Certificate CN13/20559

The management system of

Micro-Tech (Nanjing) Co., Ltd.

No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone,
Nanjing, 210032, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 26 September 2019 until 26 September 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 September 2022
Issue 10. Certified since 26 September 2013

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Digitally signed by Grabazei Alexandru
Date: 2021.12.21 17:24:48 EET
Reason: MoldSign Signature
Location: Moldova

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Micro-Tech (Nanjing) Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 10

Detailed scope

Design and Manufacture of Sterile Cytology Brush, Dilation Balloon(Disposable Dilation Balloon, Disposable Multistage Dilation Balloon Catheter), Disposable Hot Biopsy Forceps, Injection Needle, Nasal Biliary Drainage Set, Non-Vascular Stent, Snare, Spray Catheter, Stone Extraction Basket, Single-Use Cleaning Brush, Single Use Bite Block, Endoscopy Working Channel Valves, Polyp Collection Kit, Cold Snare (used for clinical endoscopic procedure), Hydro Slide Guidewire (used for clinical endoscopic procedure), Biliary Drainage Catheter and Introducer Systems, Biliary Stone Retrieval Balloon Catheter, Repositionable Hemostasis Clipping Device, Pancreatic Pseudocyst Stent with Delivery System, Sphincterotome, Fixed Wire Balloon (ABC Dilatation Balloon Catheter, Rapide™ Multistage Dilatation Balloon Catheter), Non-sterile OXY CO_2 Bite Block and Sterile Biliary Nitinol Stent Set, short-wire compatible

Provision of Sterilization Service for Medical Devices using Ethylene Oxide Gas in accordance with EN ISO 11135:2014

UKAS MANAGEMENT SYSTEMS
0005

Additional facilities

No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, 210032, Jiangsu Province, P.R. China

EC Certificate Full Quality Assurance System: Certificate CN19/41071

The management system of

Micro-Tech (Nanjing) Co., Ltd.

No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone,
Nanjing, 210032, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 26 September 2013
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/SZH 8403MDD

This is a multi-site certification.
Additional site details are listed on subsequent pages

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Micro-Tech (Nanjing) Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

Sterile Non Vascular Stent (Biliary Stent, Esophageal Stent, Intestinal Stent, Tracheal Stent)
Sterile medical devices used for clinical endoscopic procedure including Sterile Dilation Balloon (Disposable Dilation Balloon , Disposable Multistage Dilation Balloon Catheter), Sterile Disposable Hot Biopsy Forceps, Sterile Injection Needle, Sterile Nasal Biliary Drainage Set, Sterile Hot Snare Sterile Stone Extraction Basket, Sterile Cold Snare, Non Vascular sterile Hydro Slide Guidewire, Sterile Biliary Drainage Catheter, Biliary Drainage Catheter Introducer System, Biliary Drainage Catheter with Introducer System, Sterile Biliary Stone Retrieval Balloon Catheter, Sterile Repositionable Hemostasis Clipping Device to be intended for short term use Sterile Pancreatic Pseudocyst Stent with Delivery System to be intended for short term use in the body within 30 days, Sterile Sphincterotome, Non sterile OXY CO_2 Bite Block used to protect the endoscope insertion tube and oesophageal dilators from being bitten by the patient. Sterile Biliary Nitinol Stent Set, short-wire compatible
Class I (Sterility aspects only Restricted to the aspects of manufacture concerned with securing and maintaining sterile condition): Sterile Spray Catheter—used for lavage, spraying of a medical solution or contrast medium, Sterile Cytology Brush, Sterile Fixed Wire Balloon (ABC Dilatation Balloon Catheter, Rapide™ Multistage Dilatation Balloon Catheter) use in adult and adolescent populations to endoscopically dilate strictures of the esophagus for transient use

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, 210032, P.R.China

EC Certificate Full Quality Assurance System: CN13/20558

The management system of

Micro-Tech (Nanjing) Co., Ltd.

No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone,
Nanjing, 210032, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 26 September 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 September 2022
Issue 12. Certified since 26 September 2013

Certification is based on reports numbered CN/SZH 8403MDD

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Jonathan M. Hall

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Micro-Tech (Nanjing) Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 12

Detailed scope

Sterile Non Vascular Stent (Biliary Stent, Esophageal Stent, Intestinal Stent, Tracheal Stent)
Sterile medical devices used for clinical endoscopic procedure including Sterile Dilation Balloon (Disposable Dilation Balloon , Disposable Multistage Dilation Balloon Catheter), Sterile Disposable Hot Biopsy Forceps, Sterile Injection Needle, Sterile Nasal Biliary Drainage Set, Sterile Hot Snare Sterile Stone Extraction Basket, Sterile Cold Snare, Non Vascular sterile Hydro Slide Guidewire, Sterile Biliary Drainage Catheter, Biliary Drainage Catheter Introducer System, Biliary Drainage Catheter with Introducer System, Sterile Biliary Stone Retrieval Balloon Catheter, Sterile Repositionable Hemostasis Clipping Device to be intended for short term use Sterile Pancreatic Pseudocyst Stent with Delivery System to be intended for short term use in the body within 30 days, Sterile Sphincterotome, Non sterile OXY CO_2 Bite Block used to protect the endoscope insertion tube and oesophageal dilators from being bitten by the patient. Sterile Biliary Nitinol Stent Set, short-wire compatible
Class I (Sterility aspects only Restricted to the aspects of manufacture concerned with securing and maintaining sterile condition): Sterile Spray Catheter—used for lavage, spraying of a medical solution or contrast medium, Sterile Cytology Brush, Sterile Fixed Wire Balloon (ABC Dilatation Balloon Catheter, Rapide™ Multistage Dilatation Balloon Catheter) use in adult and adolescent populations to endoscopically dilate strictures of the esophagus for transient use

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, 210032, P.R. China

EC Certificate – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Chris Koci – President, LRQA Americas
Issued By: Lloyd's Register Quality Assurance Ltd

Current Certificate: 15 June 2018
Original Approval: 1 January 2014
Expiry Date: 14 June 2021
Certificate Identity Number: 10092881
LRQA Notified Body Number: 0088

Approval Certificate Number: MDD – 0078058

EC Certificate – FULL QUALITY ASSURANCE SYSTEM

CERTIFICATE IDENTITY No.10092881 SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

Class II Products

Re-useable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and surgery including:

Hot Biopsy Forceps, Plastic Biliary Stents
Metal Biliary Stent Sets
Pancreatic Stents
Sphincterotornes
Sphinctertomes (Active Cords)
Papillotomes
Polypectomy Devices
Gastrostomy Devices
Gastrostomy Devices (Adaptors)
Gastrostomy Replacement Devices
Gastro-Jejunal Feeding Tubes
Nasal Jejunal Feeding Tubes
Ligation Devices, Endoscopic Clipping Devices
Coagulation Devices
Injection Needles
Aspiration Needles
Disposable Biopsy Forceps
Endoscopic Ultra Fiducial Needles

Class IIa Products

Disposable (Cold) Biopsy Forceps
Active Cords
Injection Needles
Aspiration Needles
Gastrostomy Adaptors
Nasal Jejunal Feeding Tubes
Ligation Devices
Coagulation Devices

Class IIb Products

Hot Biopsy Forceps
Biliary Stents
Metal Biliary Stents/Sets
Pancreatic Stents
Sphincterotomes
Papillotomes
Endoscopic Ultra Fiducial Needles
Polypectomy Devices
Gastrostomy Devices
Gastrostomy Replacement Devices
Gastro Jejunal Feeding Tubes
Ligation Devices (Endoscopic Clipping Devices)
Coagulation Devices (Bipolar Probes).

Schedule Issue: 1
Date of Schedule Issue: 15 June 2018
Certificate Identity Number: 10092881
LRQA Notified Body Number: 0088

Chris Koci – President, LRQA Americas
Issued By: Lloyd's Register Quality Assurance Ltd

Lloyd's Register

Current issue date:	11 June 2020	Original approval(s):
Expiry date:	31 May 2023	ISO 13485 - 1 January 2014
Certificate identity number:	10273567	

Certificate of Approval

This is to certify that the Management System of:

Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00016927

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:
Design and Manufacturing of Reusable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and Surgery.

Cliff Muckleroy

Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Certificate identity number: 10273567

Certificate Schedule

Location	Activities
4900 Bethania Station Road, Winston-Salem, NC, 27105, United States	**ISO 13485:2016** Design and Manufacturing of Reusable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and Surgery.
5951 Grassy Creek Road, Winston-Salem, NC, 27105, United States	**ISO 13485:2016** Manufacturing, Quality Control, Packaging, Labeling, and Finished Goods Shipping.
5941 Grassy Creek Road, Winston-Salem, NC, 27105, United States	**ISO 13485:2016** Manufacturing, Purchasing, Receiving, Incoming Quality Control, and Raw material Storage.

