Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLRAȚIE
PE PROPRIE RASPUNDERE

Solicitantul ***”AG Medical” S.R.L.****, cu sediul în* ***mun. Chișinău, str. N.Testemitanu 17/6****, tel:* ***068864448****, e-mail:* sc.agmedical.srl@gmail.com,

declar pe proprie răspundere, cunoscând prevederile art. ***352[1]*** *, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:*

PRODUCT: Multiband ligation system
MBLS-6F

Sunt autentice și corespund realității

Cristina Rusu, administrator *Semnătura*

Digitally signed by Rusu Cristina
Date: 2023.10.19 15:11:36 EEST
Reason: MoldSign Signature
Location: Moldova

19.10.2023

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 19.10.2023

Solicitantul "AG Medical" S.R.L., cu sediul în mun. Chișinău, str. N.Testemitanu 17/6, tel: 068864448, e-mail: sc.agmedical.srl@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

MICRO TECH
PRODUCT: Multiband ligation system
MBLS-6F

Se anexează următoarele acte:

1. DeclarațiI de Conformitate CE
2. Certificatul de Conformitate CE
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Cristina Rusu
19.10.2023

Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

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

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 03 48850 041

Manufacturer:

Micro-Tech (Nanjing) Co., Ltd.
NO.10 Gaoke Third Road
Nanjing National Hi-Tech Industrial Development Zone
210032 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Single-Use Biopsy Forceps,
Multiple Band Ligator Set,
Endoscopic Ultrasound Aspiration Needle,
Single Use Electrosurgical Knife

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH18217EXT01

Valid from: 2018-08-19
Valid until: 2023-08-18

Date, 2018-05-28

Stefan Preiß

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

TÜV®

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

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 03 48850 041

Facility(ies):

Micro-Tech (Nanjing) Co., Ltd.
NO.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone, 210032 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Micro-Tech (Nanjing) Co., Ltd.
No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech Industrial Development Zone, 210032 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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	Multiple Band Ligator Set
REF Number	See MTN-0001278
UMDNS Code	12332
Classification:	Ⅱa (According to MDD annexⅨ, Rule 5)

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. 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

Notified Body:	TUV SUD Product Service GmbH, Ridlerstr. 65, 80339 Munchen, Germany
Identification number:	0123
Certificate Number:	G1180348850041
Expire date of the certificate:	**August 18, 2023**
Start of CE Marking:	**Oct. 12, 2016**

Signature: Frank Liu **Date:** 2018-09-17

Title: Management Representative

MICRO-TECH ™
ENDOSCOPY

CE MBLS Product List

MTN-0001278 A/0

Item	REF	Endoscope OD φ(mm)	Band Quantity (pcs)	Pull Catheter Diameter φ(mm)	Pull Thread Length (cm)	Minimum Working Channel φ(mm)	Band Type
1	MBLS-7F-NL	9.4~13.0	7	2.0±0.5	145±30	2.8	Non-Latex
2	MBLS-6F-NL	9.4~13.0	6	2.0±0.5	145±30	2.8	Non-Latex
3	MBLS-4F-NL	9.4~13.0	4	2.0±0.5	145±30	2.8	Non-Latex
4	MBLS-3F-NL	9.4~13.0	3	2.0±0.5	145±30	2.8	Non-Latex
5	MBLS-XS-7F-NL	8.6~9.2	7	2.0±0.5	145±30	2.8	Non-Latex
6	MBLS-XS-6F-NL	8.6~9.2	6	2.0±0.5	145±30	2.8	Non-Latex
7	MBLS-XS-4F-NL	8.6~9.2	4	2.0±0.5	145±30	2.8	Non-Latex
8	MBLS-XS-3F-NL	8.6~9.2	3	2.0±0.5	145±30	2.8	Non-Latex
9	MBLS- XL-7F-NL	11~14.0	7	2.0±0.5	190±30	2.8	Non-Latex
10	MBLS- XL-6F-NL	11~14.0	6	2.0±0.5	190±30	2.8	Non-Latex
11	MBLS-XL-4F-NL	11~14.0	4	2.0±0.5	190±30	2.8	Non-Latex
12	MBLS-XL-3F-NL	11~14.0	3	2.0±0.5	190±30	2.8	Non-Latex
13	MBLS-P-6F-NL	8.5	6	2.0±0.5	145±30	2.8	Non-Latex
14	MBLS-7F	9.4~13.0	7	2.0±0.5	145±30	2.8	Latex
15	MBLS-6F	9.4~13.0	6	2.0±0.5	145±30	2.8	Latex
16	MBLS-4F	9.4~13.0	4	2.0±0.5	145±30	2.8	Latex
17	MBLS-3F	9.4~13.0	3	2.0±0.5	145±30	2.8	Latex
18	MBLS-XS-7F	8.6~9.2	7	2.0±0.5	145±30	2.8	Latex
19	MBLS-XS-6F	8.6~9.2	6	2.0±0.5	145±30	2.8	Latex
20	MBLS-XS-4F	8.6~9.2	4	2.0±0.5	145±30	2.8	Latex
21	MBLS-XS-3F	8.6~9.2	3	2.0±0.5	145±30	2.8	Latex
22	MBLS- XL-7F	11~14.0	7	2.0±0.5	190±30	2.8	Latex
23	MBLS- XL-6F	11~14.0	6	2.0±0.5	190±30	2.8	Latex
24	MBLS-XL-4F	11~14.0	4	2.0±0.5	190±30	2.8	Latex
25	MBLS-XL-3F	11~14.0	3	2.0±0.5	190±30	2.8	Latex
26	MBLS-P-6F	8.5	6	2.0±0.5	145±30	2.8	Latex

