51-11118160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1600 mm
319	NBF51-11118180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*1800 mm
320	NBF51-11118230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 1.8*2300 mm
321	NBF53-11018120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
322	NBF53-11018160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1600 mm
323	NBF53-11018180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
324	NBF53-11018230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
325	NBF53-11118120	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1200	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1200 mm
326	NBF53-11118160	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1600	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1600 mm
327	NBF53-11118180	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*1800 mm
328	NBF53-11118230	Four-bar linkage	1.8	2.0	4.5	Stamping Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 4.5 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 1.8*2300 mm
329	NBF03-11023160-A	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Tapered outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Tapered outer sheath,PE coating, 2.3*1600 mm
330	NBF03-11023180-A	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Tapered outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Tapered outer sheath,PE coating, 2.3*1800 mm
331	NBF03-11023230-A	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Tapered outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Tapered outer sheath,PE coating, 2.3*2300 mm
332	NBF03-11123160-A	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Tapered outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Tapered outer sheath,PE coating, 2.3*1600 mm
333	NBF03-11123180-A	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Tapered outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Tapered outer sheath,PE coating, 2.3*1800 mm
334	NBF03-11123230-A	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Tapered outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Tapered outer sheath,PE coating, 2.3*2300 mm
335	EBF33-11023120	Cam structure	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1200	Cam structure, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1200 mm
336	EBF33-11023160	Cam structure	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1600	Cam structure, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
337	EBF33-11023180	Cam structure	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1800	Cam structure, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
338	EBF33-11023230	Cam structure	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	2300	Cam structure, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
339	EBF33-11123120	Cam structure	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1200	Cam structure, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1200 mm
340	EBF33-11123160	Cam structure	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1600	Cam structure, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1600 mm
341	EBF33-11123180	Cam structure	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1800	Cam structure, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1800 mm
342	EBF33-11123230	Cam structure	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	2300	Cam structure, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*2300 mm
343	EBF43-11023120	Cam structure	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	PE coating	1200	Cam structure, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.3*1200 mm
344	EBF43-11023160	Cam structure	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	PE coating	1600	Cam structure, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
345	EBF43-11023180	Cam structure	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	PE coating	1800	Cam structure, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
346	EBF43-11023230	Cam structure	2.3	2.8	6.7	Stamping Alligator	Without	Single outer sheath	PE coating	2300	Cam structure, 6.7 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
347	EBF43-11123120	Cam structure	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	PE coating	1200	Cam structure, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.3*1200 mm