UKAS MANAGEMENT SYSTEMS
001

Issued by: Lloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States for and on behalf of: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

EC Certificate – PRODUCTION QUALITY ASSURANCE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Chris Koci – President, LRQA Americas
Issued By: Lloyd's Register Quality Assurance Ltd

Current Certificate: 15 June 2018
Original Approval: 1 January 2014
Expiry Date: 14 June 2021
Certificate Identity Number: 10092875
LRQA Notified Body Number: 0088

Approval Certificate Number: MDD – 0078058

EC Certificate – PRODUCTION QUALITY ASSURANCE
CERTIFICATE IDENTITY No.10092875 SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

Class I Sterile Products

Re-useable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and surgery including:

Retrieval Devices
ERCP Catheters
ERCP Catheter Adaptors
Wire Guides
Wire Guide Locking Devices
Extraction Balloons
Extraction Baskets
Dilation Catheters
Balloon Dilators
Manometry Catheters
Cytology Brushes

Class I Measuring Devices

Biliary and Quantum Balloon Inflation Devices

Schedule Issue: 1
Date of Schedule Issue: 15 June 2018
Certificate Identity Number: 10092875
LRQA Notified Body Number: 0088

Chris Koci – President, LRQA Americas
Issued By: Lloyd's Register Quality Assurance Ltd

CERTIFICATO CE

Certificato n. 1812/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

mantiene nello stabilimento di:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi

Sterilizzanti chimici a freddo per dispositivi medici

Disinfettanti per dispositivi medici

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici

Disinfettanti, decontaminanti e detergenti per dispositivi medici

Disinfettanti e detergenti per dispositivi medici

Disinfettanti e decontaminanti per dispositivi medici

Sistemi di conservazione e trasporto di endoscopi

Lava disinfettatrice per endoscopi

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi
Mod. MEDIVATORS ISA
Marca Cantel Medical (Italy) S.r.l.

Sterilizzanti chimici a freddo per dispositivi medici
Modd. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Marca CANTEL

Disinfettanti per dispositivi medici
Modd. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Marca CANTEL

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici
Modd. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Marca CANTEL

Disinfettanti, decontaminanti e detergenti per dispositivi medici
Mod. ISACLEAN, PROTEODONT.
Marca CANTEL

Disinfettanti e detergenti per dispositivi medici
Modd. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Marca CANTEL

Disinfettanti e decontaminanti per dispositivi medici
Modd. PROTEAZONE; PROTEAZONE OD.
Marca CANTEL

Sistemi di conservazione e trasporto di endoscopi
Modd. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Marca CANTEL

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Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

DocuSign

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice per endoscopi
Modd. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Marca CANTEL

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

manages in the factory of:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Cold chemical washer disinfector and sterilizer for endoscopes

Cold chemical sterilant for medical devices

Disinfectants for medical devices

Multi-enzyme detergent, decontaminant disinfectant for medical devices

Disinfectants, decontaminants and detergents for medical devices

Disinfectants and detergents for medical devices

Decontaminants and disinfectants for medical devices

Storage and transport systems for endoscopes

Washer disinfector for endoscopes

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

DocuSign

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Cold chemical washer disinfector and sterilizer for endoscopes
Type ref. MEDIVATORS ISA
Trade mark Cantel Medical (Italy) S.r.l.

Cold chemical sterilant for medical devices
Type ref. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Trade mark CANTEL

Disinfectants for medical devices
Type ref. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Trade mark CANTEL

Multi-enzyme detergent, decontaminant disinfectant for medical devices
Type ref. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Trade mark CANTEL

Disinfectants, decontaminants and detergents for medical devices
Type ref. ISACLEAN, PROTEODONT.
Trade mark CANTEL

Disinfectants and detergents for medical devices
Type ref. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Trade mark CANTEL

Decontaminants and disinfectants for medical devices
Type ref. PROTEAZONE; PROTEAZONE OD.
Trade mark CANTEL

Storage and transport systems for endoscopes
Type ref. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Trade mark CANTEL

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Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Washer disinfector for endoscopes

Type ref. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Trade mark CANTEL

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: **2021 - 01 - 21**
Expires on: ***2024 - 07 - 05***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126041

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 1250.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, sviluppo, produzione di disinfettanti, sterilizzatrici e detergenti per dispositivi medici. Progettazione, sviluppo, produzione, commercializzazione e assistenza tecnica di dispositivi per il lavaggio, la disinfezione e la sterilizzazione di dispositivi medici. Progettazione, sviluppo, gestione della produzione di sistemi di conservazione e trasporto di endoscopi
Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Ulteriori informazioni riguardanti l'applicabilità dei requisiti UNI CEI EN ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1997-07-25	2021-01-21	2024-07-05

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

has established and applies a quality management system for medical devices for the following 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 and microscopy

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-06-21
Certificate Registration No.:	SX 60148788 0001
An audit was performed. Report No.:	60319405 001
This Certificate is valid until:	2023-06-20

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 2020-04-29

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Europa SE & Co. KG
Albert-Schweitzer-Ring 24-26
22045 Hamburg
Germany

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 2/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Deutschland GmbH
Albert-Schweitzer-Ring 35
22045 Hamburg
Germany

Scope:

Servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 3/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization:
Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Deutschland GmbH
Amsinckstr. 63
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 and microscopy

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 4/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus France S.A.S.
65 Rue de Monthléry
94533 Rungis
France

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

Certification Body

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

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 5/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

OLYMPUS IBERIA S.A.U.
PL. Europa 29-31
08908 L'Hospitalet de Llobregat
Barcelona
Spain

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 microscopy

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 6/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization:
Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus France S.A.S.
19 rue d'Arcueil
94150 Rungis
France

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 and microscopy

Certification Body

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

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 7/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Czech Group, s.r.o.
Evropská ul. 176/16
160 41 Praha 6
Czech Republic

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 and microscopy

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 8/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Czech Group, s. r.o.
clen koncernu
Telickova 457/29
751 24 Prerov-Predmosti
Czech Republic

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

Certification Body

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

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

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Doc. 9/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Service Facility Portugal
Tecnologies Opticas e Digitais, Lda.
Rua de Alcorredores 43 A
3020-923 Torre de Vilela (Coimbra)
Portugal

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

Certification Body

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

TÜVRheinland LGA Products GmbH – TÜVRheinland – Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

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Doc. 10/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization:
Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Vienna
Austria

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 and microscopy

Certification Body

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

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

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Doc. 11/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Nederland B.V.
Simon Smitweg 18
2353 GA Leiderdorp
Netherlands

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 and microscopy

Certification Body

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

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 12/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization:
Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Switzerland

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization:
Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Switzerland

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 and microscopy

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizaţia

OLYMPUS EUROPA SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

a implementat şi aplică un sistem de management al calităţii pentru dispozivite medicale pentru următoarele domenii:

Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

S-a furnizat dovada faptului că au fost îndeplinte cerinţele specificate în

EN ISO 13485:2016

Sistemul de management al calităţii este supus unei supravegheri anuale.

Data intrării în vigoare: 21.06.2020
Nr. înregistrare certificat: SX 60148788 0001
A fost efectuat auditul, raport nr. 60319405 001
Acest certificat este valabil până la 20.06.2023.

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl. Ing. I. Munkler

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

Data, 29.04.2020

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
Tel: +49 221 806-1371 Fax: +49 221 806-3935 email: cert-validity@de.tuv.com http://www.tuv.com/safety

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Europa SE & Co. KG
Albert-Schweitzer-Ring 24-26
22045 Hamburg
Germania

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Albert-Schweitzer-Ring 35
22045 Hamburg
Germania

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germania

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus France S.A.S.
65 Rue de Monthléry
94533 Rungis
Franţa

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Iberia S.A.U.
PL. Europa, 29-31
08908 L'Hospitalet de Llobregat
Barcelona
Spania

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

ROMÂNIA
MINISTERUL JUSTIŢIEI
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TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus France S.A.S.
19 rue d'Arcueil
94150 Rungis
Franţa

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

Data, 29.04.2020

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Czech Group, s.r.o.
Evropská ul. 176/16
160 41, Praga 6
Republica Cehă

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Czech Group, s.r.o.
clen koncernu
Telickova 457/29
751 24 Prerov-Predmosti
Republica Cehă

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Service Facility Portugal
Tecnologias Optica e Digitais, Lda.
Rua de Alcorredores, 43 A
3020-923 Torre de Vilela (Coimbra)
Portugalia

Domeniul de aplicabilitate:
Service intern pentru sisteme optice, opto-digitale, electronice şi mecanice precum şi accesorii corespunzătoare din domeniul endoscopiei.

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Viena
Austria

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Nederland B.V.
Simon Smitweg 18
2353 GA Leiderdorp
Ţările de Jos

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Elveţia

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

Data, 29.04.2020

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Elveţia

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler

Data, 29.04.2020

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

EC Certificate

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

Registration No.: HD 60123878 0001

Report No.: 12018179 022

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 and additional sites included)

Replaces Approval, Registration No.: HD 60078827 0001

Expiry Date: 2022-11-02

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: 2017-11-03

Date: 2017-10-12

Notified Body

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 60123878 0001
Report No.: 12018179 022

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
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2017-10-12

M.Sc. M. Aihara

Traducere din limba engleza

TÜVRheinland®

APROBARE

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

Nr. Înregistrare: HD 60123878 0001
Nr. Raport: 12018179 022

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 produse si locatii suplimentare incluse)
Înlocuieşte Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirarii: 02.11.2022

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: 03-11-2017

Data. 12.10.2017

TÜVRheinland

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat
Nr. de inregistrare: HD 60123878 0001
Nr. raport: 12018179 022

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
- 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: 12.10.2012

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ - FRANCEZĂ
AUT. NR. 22059
TEL.: 0745471452

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60123877 0001

Report No.: 12018179 022

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

Products:
Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Instruments used in conjunction with Endoscopes and Sterile Non Active Instruments used in conjunction with Medical Ultrasound Diagnostic Imaging Systems
Replaces Approval, Registration No.: DD 60116725 0001

Expiry Date: 2022-11-02

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-11-03

Date: 2017-10-12

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.