Confirmation Letter

We, MICRO-TECH (Nanjing) Co., Ltd,

No. 10, Gaoke 3rd Road, Nanjing National Hi-Tech Industrial Development Zone, China, 210032

hereby confirm under the sole responsibility that

MICRO-TECH Europe GmbH

Mündelheimer Weg 36, 40472 Düsseldorf, Germany

registered with the Trade Registry under No. 56142 is our distributor of Micro-Tech in Moldova and authorized to sell our products.

Micro-Tech Europe is also authorized to give authorizations to its official distributor

AG Medical SRL

N.Testemitanu Street 17/6 2025 Chisinau, Moldova

for tenders and registration in Moldova.

Date: 2023-05-30

MICRO-TECH (Nanjing) Co., Ltd,

This authorization is valid from the issuing date of this authorization letter.

Lydia Jiang

Signature

南微医学科技股份有限公司
MICRO-TECH(NAN JING)CO.,LTD.

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 Multiple Band Ligator Set

REF Number See Attachment 1

UMDNS Code 12332

Classification: Ⅱa (According to MDD annexⅨ, Rule 5)

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. 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

Notified Body: TUV SUD Product Service GmbH, Ridlerstr. 65, 80339 Munchen, Germany

Identification number: 0123

Certificate Number: G1 048850 0047

Expire date of the certificate: 2028-12-31

Start of CE Marking: 2016-08-12

Signature: Frank Liu **Date:** 2023-07-20

Title: Management Representative

The reference standards:

- 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 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 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- 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
- 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)
- ISO/TR 20416 Medical devices — post-market surveillance for manufacturers
- IMDRF MDCE WG/N56 FINAL: 2019 Clinical Evaluation
- 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 14644-1:2015 Cleanroom and associated controlled environments - Part 1:

Classification of air cleanliness

- EN 17141:2020 Cleanrooms and associated controlled environments — Biocontamination control
- ISO 8600-1-2015 Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements
- EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
- 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
- MDCG 2018-1 Guidance on basic UDI-DI and changes to UDI-DI
- MDCG-2019-1MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG-2019-7Guidance 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

Attachment 1

CE MBLS Product List

Item	REF	Endoscope OD φ(mm)	Band Quantity (pcs)	Pull Catheter Diameter φ(mm)	Pull Thread Length (cm)	Minimum Working Channel φ(mm)	Band Type
1	MBLS-7F-NL	9.4~13.0	7	2.0±0.5	145±30	2.8	Non-Latex
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17	MBLS-3F	9.4~13.0	3	2.0±0.5	145±30	2.8	Latex
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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 048850 0047 Rev. 01

Manufacturer:

Micro-Tech (Nanjing) Co., Ltd.
No. 10 Gaoke Third Road
Nanjing National Hi-Tech Industrial Development Zone
210032 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Single-Use Biopsy Forceps,
Multiple Band Ligator Set,
Endoscopic Ultrasound Aspiration Needle,
Single Use Electrosurgical Knife,
Extraction Basket / short-wire compatible,
Biliary Drainage Catheter Set / short-wire compatible,
Sphincterotome / short-wire compatible,
Retrieval Balloon / short-wire compatible,
Single-Use Coagulation Forceps

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1921726

Valid from: 2019-11-15
Valid until: 2023-08-18

Date, 2019-11-15

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 048850 0047 Rev. 01

Facility(ies):

Micro-Tech (Nanjing) Co., Ltd.
No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech Industrial Development Zone, 210032 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Micro-Tech (Nanjing) Co., Ltd.
No. 10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone, 210032 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

.