NO.	REF	Configuration Type	Diameter Of Jaws (unit: mm)	Minimum diameter of working channel (unit: mm)	Opening width of cup jaws (unit: mm）	Classification of jaws	Configuration Needle	Spring sheathType	Classification of spring tube	Woking length (unit: mm）	Description
348	EBF43-11123160	Cam structure	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	PE coating	1600	Cam structure, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.3*1600 mm
349	EBF43-11123180	Cam structure	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	PE coating	1800	Cam structure, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.3*1800 mm
350	EBF43-11123230	Cam structure	2.3	2.8	6.7	Stamping Alligator	With	Single outer sheath	PE coating	2300	Cam structure, 6.7 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.3*2300 mm
351	LCNBF63-10124160	Twin wire	2.4	2.8	9.0	Stamping Alligator	With	Single outer sheath	PE coating	1600	Twin wire, 9 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.4*1600 mm
352	LCNBF63-10024120	Twin wire	2.4	2.8	9.0	Stamping Alligator	Without	Single outer sheath	PE coating	1200	Twin wire, 9 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.4*1200 mm
353	LCNBF63-10024160	Twin wire	2.4	2.8	9.0	Stamping Alligator	Without	Single outer sheath	PE coating	1600	Twin wire, 9 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.4*1600 mm
354	LCNBF63-10024180	Twin wire	2.4	2.8	9.0	Stamping Alligator	Without	Single outer sheath	PE coating	1800	Twin wire, 9 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.4*1800 mm
355	LCNBF63-10024230	Twin wire	2.4	2.8	9.0	Stamping Alligator	Without	Single outer sheath	PE coating	2300	Twin wire, 9 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.4*2300 mm
356	LCNBF63-10124120	Twin wire	2.4	2.8	9.0	Stamping Alligator	With	Single outer sheath	PE coating	1200	Twin wire, 9 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.4*1200 mm
357	LCNBF63-10124180	Twin wire	2.4	2.8	9.0	Stamping Alligator	With	Single outer sheath	PE coating	1800	Twin wire, 9 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.4*1800 mm
358	LCNBF63-10124230	Twin wire	2.4	2.8	9.0	Stamping Alligator	With	Single outer sheath	PE coating	2300	Twin wire, 9 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.4*2300 mm
359	NBF11-11023180-A	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Tapered outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Tapered outer sheath,uncoated, 2.3*1800 mm
360	NBF11-11023230-A	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Tapered outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Tapered outer sheath,uncoated, 2.3*2300 mm
361	EBF33-11018120	Cam structure	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1200	Cam structure, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
362	EBF33-11018180	Cam structure	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	1800	Cam structure, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
363	EBF43-11018120	Cam structure	1.8	2.0	4.5	Stamping Alligator	Without	Single outer sheath	PE coating	1200	Cam structure, 4.5 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 1.8*1200 mm
364	EBF43-11018180	Cam structure	1.8	2.0	4.5	Stamping Alligator	Without	Single outer sheath	PE coating	1800	Cam structure, 4.5 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 1.8*1800 mm
365	LCEBF63-10024120	Twin wire	2.4	2.8	9.0	Stamping Alligator	Without	Single outer sheath	PE coating	1200	Twin wire, 9 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.4*1200 mm
366	LCEBF63-10024180	Twin wire	2.4	2.8	9.0	Stamping Alligator	Without	Single outer sheath	PE coating	1800	Twin wire, 9 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.4*1800 mm
367	LCEBF63-10024230	Twin wire	2.4	2.8	9.0	Stamping Alligator	Without	Single outer sheath	PE coating	2300	Twin wire, 9 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 2.4*2300 mm
368	LCEBF63-10124120	Twin wire	2.4	2.8	9.0	Stamping Alligator	With	Single outer sheath	PE coating	1200	Twin wire, 9 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.4*1200 mm
369	LCEBF63-10124180	Twin wire	2.4	2.8	9.0	Stamping Alligator	With	Single outer sheath	PE coating	1800	Twin wire, 9 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.4*1800 mm
370	LCEBF63-10124230	Twin wire	2.4	2.8	9.0	Stamping Alligator	With	Single outer sheath	PE coating	2300	Twin wire, 9 mm opening width, Stamping Alligator, With needle, Single outer sheath,PE coating, 2.4*2300 mm
371	EBF53-11023260	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
372	EBF53-11123260	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*2600 mm
373	EBF03-01023260	Four-bar linkage	2.3	2.8	5.5	MIM oval	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 5.5 mm opening width, MIM oval, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
374	EBF13-11023260	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
375	EBF13-11123260	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*2600 mm
376	EBF13-01023260	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
377	NBF03-11023260	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
378	NBF03-11123260	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*2600 mm
379	NBF03-01023260	Four-bar linkage	2.3	2.8	5.5	MIM oval	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 5.5 mm opening width, MIM oval, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
380	NBF13-11023260	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
381	NBF13-11123260	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	PE coating	2600	Four-bar linkage, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 2.3*2600 mm
382	NBF13-01023260	Four-bar linkage	2.3	2.8	5.5	MIM Alligator	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 5.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 2.3*2600 mm
383	NBF03-11018260	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*2600 mm
384	NBF03-11118260	Four-bar linkage	1.8	2.0	4.5	MIM Oval	With	Single outer sheath	PE coating	2600	Four-bar linkage, 4.5 mm opening width, MIM Oval, With needle, Single outer sheath,PE coating, 1.8*2600 mm
385	NBF13-11018260	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, Without needle, Single outer sheath,PE coating, 1.8*2600 mm
386	NBF13-11118260	Four-bar linkage	1.8	2.0	4.5	MIM Alligator	With	Single outer sheath	PE coating	2600	Four-bar linkage, 4.5 mm opening width, MIM Alligator, With needle, Single outer sheath,PE coating, 1.8*2600 mm
387	EBF53-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
388	NBF13-11023230-A	Four-bar linkage	2.3	2.8	6.7	MIM Alligator	Without	Tapered outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, MIM Alligator, Without needle, Tapered outer sheath,PE coating, 2.3*2300 mm
389	EBF51-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
390	EBF51-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*1800 mm
391	EBF51-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
392	EBF51-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,uncoated, 2.3*2300 mm
393	EBF53-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
394	EBF53-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*1800 mm
395	EBF53-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Oval	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Oval, With needle, Single outer sheath,PE coating, 2.3*2300 mm
396	EBF33-11018230	Cam structure	1.8	2.0	4.5	Stamping Oval	Without	Single outer sheath	PE coating	2300	Cam structure, 4.5 mm opening width, Stamping Oval, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
397	EBF43-11018230	Cam structure	1.8	2.0	4.5	Stamping Alligator	Without	Single outer sheath	PE coating	2300	Cam structure, 4.5 mm opening width, Stamping Alligator, Without needle, Single outer sheath,PE coating, 1.8*2300 mm
398	EBF71-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
399	EBF71-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
400	EBF71-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
401	EBF71-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,uncoated, 2.3*1600 mm
402	EBF71-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,uncoated, 2.3*1800 mm
403	EBF71-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,uncoated, 2.3*2300 mm
404	EBF73-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
405	EBF73-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
406	EBF73-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
407	EBF73-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,PE coating, 2.3*1600 mm
408	EBF73-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,PE coating, 2.3*1800 mm
409	EBF73-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,PE coating, 2.3*2300 mm
410	NBF71-11023120	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	uncoated	1200	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,uncoated, 2.3*1200 mm
411	NBF71-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,uncoated, 2.3*1600 mm
412	NBF71-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,uncoated, 2.3*1800 mm
413	NBF71-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,uncoated, 2.3*2300 mm
414	NBF71-11123120	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	uncoated	1200	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,uncoated, 2.3*1200 mm
415	NBF71-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	uncoated	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,uncoated, 2.3*1600 mm
416	NBF71-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	uncoated	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,uncoated, 2.3*1800 mm
417	NBF71-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	uncoated	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,uncoated, 2.3*2300 mm