Traducere din limba engleza

TÜVRheinland

CERTIFICAT CE
Directiva CE 93/42/CEE Anexa V
Asigurarea calităţii producţiei
Echipamente medicale

Nr. Înregistrare: DD 60123877 0001
Nr. Raport: 12018179 022

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

Produse: Echipamentelor sterile pentru endoterapie, utilizate împreuna cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape şi instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.
Înlocuieşte Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirarii: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei V 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 V, secţiunea 4 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa IIb şi clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate du Anexa III.

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

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60129455 0001

Report No.: 15055315 008

Manufacturer:

Hefei C & P Nonwoven
Products Co., Ltd.
No. 22 Park Road
Feidong New City Development
Hefei
231600 Anhui
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Sterile Surgical Drapes, Sterile Surgical Packs, Sterile Surgical Gowns, Sterile Nonwoven Bedsheets, Sterile Nonwoven Pillowcases, Sterile Nonwoven Masks

Replaces Approval, Registration No.: DD 60084732 0001

Expiry Date: 2023-01-18

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

X. Ren

Effective Date: 2018-05-15

Date: 2018-05-15

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.

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 01 81710 019

Manufacturer:

Hangzhou AGS MedTech Co., Ltd.
Building 6, Kangxin Road No. 597
Qianjiang Economic Development Area
311106 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Stone Retrieval Balloon,
Disposable Guide Wire,
Disposable Biopsy Forceps,
Disposable Grasping Forceps,
Disposable Swinging Biopsy Forceps,
Disposable Stone Extraction Basket,
Disposable Sclerotherapy Needle,
Hemoclip,Polypectomy Snare,
Sphincterotome, Biliary Stent,
Nasal Biliary Drainage Catheter

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.: SH18718EXT01

Valid from: 2018-03-19
Valid until: 2023-03-18

Date, 2018-01-22

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 01 81710 019

Facility(ies):

Hangzhou AGS MedTech Co., Ltd.
Building 6, Kangxin Road No. 597, Qianjiang
Economic Development Area, 311106 Hangzhou,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

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

TÜV®

EC Declaration of Conformity

Manufacturer:

HEFEI C&P NONWOVEN PRODUCTS CO.,LTD
No.22Park Road,Feidong new city Development area,Hefei,Anhui,China

whose single Authorized Representative:

MJ-sales
DK-7000 Fredericia,Denmark
Tel : +45 61681866
Fax : +45 61681866

We, the manufacturer, herewith declare that the products

Surgical Nonwoven Drape

Types: General,Angiography,Eye,Orthopaedic

UMDNS-Code: **12368** ;

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to **Class Is** according to Annex V of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD601294550001
Issue date: 2018-05-15
Expiry date: 2023-01-18

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: HEFEI C&P NONWOVEN PRODUCTS CO.,LTD

Address: No.22Park Road,Feidong new city Development area,Hefei,Anhui,China

Hefei,10-03-2018
Place, date

Wang Xing
Legally binding signature, Function

EC Certificate

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

Registration No.: HD 60141076 0001

Report No.: 15082678 007

Manufacturer:
Jiangsu Vedkang Medical Science & Technology Co., Ltd.
No. 52, Guoxiang Road
Wujin Economic Development Zone
Changzhou
213149 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60136146 0001

Expiry Date: 2024-05-27

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: 2019-07-22

Date: 2019-07-22

Notified Body

Fuxiu Sheng

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60141076 0001
Report No.: 15082678 007

Manufacturer:
Jiangsu Vedkang Medical Science & Technology Co., Ltd.
No. 52, Guoxiang Road
Wujin Economic Development Zone
Changzhou
213149 Jiangsu
China

Products:

Disposable Polyp Snares, Injection Needles, Disposable Non-electric Biopsy Forceps, Gastrointestinal and Biliary Balloon Catheters, Stone Extraction Baskets, Stone Extraction Balloons, Non-vascular Guidewires, Disposable Nasal Biliary Drainage Tubes, Disposable Endoscopic Hemoclips, Disposable Cytology Brushes, Disposable Bougie Dilators, Disposable Grasping Forceps, Disposable Hot Biopsy Forceps, Kyphoplasty Balloon Catheters, Disposable Cold Snares;

Aspects of manufacture concerned with securing and maintaining sterile conditions:
Disposable Spray Catheters, Balloon Inflators, Disposable Bite Blocks, Biopsy Valve, Polyp Traps, Cleaning Brushes for Endoscope

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-07-22

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Jiangsu Vedkang Medical Science &
Technology Co., Ltd.
No. 52, Guoxiang Road
Wujin Economic Development Zone
Changzhou
213149 JIANGSU
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date July 22, 2019

Application for : Vollst. QMS, Anhang II MDD
Certificate No. : HD 60141076 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. HD 60141076 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Zhuji Pengtian Medical Instrument Co., Ltd.
No.8, Jinjin Road, Jiyang Economic Development District
311800 Zhuji, Zhejiang
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-08-16
Certificate Registration No.:	SX 60122487 0001
An audit was performed. Report No.:	15069771 004
This Certificate is valid until:	2020-08-05

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 2017-08-16

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60122487 0001
Report No.: 15069771 004

Organization:
Zhuji Pengtian Medical Instrument Co., Ltd.
No.8, Jinjin Road, Jiyang
Economic Development District
311800 Zhuji, Zhejiang
China

Scope:

Products:

- Disposable Biopsy Forceps
- Disposable Biopsy Needles
- Disposable Cytology Brushes
- Disposable Endoscope Injection Needles
- Biopsy Forceps (Reusable)
- Cleaning Brushes
- Retrieval Baskets (Reusable)
- Spray Catheters (Reusable)
- Bite Blocks
- Disposable Grasping Forceps
- Disposable Stone Extraction Baskets
- Disposable Polyp Snares
- Disposable Hemoclips

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

X. Ren

Date: 2017-08-16

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 081710 0020 Rev. 00

Holder of Certificate: **Hangzhou AGS MedTech Co., Ltd.**
Building 5, Building 6, No. 597 Kangxin Road
Yuhang District
311106 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Disposable Biopsy Forceps, Disposable Grasping Forceps, Disposable Guide Wire, Stone Retrieval Balloon, Disposable Swinging Biopsy Forceps, Disposable Stone Extraction Basket, Polypectomy Snare, Sphincterotome, Disposable Sclerotherapy Needle, Hemoclip, Endoscopic CO2 Regulation Unit, Biliary Stent, Nasal Biliary Drainage Catheter**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1871808

Valid from: 2018-10-25
Valid until: 2021-10-24

Date, 2018-10-12

Stefan Preiß

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

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 081710 0020 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Hangzhou AGS MedTech Co., Ltd.
Building 5, Building 6, No. 597 Kangxin Road, Yuhang District,
311106 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

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

A4 / 07.17

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

TÜV®

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Jiangsu Vedkang Medical Science &
Technology Co., Ltd.
No. 52, Guoxiang Road
Wujin Economic Development Zone
Changzhou
213149 JIANGSU
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date December 28, 2017

Application for : QMS
Certificate No. : SX 60124622 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60124622 0001
replacing the previous certificate.

Kind regards

Certification body

X. Ren

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Jiangsu Vedkang Medical Science & Technology Co., Ltd.
No. 52, Guoxiang Road
Wujin Economic Development Zone
Changzhou
213149 Jiangsu
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Disposable Endoscopic Surgical Instruments for the area of Gastroenterology and Urology

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-12-28
Certificate Registration No.:	SX 60124622 0001
An audit was performed. Report No.:	15082678 003
This Certificate is valid until:	2020-08-18

Certification Body

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

Date 2017-12-28

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Déclaration de conformité CE
CE Declaration of conformity

La société :
The company :

Nova LightSystems
Les Danjauds la Ferme de Verdolette
13610 Le Puy Sainte-Réparade, France

Déclare que les Dispositifs Médicaux mentionnés ci-dessous
Hereby certifies that the medical device described below

Désignation et Description Descriptive summary	**Références** References	**Classe** Product Class
Cale dents Adulte Bite block - Adult	**NLS/BBA**	I

Sont conformes aux articles de la Directive 93/42/CE du 14 juin 1993 modifiée par la Directive 2007/47/CE du 5 septembre 2007 et au livre V bis du code de la santé publique (article R 665-1 et suivants, quand ils s'appliquent).

