Certificate

mdc medical device certification GmbH
certifies that

Medi-Globe GmbH
Medi-Globe Straße 1-5
83101 Achenmühle
Germany

for the scope

design and development, production, storage and distribution of products for endoscopy, pneumology, urology, internal medicine, surgery and ENT

with the location and the scope

Südring 21
46342 Velen-Ramsdorf

storage and distribution of products for endoscopy, pneumology, urology, internal medicine, surgery and ENT

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2017-06-28
Valid until	2020-06-22
Registration no.	D1314600016
Report no.	P17-00553-95670
Stuttgart	2017-06-28

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-25359740
Fax: +49-(0)711-25359749
Internet: http://www.mdc-ce.de

ENDO-FLEX®
A MEDI-GLOBE COMPANY

Konformitätserklärung
Declaration of Conformity

Wir
We

Name und Adresse des Herstellers:
Name and address of manufacturer:

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

erklären in alleiniger Verantwortung, dass das Medizinprodukt
declare on our own responsibility that the medical device

Name / Produktgruppe:
Name/ Name group:

Polypektomie-Schlingen, Mukosektomie-Schlingen SU/RU[1]
Polypectomy Snares, Mucosectomy Snares SU/RU

Klasse:
Class:

IIb

Artikelnummer:
Article number :

SU:

NOE3222-G	NOE342214M-G	NOE372214-G
NOE3322-G	NOE342216-C	NOE372216-G
NOE341816-C	NOE342216-G	NOE372217-G
NOE342212M-G	NOE342216M-C	OE3322-G
NOE342213-G	NOE342216M-G	OE342214M-G
NOE342213M-G	NOE342217-C	OE342215-G
NOE342214-C	NOE342217-G	OE342216-G
NOE342214-G	NOE342217-M	OE342217-C
NOE342214-M	NOE342217M-G	OE342217-G
NOE342214M-C		OE342246-G

RU:

3222-G	D342206-G	OK342215-G
3322-G	D342207-C	OK342215M-G
341815-G	D342207-G	OK342216-C
341815M-G	D342215-G	OK342216-G
342214-G	D342216-G	OK342216M-G
342215-G	D342217-G	OK342217-C
342216-G	OK3122-G	OK342217-G
342217-G	OK3222-G	OK342237-G
D3022-G	OK3322-G	OK342267-G
D3222-G	OK342205-G	OK372206-G
D3322-G	OK342206-G	OK372207-G
D342205-G	OK342207-G	OK6522601-G

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG Anhang I entspricht.
meets all applicable requirements of the Directive 93/42/EEC Annex I.

[1] SU: Single use / RU: Reusable

ENDO-FLEX®
A MEDI-GLOBE COMPANY

Konformitätserklärung
Declaration of Conformity

Benannte Stelle: *Notified body:*	mdc medical device certification GmbH Kriegerstraße 6 70191 Stuttgart Germany 0483
Konformitätsbewertungsverfahren: *Conformity assessment procedure:*	Richtlinie 93/42/EWG, Anhang II ohne (4) Directive 93/42/EEC, Annex II excluding (4)
Zertifikatsnummer : *Certificate No. :*	D1033500039
Erstmalige CE-Kennzeichnung: *first CE mark:*	1997
Gültig bis: *Valid until:*	23.01.2023

Voerde 09.01.2020
ENDO-FLEX GmbH

Jens Kühnemund
Sicherheitsbeauftragter
Safety Representative

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11
78532 Tuttlingen
Germany

for the scope

instruments for high frequency surgery,
endoscopic instruments and devices with accessories,
suction- and irrigation units, battery operated units
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2021-05-20
Valid until	2023-07-04
Registration no.	D1043500083
Report no.	P21-00826-205644
Stuttgart	2021-05-20

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1043500083 Date 2021-05-20 Page 1 of 1

Product category	Product	Class	Product code
Instruments for high frequency surgery	Electrosurgical units with accessories	IIb	11-490
	HF-handles	IIb	11-499
	Bipolar coagulation forceps Bipolar forceps	IIb	11-502
	Monoplar and bipolar electrodes Coagulation electrodes, coagulation grippers, scissors	IIb	16-206
	Electrodes, electrosurgical, sterile and non sterile Bipolar coagulation forceps EVO II Bipolar clamps and scissors-clamps Monopolar laparoscopic electrodes	IIb	16-860
	Pistol handle, with HF	IIa	15-206
Endoscopic instruments and devices with accessories	Pistol handle, without HF	IIa	15-206
	Laparoscopic instruments for electrosurgery	IIb	11-502
	Resectoscopes monoplar and bipolar	IIb	13-335
	Insufflators, laparoscopy with accessories	IIb	16-849
	Arthroscopic shaver systems with accessories	IIa	17-918
Suction- and irrigation units	Suction- /irrigation unit MULTI PUMP and accessories Pump for arthroscopy ART PUMP II and accessories Pump for arthroscopy ART PUMP II D and accessories Pump for hysteroscopy HYS PUMP II and accessories Pump for urology URO PUMP II and accessories	IIa	17-424
Battery operated units	Drill, battery operated and accessories Saw, battery operated and accessories	IIa	16-868

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

Endoscopic instruments, HF-instruments and accessories,
Needle systems and Drainage systems
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

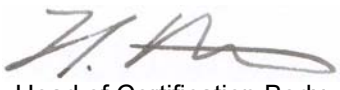
The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2019-11-19
Valid until	2023-01-23
Registration no.	D1033500039
Report no.	P14-01606-30841
Stuttgart	2019-11-19



Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1033500039 Date 2019-11-19 Page 1 of 1

Product category	Product	Class
Drainage systems	Nasal Biliary Drainage Probes SU	IIa
	Biliary Stents SU	IIb
	Pancreatic Stents SU	IIb
	Self-expanding Stents SU (Biliary, Bronchial/Tracheal, Colonic, Duodenal, Esophageal)	IIb
Endoscopic instruments	Stone extraction Balloons SU	IIa
	Scissors RU	IIa
	Cytology Brushes SU	IIa
	Spray Catheters SU/RU	IIa
	Suture Punches RU	IIa
	Foreign Body Retrievers / Polyp Retrievers SU/RU	IIa
	Biopsy Forceps SU/RU	IIa
	Multi Band Ligation Device SU	IIa
	Clip applicator set SU	IIa
HF-instruments and accessories	Handles incl. HF connector RU	IIb
	Cysto Gastro Sets SU	IIb
	Sphincterotomes SU/RU	IIb
	Polypectomy Snares, Mukosectomy Snares SU/RU	IIb
	HOT Biopsy Forceps SU/RU	IIb
Needle systems	Fibrin Application Needles SU/RU	IIa
	FNA Systems for ultrasound endoscopy SU	IIa
	Transbronchial Aspiration Needles SU	IIa
	Injection Needles SU/RU	IIa

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11
78532 Tuttlingen
Germany

for the scope

development, manufacturing and distribution of surgical instruments and accessories, endoscopic instruments and devices with accessories, dental instruments, instruments and implants for osteosynthesis, OR-lamps, OR-tables and accessories and repair service for rigid endoscopes

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-07-05
Valid until	2024-07-04
Registration no.	D1043500084
Report no.	P21-00826-205639
Stuttgart	2021-06-23

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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

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.

Authorised by

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

UKAS MANAGEMENT SYSTEMS
0005

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

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

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