NO.	REF	Configuration Type	Diameter Of Jaws (unit: mm)	Minimum diameter of working channel (unit: mm)	Opening width of cup jaws (unit: mm）	Classification of jaws	Configuration Needle	Spring sheathType	Classification of spring tube	Woking length (unit: mm）	Description
418	NBF73-11023120	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	PE coating	1200	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,PE coating, 2.3*1200 mm
419	NBF73-11023160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,PE coating, 2.3*1600 mm
420	NBF73-11023180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,PE coating, 2.3*1800 mm
421	NBF73-11023230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	Without	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, Without needle, Single outer sheath,PE coating, 2.3*2300 mm
422	NBF73-11123120	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	PE coating	1200	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,PE coating, 2.3*1200 mm
423	NBF73-11123160	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	PE coating	1600	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,PE coating, 2.3*1600 mm
424	NBF73-11123180	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	PE coating	1800	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,PE coating, 2.3*1800 mm
425	NBF73-11123230	Four-bar linkage	2.3	2.8	6.7	Stamping Full Alligator	With	Single outer sheath	PE coating	2300	Four-bar linkage, 6.7 mm opening width, Stamping Full Alligator, With needle, Single outer sheath,PE coating, 2.3*2300 mm
426	EBF03-11018260	Four-bar linkage	1.8	2.0	4.5	MIM Oval	Without	Single outer sheath	PE coating	2600	Four-bar linkage, 4.5 mm opening width, MIM Oval, Without needle, Single outer sheath,PE coating, 1.8*2600 mm
427	100575	Twin wire	2.3	2.8	6.7	MIM Alligator	With	Single outer sheath	FEP coating	2300	Twin wire, 6.7 mm opening width, MIM Alligator, With needle, Single outer sheath,FEP coating, 2.3*2300 mm
428	100576	Twin wire	2.3	2.8	6.7	MIM Alligator	Without	Single outer sheath	FEP coating	2300	Twin wire, 6.7 mm opening width, MIM Alligator, Without needle, Single outer sheath,FEP coating, 2.3*2300 mm
429	100577	Twin wire	2.3	2.8	6.7	MIM Oval	With	Single outer sheath	FEP coating	2300	Twin wire, 6.7 mm opening width, MIM Oval, With needle, Single outer sheath,FEP coating, 2.3*2300 mm
430	100578	Twin wire	2.3	2.8	6.7	MIM Oval	Without	Single outer sheath	FEP coating	2300	Twin wire, 6.7 mm opening width, MIM Oval, Without needle, Single outer sheath,FEP coating, 2.3*2300 mm

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737205 R000

Manufacturer: Micro-Tech (Nanjing) Co., Ltd.

Address:
No. 10 Gaoke Third Road
Nanjing National Hi-Tech
Industrial Development Zone
Nanjing
Jiangsu
210032
China

Single Registration Number: CN-MF-000006950

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestrasse 80
Hamburg
20537
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-12-10**

Current Issue Date: **2024-08-02**

Starting Validity Date: **2024-08-02**

Expiry Date: **2026-12-09**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737205 R000

Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	**Intended purpose**
Sterile Repositionable Hemostasis Clipping Device	Device is intended to be used for hemostasis for mucosal/submucosal defects in digestive tract.
Class IIb	**Intended purpose**
Mono- And Bipolar Surgical Instruments, Single-Use	The Single Use Electrosurgical Knife has been designed to be used with endoscopes and electrosurgical units for marking, dissection, elevation, irrigation and preparation of tissue layers in combination with monopolar cutting and coagulation within the digestive tract.
Gastrointestinal Endoscopy, Forceps, Single Use	The Ensure™ Single-Use Coagulation Forceps have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract. The Disposable Hot Biopsy Forceps are used endoscopically in conjunction with monopolar electrosurgical current to obtain digestive tissue biopsies and/or remove polyps.
Polypectomy Snares	The Sterile Hot Snare is used in the endoscope to remove polyps or tissues in the gastrointestinal tract through high-frequency current. The Single Use Snares are indicated for use endoscopically for the removal and or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

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Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737205 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Biopsy Needles and Kits	Class IIa
Gastrointestinal Tubes and Sets	Class IIa
Gastrointestinal Endoscopy Devices	Class IIa

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 737205 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-12-10	3297360	Issued
2023-01-13	3794250	Supplemented – Addition of device group Biopsy Needles and Kits.
2023-12-07	30000196	Supplemented – Addition of device group Gastrointestinal Tubes and Sets
2024-06-04	30035290	Supplemented – Addition of device group Gastrointestinal Endoscopy Devices. Amended – Addition of new suppliers relating to the group Biopsy Needles and Kits.
Current	30193148	Supplemented – Addition of device categories for Mono- And Bipolar Surgical Instruments, Single-Use, Gastrointestinal Endoscopy, Forceps, Single Use, and Polypectomy Snares.

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