Complies with Directive 93/42 CE dated June, 14th 1993 modified by the Directive 2007/47 CE dated September, 5th 2007 and book No. Vbis from the public health code (article R 665-1 et al., if applicable).

Lieu / Place : Le Puy Sainte-Réparade

Date / *Date*: 11/09/2015

Nom du Dirigeant / Name : Margarita Pedrolo

Déclaration de conformité CE
CE Declaration of conformity

La société :
The company :

Nova LightSystems
Les Danjauds la Ferme de Verdolette
13610 Le Puy Sainte-Réparade, France

Déclare que les Dispositifs Médicaux mentionnés ci-dessous
Hereby certifies that the medical device described below

Désignation et Description Descriptive summary	**Références** References	**Classe** Product Class
Cale dents à oxygène Bite block with oxygène pipe	**NLS/BBS-O2**	I

Sont conformes aux articles de la Directive 93/42/CE du 14 juin 1993 modifiée par la Directive 2007/47/CE du 5 septembre 2007 et au livre V bis du code de la santé publique (article R 665-1 et suivants, quand ils s'appliquent).

Complies with Directive 93/42 CE dated June, 14th 1993 modified by the Directive 2007/47 CE dated September, 5th 2007 and book No. Vbis from the public health code (article R 665-1 et al., if applicable).

Lieu / Place : Le Puy Sainte-Réparade

Date / *Date*: 20/01/2015

Nom du Dirigeant / Name : Margarita Pedrollo

Déclaration de conformité
Conformity declaration

La société :
The company :

Nova LightSystems
Les Danjauds la Ferme de Verdolette,
13610 Le Puy Sainte-Réparade, France

Déclare que les Dispositifs Médicaux mentionnés ci-dessous :

Hereby certifies that the medical device described below:

Ecouvillons – Classe I Non sterile

Sont conformes aux articles de la Directive 93/42/CE du 14 juin 1993 modifiée par la Directive 2007/47/CE du 5 septembre 2007 et au livre V bis du code de la santé publique (article R 665-1 et suivants, quand ils s'appliquent).

Complies with Directive 93/42 CE dated June, 14th 1993 modified by the Directive 2007/47 CE dated September, 5th 2007 and book No. Vbis from the public health code (article R 665-1 et al., if applicable).

Lieu / Place : Bagnolet
Date */ Date*: Mai 2015 – *May 2015*
Nom du Dirigeant / Name : Margarita Pedrolo

Ecouvillon – Classe I Non sterile

ENDOSCOPES PETITS DIAMETRES : BRONCHIQUES ET PEDIATRIQUES

CJ-EDB-120-02	Endoscope
CJ-EDB-230-02	bronchique
CJ-EDB-120-03	pédiatrique
CJ-EDB-230-03	Pour canal air/eau d'endoscopes
CJ-EDB-300-03	Endoscope

ENDOSCOPES, ENTEROSCOPES & CYSTOSCOPES ADULTES

CJ-ESB-020-06	Pour l'entrée du canal air/eau d'endoscopes
CJ-ESB-230-06	Endoscope adulte
CJ-EDB-120-06	Endoscope et cystoscope
CJ-EDB-230-06	Endoscope adulte
CJ-EDB-300-06	Entéroscope

BROSSE POUR CAGE A PISTON

CJ-GDB-11-05	Brosse pour cage à piston

KITS POUR ENDOSCOPES PETITS DIAMETRES : BRONCHIQUES ET PEDIATRIQUES

CJ-KEDB-120-02	Kit pour endoscope bronchique pédiatrique
CJ-KEDB-120-03	Kit pour endoscope bronchique
CJ-KEDB-230-03	Kit pour endoscope pédiatrique
CJ-KEDB-300-03	Kit pour entéroscope pédiatrique

KITS POUR ENDOSCOPES, ENTEROSCOPES & CYSTOSCOPES ADULTES

CJ-KEDB-120-06	Kit pour endoscope et cystoscope
CJ-KESB-230-06	Kit pour endoscope adulte
CJ-KEDB-230-06	Kit pour endoscope adulte
CJ-KEDB-300-06	Kit pour entéroscope

CJ-KE-230-06-230-02	Endoscope adulte PENTAX
	Pour canal air/eau d'endoscopes
	Brosse pour cage à piston
CJ-KE-120-03-020-06	Endoscope bronchique
	Pour l'entrée du canal air/eau d'endoscopes
	Brosse pour cage à piston

Déclaration de conformité
Conformity declaration

La société :
The company :

Nova LightSystems
Les Danjauds la Ferme de Verdolette,
13610 Le Puy Sainte-Réparade, France

Déclare que les Dispositifs Médicaux mentionnés ci-dessous :
Hereby certifies that the medical device described below:

Ecouvillon – Classe I Non stérile

Sont conformes aux articles de la Directive 93/42/CE du 14 juin 1993 modifiée par la Directive 2007/47/CE du 5 septembre 2007 et au livre V bis du code de la santé publique (article R 665-1 et suivants, quand ils s'appliquent).

Complies with Directive 93/42 CE dated June, 14th 1993 modified by the Directive 2007/47 CE dated September, 5th 2007 and book No. Vbis from the public health code (article R 665-1 et al., if applicable).

Lieu / Place : Bagnolet
Date / *Date*: 15 Janvier 2015 – *January 15th 2015*
Nom du Dirigeant / Name : Margarita Pedrolo

Ecouvillon – Classe I Non stérile

Kit écouvillon pour endoscope

NLS/KETB-230- 06S05
NLS/KEDB-230-06
NLS/KEDB-120-03

U-brush

NLS/Ubrush

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 336/2004 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 130076 OBL

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **NOVA LIGHTSYSTEMS**
13, Rue Gustave Nickles, 93170 Bagnolet, France

for design, manufacturing and final inspection of medical device(s)

Medical stent (for digestive and tracheo-bronchial ducts) conditionned in introducer – sterile – class IIb – See attachement

meets the provisions of Annex 2 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 4 of Government Order No. 336/2004 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **301225-01 of: 22.03.2013**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 5 of Government Order No. 336/2004 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 4 of Government Order 336/2004 Coll. (Annex II clause 5 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from with validity until
The validity of this Certificate is limited until: 31.8.2016

Elektrotechnický zkušební ústav, s.p. Pod Lisem 129, 171 02 Praha 8 - Troja 1

25.7.2013

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 1 3 0 0 7 6 0 B L *

301225-01

Attachement to Certificat No. : MED 130076 OBL

Medical stent (for digestive and tracheo-bronchial ducts) conditionned in introducer – sterile – class IIb

REFERENCE	DESCRIPTION	Classe
Oesophagus stent		
EFI/ES32-18060	Self-expandable esophagus stent made of Nitinol, tulip type ends, half covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ES32-18080		IIb
EFI/ES32-18100		IIb
EFI/ES32-18120		IIb
EFI/ES32-18140		IIb
EFI/ES32-18150		IIb
EFI/ES32-18160		IIb
EFI/ES33-18060	Self-expandable esophagus stent made of Nitinol, tulip type ends, full covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ES33-18080		IIb
EFI/ES33-18100		IIb
EFI/ES33-18120		IIb
EFI/ES33-18140		IIb
EFI/ES33-18150		IIb
EFI/ES33-18160		IIb
EFI/ES32-20060	Self-expandable esophagus stent made of Nitinol, tulip type ends, half covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ES32-20080		IIb
EFI/ES32-20100		IIb
EFI/ES32-20120		IIb
EFI/ES32-20140		IIb
EFI/ES32-20150		IIb
EFI/ES32-20160		IIb
EFI/ES33-20060	Self-expandable esophagus stent made of Nitinol, tulip type ends, full covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ES33-20080		IIb
EFI/ES33-20100		IIb
EFI/ES33-20120		IIb
EFI/ES33-20140		IIb
EFI/ES33-20150		IIb
EFI/ES33-20160		IIb
EFI/ES32-24060	Self-expandable esophagus stent made of Nitinol, tulip type ends, half covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ES32-24080		IIb
EFI/ES32-24100		IIb
EFI/ES32-24120		IIb
EFI/ES32-24140		IIb
EFI/ES32-24150		IIb
EFI/ES32-24160		IIb