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road
Nanjing National Hi-Tech Industrial
Development Zone,
Nanjing
Jiangsu
210032
China

05 July 2023

Notified Body Confirmation Letter
Reference: EU2023-607/646945

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road
Nanjing National Hi-Tech Industrial
Development Zone,
Nanjing
Jiangsu
210032
China

SRN Number (if available): CN-MF-000006950

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 of the corresponding devices 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 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer 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 the 20 Mar 2023 for the relevant devices.

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:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 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 BSI Group The Netherlands B.V.,

Chiara Sparks

Chiara Sparks
Digitally signed by Chiara Sparks
Date: 2023.07.05 14:06:11 -04'00'

Chiara Sparks

BSI Scheme Manager

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
N/A	N/A	N/A	N/A

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
Single-Use Biopsy Forceps	Class IIa	N/A	MDD Certificate G1 048850 0047 Rev. 01 and expiry date 20230818; NB TÜV SÜD Product Service GmbH, CE 0123
Single Use Electrosurgical Knife	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate G1 048850 0047 Rev. 01 and expiry date 20230818; NB TÜV SÜD

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
			Product Service GmbH, CE 0123
Single Use Coagulation Forceps	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate G1 048850 0047 Rev. 01 and expiry date 20230818; NB TÜV SÜD Product Service GmbH, CE 0123
Endoscopic Ultrasound Aspiration Needle	Class IIa	N/A	MDD Certificate G1 048850 0047 Rev. 01 and expiry date 20230818; NB TÜV SÜD Product Service GmbH, CE 0123
Sterile Disposable Hot Biopsy Forceps	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate CN19/41071 and expiry date 20240524; NB SGS Belgium NV, CE 1639
Sterile Hot Snare	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate CN19/41071 and expiry date 20240524; NB SGS Belgium NV, CE 1639
Multiple Band Ligator Set	Class IIa	N/A	MDD Certificate G1 048850 0047 Rev. 01 and expiry date 20230818; NB TÜV SÜD Product Service GmbH, CE 0123
Sterile Cold Snare	Class IIa	N/A	MDD Certificate CN19/41071 and expiry date 20240524; NB SGS Belgium NV, CE 1639
Sterile Repositionable Hemostasis Clipping Device	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate CN19/41071 and expiry date 20240524; NB SGS Belgium NV, CE 1639
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/07/05	Initial issue

Manufacturer Self-Declaration

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
Product Name and Classification	Please refer to Attachment 1

We declare that our devices comply with the following aspects:

a) those devices continue to comply with Directive 93/42/EEC;
b) there are no significant changes in the design or intended purpose;
c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
d) we have put in place a quality management system in accordance with Article 10(9) of MDR 2017/745, before 26 May 2024;
e) we have lodged a formal application with BSI before 26 May 2024 in accordance with Section 4.3, first subparagraph, of Annex VII of MDR 2017/745 for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, we have signed a written agreement with BSI before 26 September 2024 in accordance with Section 4.3, second subparagraph, of Annex VII of MDR 2017/745.
f) we have undergone the first On-site audit under MDR by BSI Group The Netherlands B.V. in February 2020, and undergone the Surveillance Assessment under MDR in February 2023.

Signature: Becky Li

Place and date of issue: Nanjing, 2023-07-19

Name: Becky Li

Position: Person Responsible for Regulatory Compliance

Attachment 1 Product List

No.	Device Name	Classification	Certificate Number	Surveillance NB	Expiry Date
1	Single-Use Biopsy Forceps	Class IIa	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
2	Single Use Electrosurgical Knife	Class IIb - Non Implantable	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
3	Single Use Coagulation Forceps	Class IIb - Non Implantable	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
4	Endoscopic Ultrasound Aspiration Needle	Class IIa	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
5	Multiple Band Ligator Set	Class IIa	G1 048850 0047 Rev.01	BSI Group The Netherlands B.V.(2797)	31 December 2028
6	Sterile Disposable Hot Biopsy Forceps	Class IIb - Non Implantable	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028
7	Sterile Hot Snare	Class IIb - Non Implantable	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028
8	Sterile Cold Snare	Class IIa	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028
9	Sterile Repositionable Hemostasis Clipping Device	Class IIa	CN19/41071	BSI Group The Netherlands B.V.(2797)	31 December 2028