Elektrotechnický zkušební ústav, s.p.
Pod Lisem 129, 171 02 Praha 8 - Trója
1

Attachement to Certificat No. : MED 130076 OBL

EFI/ES33-24060	Self-expandable esophagus stent made of Nitinol, tulip type ends, full covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ES33-24080		IIb
EFI/ES33-24100		IIb
EFI/ES33-24120		IIb
EFI/ES33-24140		IIb
EFI/ES33-24150		IIb
EFI/ES33-24160		IIb
EFI/ER32-18060	Anti-refluent Self-expandable esophagus stent made of Nitinol, tulip type ends, half covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ER32-18080		IIb
EFI/ER32-18100		IIb
EFI/ER32-18120		IIb
EFI/ER32-18140		IIb
EFI/ER32-18150		IIb
EFI/ER32-18160		IIb
EFI/ER33-18060	Anti-refluent Self-expandable esophagus stent made of Nitinol, tulip type ends, full covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ER33-18080		IIb
EFI/ER33-18100		IIb
EFI/ER33-18120		IIb
EFI/ER33-18140		IIb
EFI/ER33-18150		IIb
EFI/ER33-18160		IIb
EFI/ER32-20060	Anti-refluent Self-expandable esophagus stent made of Nitinol, tulip type ends, half covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ER32-20080		IIb
EFI/ER32-20100		IIb
EFI/ER32-20120		IIb
EFI/ER32-20140		IIb
EFI/ER32-20150		IIb
EFI/ER32-20160		IIb
EFI/ER33-20060	Anti-refluent Self-expandable esophagus stent made of Nitinol, tulip type ends, full covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ER33-20080		IIb
EFI/ER33-20100		IIb
EFI/ER33-20120		IIb
EFI/ER33-20140		IIb
EFI/ER33-20150		IIb
EFI/ER33-20160		IIb
EFI/ER32-24060	Anti-refluent Self-expandable esophagus stent made of Nitinol, tulip type ends, half covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ER32-24080		IIb
EFI/ER32-24100		IIb
EFI/ER32-24120		IIb
EFI/ER32-24140		IIb
EFI/ER32-24150		IIb
EFI/ER32-24160		IIb

Elektrotechnický zkušební ústav, s.p.
Pod Lisem 129, 171 02 Praha 8 - Troja
1

EFI/ER33-24060	Anti-refluent Self-expandable esophagus stent made of Nitinol, tulip type ends, full covered; Delivery system diameter 24F in 700mm long	IIb
EFI/ER33-24080		IIb
EFI/ER33-24100		IIb
EFI/ER33-24120		IIb
EFI/ER33-24140		IIb
EFI/ER33-24150		IIb
EFI/ER33-24160		IIb

Elektrotechnický zkušební ústav, s.p.
Pod Lisem 129, 171 02 Praha 8 - Troja
1

Biliary stent		
EFI/BP11-08040	PTCD Self-expandable biliary stent made of Nitinol, vertical cylinder structure, non covered;Delivery system diameter 8F in 500mm long	IIb
EFI/BP11-08060		IIb
EFI/BP11-08080		IIb
EFI/BP11-08100		IIb
EFI/BP11-10040	PTCD Self-expandable biliary stent made of Nitinol, vertical cylinder structure, non covered;Delivery system diameter 8F in 500mm long	IIb
EFI/BP11-10060		IIb
EFI/BP11-10080		IIb
EFI/BP11-10100		IIb
EFI/BP13-08040	PTCD Self-expandable biliary stent made of Nitinol, vertical cylinder structure, full covered;Delivery system diameter 8F in 500mm long	IIb
EFI/BP13-08060		IIb
EFI/BP13-08080		IIb
EFI/BP13-08100		IIb
EFI/BP13-10040	PTCD Self-expandable biliary stent made of Nitinol, vertical cylinder structure, full covered;Delivery system diameter 8F in 500mm long	IIb
EFI/BP13-10060		IIb
EFI/BP13-10080		IIb
EFI/BP13-10100		IIb
EFI/BE11-08040	ERCP Self-expandable biliary stent made of Nitinol, vertical cylinder structure, non covered;Delivery system diameter 8F in 1850mm long	IIb
EFI/BE11-08060		IIb
EFI/BE11-08080		IIb
EFI/BE11-08100		IIb
EFI/BE11-10040	ERCP Self-expandable biliary stent made of Nitinol, vertical cylinder structure, non covered;Delivery system diameter 8F in 1850mm long	IIb
EFI/BE11-10060		IIb
EFI/BE11-10080		IIb
EFI/BE11-10100		IIb
EFI/BE13-08040	ERCP Self-expandable biliary stent made of Nitinol, vertical cylinder structure, full covered;Delivery system diameter 8F in 1850mm long	IIb
EFI/BE13-08060		IIb
EFI/BE13-08080		IIb
EFI/BE13-08100		IIb
EFI/BE13-10040	ERCP Self-expandable biliary stent made of Nitinol, vertical cylinder structure, full covered;Delivery system diameter 8F in 1850mm long	IIb
EFI/BE13-10060		IIb
EFI/BE13-10080		IIb
EFI/BE13-10100		IIb

Elektrotechnický zkušební ústav, s.p.
Pod Lisem 129, 171 02 Praha 8 - Troja
1

Attachement to Certificat No. : MED 130076 OBL

Duodenal TTS		
EFI/DS81-20060	Self-expandable duodenal stent made of Nitinol, distal and proximal end ball type shape, non covered.;Delivery system diameter 10F in 2300mm long	IIb
EFI/DS81-20080		IIb
EFI/DS81-20100		IIb
EFI/DS81-20120		IIb
EFI/DS81-22060	Self-expandable duodenal stent made of Nitinol, distal and proximal end ball type shape, non covered.;Delivery system diameter 10F in 2300mm long	IIb
EFI/DS81-22080		IIb
EFI/DS81-22100		IIb
EFI/DS81-22120		IIb
Colon TTS		
EFI/CS81-25060	Self-expandable colonic stent made of Nitinol, distal and proximal end ball type shape, non covered.;Delivery system diameter 10F in 2300mm long	IIb
EFI/CS81-25080		IIb
EFI/CS81-25100		IIb
EFI/CS81-25120		IIb
EFI/CS81-28060	Self-expandable colonic stent made of Nitinol, distal and proximal end ball type shape, non covered.;Delivery system diameter 10F in 2300mm long	IIb
EFI/CS81-28080		IIb
EFI/CS81-28100		IIb
EFI/CS81-28120		IIb
Rectal Stent		
EFI/RS81-30060	Self-expandable Rectal stent made of Nitinol, distal and proximal end ball type shape, non covered.;Delivery system diameter 24F in 700mm long	IIb
EFI/RS81-30080		IIb
EFI/RS81-30100		IIb
EFI/RS81-30120		IIb

Elektrotechnický zkušební ústav, s.p.
Pod Lisem 129, 171 02 Praha 8 - Troja
1

Tracheo-Bronchial		
EFI/TB11-12020	Self-expandable tracheal / bronchial stents made of Nitinol, vertical cylinder structure, non covered;Delivery system diameter 18F in 600mm long	IIb
EFI/TB11-12030		IIb
EFI/TB11-12040		IIb
EFI/TB11-14020		IIb
EFI/TB11-14030		IIb
EFI/TB11-14040		IIb
EFI/TB11-16040		IIb
EFI/TB11-16050		IIb
EFI/TB11-16060		IIb
EFI/TB11-18040		IIb
EFI/TB11-18050		IIb
EFI/TB11-18060		IIb
EFI/TB11-20040		IIb
EFI/TB11-20050		IIb
EFI/TB11-20060		IIb
EFI/TB11-22040		IIb
EFI/TB11-22050		IIb
EFI/TB11-22060		IIb
EFI/TB71-16040	Self-expandable tracheal / bronchial stents made of Nitinol, Y shape structure, non covered;Delivery system diameter 24F in 600mm long	IIb
EFI/TB71-16050		IIb
EFI/TB71-16060		IIb
EFI/TB71-18040		IIb
EFI/TB71-18050		IIb
EFI/TB71-18060		IIb
EFI/TB71-20040		IIb
EFI/TB71-20050		IIb
EFI/TB71-20060		IIb
EFI/TB73-16040	Self-expandable tracheal / bronchial stents made of Nitinol, Y shape structure, covered;Delivery system diameter 24F in 600mm long	IIb
EFI/TB73-16050		IIb
EFI/TB73-16060		IIb
EFI/TB73-18040		IIb
EFI/TB73-18050		IIb
EFI/TB73-18060		IIb
EFI/TB73-20040		IIb
EFI/TB73-20050		IIb
EFI/TB73-20060		IIb

Elektrotechnický zkušební ústav, s.p.
Pod Lisem 129, 171 02 Praha 8 - Troja
1

EC Certificate

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

Registration No.: HD 60096796 0001

Report No.: 15073963 001

Manufacturer:
Changzhou Jiuhong
Medical Instrument Co., Ltd.
No. 256 Mingxin Middle Road
Wujin District
Changzhou
213164 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60080302 0001

Expiry Date: 2019-10-20

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: 2014-10-21

Date: 2014-10-21

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Ren
Zertifizierungsstelle

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 60096796 0001
Report No.: 15073963 001

Manufacturer:
Changzhou Jiuhong
Medical Instrument Co., Ltd.
No. 256 Mingxin Middle Road
Wujin District
Changzhou
213164 Jiangsu
China

Products:

Disposable Endoscopic Hemoclips, Disposable Polyp Snares, Disposable Electric Biopsy Forceps, Disposable Non-electric Biopsy Forceps, Disposable Cytology Brushes, Gastrointestinal and Biliary Balloon Catheters, Grasping Forceps, Non-vascular Guidewires, Stone Extraction Balloons, Stone Extraction Baskets, Kyphoplasty Balloon Catheters, Multiple Band Ligators, Injection Needles, Balloon Kyphoplasty Kits;

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

Disposable Bite Blocks, Cleaning Brushes for Endoscope, Bougie Dilator Sets, Balloon Inflators, Biopsy Valves, Polyp Traps

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

X. Ren

Date: 2014-10-21

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 336/2004 Coll. (Annex V of Directive 93/42/EEC)

No.: MED 150072 OBL

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **Nova LightSystems**
Les Danjauds la Ferme de Verdolette, 13610 Le Puy Sainte-Réparade, France

for manufacturing and final inspection of medical device(s)

Sterile ERCP field with pockets, Class I sterile
See annex

meets the provisions of Annex 5 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex V of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. 500376-01/01 of: 30.04.2015.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 336/2004 Coll. (Annex V clause 4 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate was issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

This certificate can be used for class IIb and III medical devices together with EC Type-Examination Certificate only, issued in accordance with Annex 3 of Government Order 336/2004 Coll. (Annex III of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from with validity until
The validity of this Certificate is limited until: 18.1.2018

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja

5.5.2015

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 1 5 0 0 7 2 0 B L *

500376-01

Description	Reference
ERCP field with pockets – Class 1 sterile	
ERCP field with 3 pockets - Small	NLS/SF3-S
ERCP field with 3 pockets - Medium	NLS/SF3-M
ERCP field with 3 pockets - Large	NLS/SF3-L
ERCP field with 4 pockets - Small	NLS/SF4-S
ERCP field with 4 pockets - Medium	NLS/SF4-M
ERCP field with 4 pockets - Large	NLS/SF4-L

elektrotechnický zkušební ústav
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-1-
Pod Lisem 129, 171 02 Praha 8-Troja

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 336/2004 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 140041 OBL

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **NOVA LIGHTSYSTEMS**
Les Danjauds la Ferme de Verdolette 13610 Le Puy Sainte-Réparade, France

for design, manufacturing and final inspection of medical device(s)

Steril accessories for endoscopic use such as:
- **Stone Extraction Basket – Class IIa,**
- **Easy Way Guide wire– Class IIa,**
- **Stone Retrieval Balloon– Class IIa,**
- **Hemoclip– Class IIb**

See Annex

meets the provisions of Annex 2 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 4 of Government Order No. 336/2004 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **400818-01 of: 18.02.2014**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 5 of Government Order No. 336/2004 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 4 of Government Order 336/2004 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from with validity until
The validity of this Certificate is limited until: 18.3.2018

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja

2.7.2014 corrigendum 17.12.2014

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 1 4 0 0 4 1 0 B L *

400818-01

Description	References Nova LightSystems
Stone extraction basket - Class IIa	
S.E. Basket - Nitinol Common	NLS/BK-10-18-195
S.E. Basket - Nitinol Common	NLS/BK-20-18-195
S.E. Basket - Nitinol Common	NLS/BK-25-18-195
S.E. Basket - Nitinol Common	NLS/BK-30-18-195
S.E. Basket - Nitinol Common	NLS/BK-20-24-195
S.E. Basket - Nitinol Common	NLS/BK-25-24-195
S.E. Basket - Nitinol Common	NLS/BK-30-24-195
S.E. Basket - Nitinol Common - Guide wire	**NLS/BK-20-24-195G**
S.E. Basket - Nitinol Common - Guide wire	NLS/BK-25-24-195G
S.E. Basket - Nitinol Common - Guide wire	**NLS/BK-30-24-195G**
S.E. Basket - Nitinol Spirale	NLS/BKS-10-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS-20-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS-25-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS-30-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS-20-24-195
S.E. Basket - Nitinol Spirale	NLS/BKS-25-24-195
S.E. Basket - Nitinol Spirale	NLS/BKS-30-24-195
S.E. Basket - Nitinol Spirale - Guide wire	NLS/BKS-20-24-195G
S.E. Basket - Nitinol Spirale - Guide wire	NLS/BKS-25-24-195G
S.E. Basket - Nitinol Spirale - Guide wire	NLS/BKS-30-24-195G
S.E. Basket - Nitinol Spirale	NLS/BKS8-10-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS8-20-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS8-25-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS8-30-18-195
S.E. Basket - Nitinol Spirale	NLS/BKS8-20-24-195
S.E. Basket - Nitinol Spirale	NLS/BKS8-25-24-195
S.E. Basket - Nitinol Spirale	NLS/BKS8-30-24-195
S.E. Basket - Nitinol Spirale - Guide wire	NLS/BKS8-20-24-195G
S.E. Basket - Nitinol Spirale - Guide wire	NLS/BKS8-25-24-195G
S.E. Basket - Nitinol Spirale - Guide wire	NLS/BKS8-30-24-195G
S.E. Basket - Stainless steel	NLS/BKA-10-24-195
S.E. Basket - Stainless steel	NLS/BKA-25-24-195
S.E. Basket - Stainless steel	NLS/BKA-30-24-195
S.E. Basket - Stainless steel - Guide wire	NLS/BKA-20-28-195G
S.E. Basket - Stainless steel - Guide wire	NLS/BKA-25-28-195G
S.E. Basket - Stainless steel - Guide wire	NLS/BKA-30-28-195G
S.E. Basket - Stainless steel	NLS/BKA8-20-24-195
S.E. Basket - Stainless steel	NLS/BKA8-25-24-195
S.E. Basket - Stainless steel	NLS/BKA8-30-24-195
S.E. Basket - Stainless steel - Guide wire	NLS/BKA8-20-24-195G
S.E. Basket - Stainless steel - Guide wire	NLS/BKA8-25-24-195G
S.E. Basket - Stainless steel - Guide wire	NLS/BKA8-30-24-195G

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129 171 02 Praha 8 - Troja

17.12.2014

Easy Way Guide Wire - Class IIa	
Guide wire Straight	NLS/GWS-18-200
Guide wire Straight	NLS/GWS-18-260
Guide wire Straight	NLS/GWS-18-360
Guide wire Straight	NLS/GWS-18-450
Guide wire Straight	NLS/GWS-21-200
Guide wire Straight	NLS/GWS-21-260
Guide wire Straight	NLS/GWS-21-360
Guide wire Straight	NLS/GWS-21-450
Guide wire Straight	NLS/GWS-21-500
Guide wire Straight	NLS/GWS-25-200
Guide wire Straight	**NLS/GWS-25-260**
Guide wire Straight	NLS/GWS-25-360
Guide wire Straight	**NLS/GWS-25-450**
Guide wire Straight	NLS/GWS-25-500
Guide wire Straight	NLS/GWS-35-200
Guide wire Straight	**NLS/GWS-35-260**
Guide wire Straight	NLS/GWS-35-360
Guide wire Straight	**NLS/GWS-35-450**
Guide wire Straight	NLS/GWS-35-500
Guide wire Straight	NLS/GWS-38-200
Guide wire Straight	NLS/GWS-38-260
Guide wire Straight	NLS/GWS-38-360
Guide wire Straight	NLS/GWS-38-450
Guide wire Straight	NLS/GWS-38-500
Guide wire Angled	NLS/GWA-18-200
Guide wire Angled	NLS/GWA-18-260
Guide wire Angled	NLS/GWA-18-360
Guide wire Angled	NLS/GWA-18-450
Guide wire Angled	NLS/GWA-21-200
Guide wire Angled	NLS/GWA-21-260
Guide wire Angled	NLS/GWA-21-360
Guide wire Angled	NLS/GWA-21-450
Guide wire Angled	NLS/GWA-21-500
Guide wire Angled	NLS/GWA-25-200
Guide wire Angled	NLS/GWA-25-260
Guide wire Angled	NLS/GWA-25-360
Guide wire Angled	NLS/GWA-25-450
Guide wire Angled	NLS/GWA-25-500
Guide wire Angled	NLS/GWA-35-200
Guide wire Angled	**NLS/GWA-35-260**
Guide wire Angled	NLS/GWA-35-360
Guide wire Angled	**NLS/GWA-35-450**
Guide wire Angled	NLS/GWA-35-500
Guide wire Angled	NLS/GWA-38-200
Guide wire Angled	NLS/GWA-38-260
Guide wire Angled	NLS/GWA-38-360
Guide wire Angled	NLS/GWA-38-450
Guide wire Angled	NLS/GWA-38-500

17.12.2014

Guide wire Straight & Stiff	NLS/GWSS-18-260
Guide wire Straight & Stiff	NLS/GWSS-18-450
Guide wire Straight & Stiff	NLS/GWSS-25-200
Guide wire Straight & Stiff	NLS/GWSS-25-260
Guide wire Straight & Stiff	NLS/GWSS-25-360
Guide wire Straight & Stiff	NLS/GWSS-25-450
Guide wire Straight & Stiff	NLS/GWSS-35-200
Guide wire Straight & Stiff	NLS/GWSS-35-260
Guide wire Straight & Stiff	NLS/GWSS-35-360
Guide wire Straight & Stiff	NLS/GWSS-35-450
Guide wire Straight & Stiff	NLS/GWSS-35-500
Guide wire Straight & Stiff	NLS/GWSS-38-200
Guide wire Straight & Stiff	NLS/GWSS-38-260
Guide wire Straight & Stiff	NLS/GWSS-38-360
Guide wire Straight & Stiff	NLS/GWSS-38-450
Guide wire Straight & Stiff	NLS/GWSS-38-500
Guide wire Angle & Stiff	NLS/GWAS-18-260
Guide wire Angle & Stiff	NLS/GWAS-18-450
Guide wire Angle & Stiff	NLS/GWAS-25-200
Guide wire Angle & Stiff	NLS/GWAS-25-260
Guide wire Angle & Stiff	NLS/GWAS-25-360
Guide wire Angle & Stiff	NLS/GWAS-25-450
Guide wire Angle & Stiff	NLS/GWAS-35-200
Guide wire Angle & Stiff	NLS/GWAS-35-260
Guide wire Angle & Stiff	NLS/GWAS-35-360
Guide wire Angle & Stiff	NLS/GWAS-35-450
Guide wire Angle & Stiff	NLS/GWAS-35-500
Guide wire Angle & Stiff	NLS/GWAS-38-200
Guide wire Angle & Stiff	NLS/GWAS-38-260
Guide wire Angle & Stiff	NLS/GWAS-38-360
Guide wire Angle & Stiff	NLS/GWAS-38-450
Guide wire Angle & Stiff	NLS/GWAS-38-500
Guide wire Double tip	NLS/GWD-18-260
Guide wire Double tip	NLS/GWD-18-450
Guide wire Double tip	NLS/GWD-25-200
Guide wire Double tip	NLS/GWD-25-260
Guide wire Double tip	NLS/GWD-25-360
Guide wire Double tip	NLS/GWD-25-450
Guide wire Double tip	NLS/GWD-35-200
Guide wire Double tip	NLS/GWD-35-260
Guide wire Double tip	NLS/GWD-35-360
Guide wire Double tip	NLS/GWD-35-450
Guide wire Double tip	NLS/GWD-35-500

17.12.2014

elektrotechnický zkušební ústav ezú -1- PNT Liseň 122, 171 02 Praha 8 - Troja

Guide wire Double tip	NLS/GWD-38-200
Guide wire Double tip	NLS/GWD-38-260
Guide wire Double tip	NLS/GWD-38-360
Guide wire Double tip	NLS/GWD-38-450
Guide wire Double tip	NLS/GWD-38-500
Guide wire Double Tip & Stiff	NLS/GWDS-18-260
Guide wire Double Tip & Stiff	NLS/GWDS-18-450
Guide wire Double Tip & Stiff	NLS/GWDS-25-200
Guide wire Double Tip & Stiff	NLS/GWDS-25-260
Guide wire Double Tip & Stiff	NLS/GWDS-25-360
Guide wire Double Tip & Stiff	NLS/GWDS-25-450
Guide wire Double Tip & Stiff	NLS/GWDS-35-200
Guide wire Double Tip & Stiff	NLS/GWDS-35-260
Guide wire Double Tip & Stiff	NLS/GWDS-35-360
Guide wire Double Tip & Stiff	NLS/GWDS-35-450
Guide wire Double Tip & Stiff	NLS/GWDS-35-500
Guide wire Double Tip & Stiff	NLS/GWDS-38-200
Guide wire Double Tip & Stiff	NLS/GWDS-38-260
Guide wire Double Tip & Stiff	NLS/GWDS-38-360
Guide wire Double Tip & Stiff	NLS/GWDS-38-450
Guide wire Double Tip & Stiff	NLS/GWDS-38-500
Hemoclip - Class IIb	
Hemoclip 90°	NLS/HC-90-26-165
Hemoclip 90°	NLS/HC-90-26-195
Hemoclip 90°	NLS/HC-90-26-230
Hemoclip 90°	NLS/HC-90-26-270
Hemoclip 135°	NLS/HC-26-165
Hemoclip 135°	NLS/HC-26-195
Hemoclip 135°	**NLS/HC-26-230**
Hemoclip 135°	NLS/HC-26-270
Hemoclip 90°	NLS/HC-S90-26-165
Hemoclip 90°	NLS/HC-S90-26-195
Hemoclip 90°	NLS/HC-S90-26-230
Hemoclip 90°	NLS/HC-S90-26-270
Hemoclip 135°	NLS/HC-S-26-165
Hemoclip 135°	NLS/HC-S-26-195
Hemoclip 135°	NLS/HC-S-26-230
Hemoclip 135°	NLS/HC-S-26-270

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja

17.12.2014

Stone Retrieval Balloon - Class IIa	
S.E. balloon - 3 Lumen	NLS/BLT-85-23-200
S.E. balloon - 3 Lumen	NLS/BLT-12-23-200
S.E. balloon - 3 Lumen	NLS/BLT-15-23-200
S.E. balloon - 3 Lumen	NLS/BLT-18-23-200
S.E. balloon - 3 Lumen - 3 diameters	NLS/BLT-S-23-200
S.E. balloon - 3 Lumen - 3 diameters	NLS/BLT-L-23-200
S.E. balloon - 3 Lumen	NLS/BLT-85-20-200
S.E. balloon - 3 Lumen	NLS/BLT-12-20-200
S.E. balloon - 3 Lumen	NLS/BLT-15-20-200
S.E. balloon - 3 Lumen	NLS/BLT-18-20-200
S.E. balloon - 3 Lumen - 3 diameters	NLS/BLT-S-20-200
S.E. balloon - 3 Lumen - 3 diameters	NLS/BLT-L-20-200
S.E. balloon - 2 Lumen	NLS/BLD-85-23-200
S.E. balloon - 2 Lumen	NLS/BLD-12-23-200
S.E. balloon - 2 Lumen	NLS/BLD-15-23-200
S.E. balloon - 2 Lumen	NLS/BLD-18-23-200
S.E. balloon - 2 Lumen - 3 diameters	NLS/BLD-S-23-200
S.E. balloon - 2 Lumen - 3 diameters	NLS/BLD-L-23-200
S.E. balloon - 2 Lumen	NLS/BLD-85-20-200
S.E. balloon - 2 Lumen	NLS/BLD-12-20-200
S.E. balloon - 2 Lumen	NLS/BLD-15-20-200
S.E. balloon - 2 Lumen	NLS/BLD-18-20-200
S.E. balloon - 2 Lumen - 3 diameters	NLS/BLD-S-20-200
S.E. balloon - 2 Lumen - 3 diameters	NLS/BLD-L-20-200
S.E. balloon - 2 Lumen	NLS/BLD-85-17-200
S.E. balloon - 2 Lumen	NLS/BLD-12-17-200
S.E. balloon - 2 Lumen	NLS/BLD-15-17-200
S.E. balloon - 2 Lumen	NLS/BLD-18-17-200
S.E. balloon - 2 Lumen - 3 diameters	NLS/BLD-S-17-200
S.E. balloon - 2 Lumen - 3 diameters	NLS/BLD-L-17-200
S.E. balloon - Rapide Exchange	NLS/BL-85-23-200
S.E. balloon - Rapide Exchange	NLS/BL-12-23-200
S.E. balloon - Rapide Exchange	NLS/BL-15-23-200
S.E. balloon - Rapide Exchange	NLS/BL-18-23-200
S.E. balloon - Rapide Exchange - 3 diameters	**NLS/BL-S-23-200**
S.E. balloon - Rapide Exchange - 3 diameters	**NLS/BL-L-23-200**
S.E. balloon - Rapide Exchange	NLS/BL-85-20-200
S.E. balloon - Rapide Exchange	NLS/BL-12-20-200
S.E. balloon - Rapide Exchange	NLS/BL-15-20-200
S.E. balloon - Rapide Exchange	NLS/BL-18-20-200
S.E. balloon - Rapide Exchange - 3 diameters	NLS/BL-S-20-200
S.E. balloon - Rapide Exchange - 3 diameters	NLS/BL-L-20-200

elektrotechnický zkušební ústav ezú -1- Prosecká 129, 171 02 Praha 8 - Troja

17.12.2014

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 150073 OBL

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **Nova LightSystems**
Les Danjauds la Ferme de Verdolette, 13610 Le Puy Sainte-Réparade, France

for design, manufacturing and final inspection of medical device(s)

- Hemoclips
- Hot Biopsy Forceps
Class IIb - Sterile
See annex

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **500376-02/01 of: 30.04.2015**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from with validity until
The validity of this Certificate is limited until: 20.10.2019

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja

5.5.2015

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

CER/MED150073OBL

500376-02

Description	Reference
Hot biopsy forceps – Class IIb sterile	
w/o spike, w/o alligator teeth	CJ-PC–23-230
w/o spike, w/o alligator teeth	CJ-PC–23-160
w/o spike, w/o alligator teeth	CJ-PC–18-160
w/o spike, w/o alligator teeth	CJ-PC–18-110
w/o spike, alligator teeth	CJ-PCC–23-230
w/o spike, alligator teeth	CJ-PCC–23-160
w/o spike, alligator teeth	CJ-PCC–18-160
w/o spike, alligator teeth	CJ-PCC–18-110
spike, w/o alligator teeth	CJ-PCA–23-230
spike, w/o alligator teeth	CJ-PCA–23-160
spike, w/o alligator teeth	CJ-PCA–18-160
spike, w/o alligator teeth	CJ-PCA–18-110
spike, alligator teeth	CJ-PCCA–23-230
spike, alligator teeth	CJ-PCCA–23-160
spike, alligator teeth	CJ-PCCA–18-160
spike, alligator teeth	CJ-PCCA–18-110

Description	Reference
Hemoclip – Class IIb sterile	
Hemoclip 09 mm	CJ-HC09-25-110
Hemoclip 09 mm	CJ-HC09-25-160
Hemoclip 09 mm	CJ-HC09-25-230
Hemoclip 11 mm	CJ-HC11-25-110
Hemoclip 11 mm	CJ-HC11-25-160
Hemoclip 11 mm	CJ-HC11-25-230
Hemoclip 13 mm	CJ-HC13-25-110
Hemoclip 13 mm	CJ-HC13-25-160
Hemoclip 13 mm	CJ-HC13-25-230

elektrotechnický zkušební ústav ezú Pod Lisem 129, 171 02 Praha 8-Troja -1-

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 336/2004 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 140042 OBL

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **SARL NOVA LIGHTSYSTEMS**
LA FERME DE VERDOLETTE LES DANJAUDS, 13610 LE PUY SAINTE-REPARADE, FRANCE

for design, manufacturing and final inspection of medical device(s)

Steril accessories for endoscopic use such as:
- **Polypectomy Snare-Class IIb**
- **Biopsy Forceps-Class IIa**
- **Dilation Balloon-Class IIa**

See annex

meets the provisions of Annex 2 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 4 of Government Order No. 336/2004 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **405205-01 of: 21.11.2014**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 5 of Government Order No. 336/2004 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 4 of Government Order 336/2004 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 2

The first issue of this Certificate from 2.7.2014 with validity until 3.11.2014
The validity of this Certificate is limited until: 20.10.2019

25.11.2014

Prague

Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja

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CER/MED140042OBL

405205-01

Description	Référence Nova Light Systems
POLYPECTOMY SNARES - Class IIb	
Oval Snare	CJ-ADR-23-230-O10
Oval Snare	CJ-ADR-23-230-O15
Oval Snare	CJ-ADR-23-230-O25
Oval Snare	CJ-ADR-23-230-O30
Oval Snare	CJ-ADR-23-230-O35
Hexagonal Snare	CJ-ADR-23-230-H25
Hexagonal Snare	CJ-ADR-23-230-H30
Hexagonal Snare	CJ-ADR-23-230-H35
Crescent Snare	CJ-ADR-23-230-C15
Crescent Snare	CJ-ADR-23-230-C25
Enteroscopic snares	CJ-ADR-23-300-O25
Enteroscopic snares	CJ-ADR-23-300-O30
Enteroscopic snares	CJ-ADR-23-300-O35
POLYPECTOMY SNARES - Class IIb	
Oval Snare - Rotative	CJ-ADR2-23-230-O10
Oval Snare - Rotative	CJ-ADR2-23-230-O15
Oval Snare - Rotative	CJ-ADR2-23-230-O25
Oval Snare - Rotative	CJ-ADR2-23-230-O30
Oval Snare - Rotative	CJ-ADR2-23-230-O35
Hexagonal Snare - Rotative	CJ-ADR2-23-230-H25
Hexagonal Snare - Rotative	CJ-ADR2-23-230-H30
Hexagonal Snare - Rotative	CJ-ADR2-23-230-H35
Crescent Snare - Rotative	CJ-ADR2-23-230-C15
Crescent Snare - Rotative	CJ-ADR2-23-230-C25
Enteroscopic snares - Rotative	CJ-ADR2-23-300-O25
Enteroscopic snares - Rotative	CJ-ADR2-23-300-O30
Enteroscopic snares - Rotative	CJ-ADR2-23-300-O35
BIOPSY FORCEPS - Class IIa	
Trachéo-bronchial / Smooth	CJ-PPT-18-110
Trachéo-bronchial / Notch /	CJ-PPTC-18-110
Trachéo-bronchial / Smooth / With needle	CJ-PPT-18-110-A
Paediatric / Smooth /	CJ-PPT-18-160
Adult Standard / Smooth /	CJ-PAT-23-160
Adult Standard / Smooth / With needle	CJ-PAT-23-160-A
Adult Standard / Notch /	CJ-PATC-23-160
Adult Standard / Notch / With needle	CJ-PATC-23-160-A
Adult Standard / Smooth /	CJ-PAT-23-230
Adult Standard / Smooth / With needle	CJ-PAT-23-230-A
Adult Standard / Notch /	CJ-PATC-23-230
Adult Standard / Notch / With needle	CJ-PATC-23-230-A

Dilation Balloon - Class IIa	
Dilation Balloon	CJ-JHY-BD-06-40-250
Dilation Balloon	CJ-JHY-BD-08-40-250
Dilation Balloon	CJ-JHY-BD-10-40-250
Dilation Balloon	CJ-JHY-BD-12-60-250
Dilation Balloon	CJ-JHY-BD-14-60-250
Dilation Balloon	CJ-JHY-BD-18-80-250
Dilation Balloon	CJ-JHY-BD-20-80-250
Achalasia balloon	CJ-JHY-BD-30-80-90
Achalasia balloon	CJ-JHY-BD-35-80-90

25.11.2014

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ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 336/2004 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 150028

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **Nova LightSystem**
Les Danjauds la Ferme de Verdolette, 13610 Le Puy Sainte-Réparade, France

for design, manufacturing and final inspection of medical device(s)

Intragastric balloon and reinflation set, medical device for endoscopic use, class IIb, see enclosure

meets the provisions of Annex 2 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 4 of Government Order No. 336/2004 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **402003-01 of: 17.06.2014**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 5 of Government Order No. 336/2004 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 4 of Government Order 336/2004 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from with validity until
The validity of this Certificate is limited until: 5.3.2020

6.3.2015

Prague

Miroslav Sedláček
Head of Certification Body

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* C E R / M E D 1 5 0 0 2 8 *

Description	Référence Nova LightSystems
Medical device class IIb	
Intragastric balloon Intragastric balloon for treating obesity	**NLS/ELB-800**
Reinflation set Set of accessories for adjusting the volume of the balloon	**NLS/ELB-KITREG**

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ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 336/2004 Coll. (Annex V of Directive 93/42/EEC)

No.: MED 140039 OBL

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried audit results has decided that the quality system limited to the manufacturing aspects relevant to securing and maintaining sterile conditions established at the

manufacturer **Nova LightSystems**
Les Danjauds la Ferme de Verdolette 13610 Le Puy Sainte-Réparade, France

for medical device(s)

Steril accessory for endoscopic use such as:
• Inflation Device-Class I sterile
See Annex

meets the provisions of Annex 5 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex V of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. 405702-01 of: 18.12.2014.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 336/2004 Coll. (Annex V clause 4 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

Edition 2

The first issue of this Certificate from 23.6.2014 with validity until 27.10.2014
The validity of this Certificate is limited until: 13.8.2019

elektrotechnický zkušební ústav ezú Pod Lisem 129, 171 02 Praha 8 - Troja -1-

6.1.2015

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 1 4 0 0 3 9 0 B L *

405702-01

Inflation Device - Class I Stérile

Description	Reference Nova LightSystems
Inflation device 30ml	NLS/ID30I
Inflation device 30ml	**NLS/ID30X**
Inflation device 40ml	NLS/ID40I
Inflation device 40ml	NLS/ID40X

6.1.2015

elektrotechnický zkušební ústav
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Pod Lisinou 129, 171 02 Praha 8 - Troja

Déclaration de conformité CE
CE Declaration of conformity

La société :
The company :

Nova LightSystems
Les Danjauds la Ferme de Verdolette
13610 Le Puy Sainte-Réparade, France

Déclare que les Dispositifs Médicaux mentionnés ci-dessous
Hereby certifies that the medical device described below

Désignation et Description Descriptive summary	**Références** References	**Classe** Product Class
Ballon d'écho-endoscopie / Echo-endoscopic balloon	**NLS/84420**	I
Ballon d'écho-endoscopie / Echo-endoscopic balloon	**NLS/84460**	I
Ballon d'écho-endoscopie / Echo-endoscopic balloon	**NLS/84465**	I
Ballon d'écho-endoscopie / Echo-endoscopic balloon	**NLS/86642**	I
Ballon d'écho-endoscopie / Echo-endoscopic balloon	**NLS/84425**	I
O-ring	**NLS/3381635**	I

Sont conformes aux articles de la Directive 93/42/CE du 14 juin 1993 modifiée par la Directive 2007/47/CE du 5 septembre 2007 et au livre V bis du code de la santé publique (article R 665-1 et suivants, quand ils s'appliquent).

Complies with Directive 93/42 CE dated June, 14th 1993 modified by the Directive 2007/47 CE dated September, 5th 2007 and book No. Vbis from the public health code (article R 665-1 et al., if applicable).

Lieu / Place : Le Puy Sainte-Réparade

Date */ Date*: 24/09/2015

Nom du Dirigeant / Name : Margarita Pedrolo

NOVA LIGHTSYSTEMS
432 chemin des Danjauds
13610 - LE PUY SAINTE REPARADE
RCS AIX EN PROVENCE - 521347120