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	2019-01-04
Valid until	2023-01-23
Registration no.	D1033500036
Report no.	P18-01361-131197
Stuttgart	2019-01-04

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. D1033500036 Date 2019-01-04 Page 1 of 1

Product category	Product	Class
Drainage systems	Nasal Biliary Drainage Probes SU	IIa
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
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
Drainage systems	Biliary Stents SU	IIb
	Pancreatic Stents SU	IIb
	Self-expanding Stents SU (Biliary, Bronchial/Tracheal, Colonic, Duodenal, Esophageal)	IIb
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

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

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
(see attachment)

has introduced and applies a

Quality System

for the aspects of manufacture concerned with securing and maintaining sterile conditions as specified in Annex V, Section 3.

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

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2019-01-04
Valid until	2023-01-23
Registration no.	D1033500037
Report no.	P18-01361-131199
Stuttgart	2019-01-04

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. D1033500037 Date 2019-01-04 Page 1 of 1

Product category	Product	Class
endoscopic instruments	E.R.C.P. Catheters SU/RU Suction / Flushing Catheters SU Stone Extraction Baskets SU/RU Lithotripsy Baskets / Lithotripsy Spirals SU/RU Guiding Catheters SU/RU Pushers SU/RU Stent Placement Sets SU/RU Biliary Dilation Catheters SU Polyp & Foreign Body Retriever "EasyCollect" SU Guide Wires SU/RU Dilation Balloons SU	I (steril)

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

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 540595**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

In respect of:

The design and manufacture of non active digestive tract devices; non active gynecological devices; non active regional anaesthesia devices; non active respiratory devices; non active surgical devices; non active urology devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 January 2009** Date: **28 August 2015** Expiry Date: **07 September 2020**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Arrow International CR, a.s. Jamska 2359/47 59101 Zdar nad Sazavou Czech Republic	**Control of Sterilization** **Design** **Manufacture**
Arrow International CR, a.s. Prazska 209 50004 Hradec Kralove Czech Republic	**Control of Sterilization** **Design** **Manufacture**
Arrow Medical Ltd Hatton Gardens Industrial Estate Kington HR5 3RB United Kingdom	**Crucial Supplier**
CeMed GmbH Oberdorf 41 72419 Neufra Germany	**Control of Sterilization** **Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Chelle Medical Limited PO Box 221 Le Rocher Victoria Mahe Seychelles	**Crucial Supplier**
Forefront (Xiamen) Medical Devices Co., Ltd No 26 & 28 Haijing Dong Lu Haicang Xiamen Export Processing Zone 361026, Xiamen, Fujian China	**Crucial Supplier**
Forefront Medical Technology Pte Ltd 35 Joo Koon Circle, 6th Floor Singapore 629110 Singapore	**Crucial Supplier**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	**Crucial Supplier**
Parker Medical Systems Division - Merrillville 1201 East 86th Place Merrillville Indiana 46410 USA	**Crucial Supplier**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas 30020 Ipoh Perak Malaysia	**Crucial Supplier**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
SP Medical A/S Møllevej 1 4653 Karise Denmark	**Control of Sterilization** **Design** **Manufacture**
Süddeutsche Feinmechanik GmbH (SFM) Brückenstrasse 5 D-63607 Wächtersbach Germany	**Control of Sterilization** **Manufacture**
Teleflex Medical Sdn. Bhd. Lot PT2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**Control of Sterilization** **Design** **Manufacture**
Teleflex Medical Asia Pte. Ltd. 6 Battery Road #07-02 049909 Singapore	**Control of Sterilization** **Design** **Manufacture**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park, Kulim 09000 Malaysia	**Crucial Supplier**
Tianjin Medis Medical Device Co. Ltd 10A Tianzhi Industrial Centre No 12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin City China	**Control of Sterilization** **Manufacture**
Willy Rüsch GmbH Willy Rüsch-Strasse 4-10 D-71394 Kernen Germany	**Control of Sterilization** **Design** **Manufacture**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **28 August 2015**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
13 January 2009	7245725	First issue
17 March 2009	7325719	Company address amended. Extension to scope. Addition of Willy Rüsch, Germany as subcontractor for design and manufacture
25 August 2009	7399879	Addition of 'epidural catheter Epistar and Epistar CSE' to scope. Addition of SFM as significant subcontractor for manufacture. Addition of 'design' to services supplied by Teleflex Medical Malaysia, Arrow International CR, a.s. and Arrow International Inc., Czech Republic
11 November 2009	7455515	Addition of CeMed GmbH for manufacturing to the list of significant subcontractors
20 April 2010	7497906	Laryngeal Mask added to scope. Addition of Tianjin Medis Medical Device Co. Ltd as significant subcontractor for manufacture
08 September 2010	7558508	Scope reworded in accordance with generic device groups. Certificate renewal
23 May 2012	7778467	Correction of significant subcontractor address and addition of new scope activities for subcontractors

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **28 August 2015**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
04 February 2013	7932588	The addition of a significant subcontractor SP Medical A/S
14 May 2014	8134266	Addition of peripheral angioplasty balloon catheters to product family, covered by scope expression 'non-active surgical devices'. Addition of significant subcontractors Hotspur Technologies, Inc and Teleflex Medical Asia Pte Ltd
09 March 2015	8293488	Addition of 8 crucial suppliers
28 August 2015	8406490	Certificate renewal. Removal of Hotspur Technologies, Inc. from list of significant subcontractors.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 14 12 10578 004

Manufacturer:

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
GERMANY

Facility(ies):

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Drägerwerk AG & Co. KGaA
Revalstraße 1, 23560 Lübeck, GERMANY

Product Category(ies):

Anaesthetic equipment with standard accessories,
Infusion equipment with standard accessories,
Pediatric equipment with standard accessories,
Lung ventilator equipment with standard accessories,
Monitoring equipment with standard accessories,
Equipment for suction, breathing-, inhalation-,
oxygen- and aerosol-therapy with standard accessories,
Medical supply units and terminal units for pressurized medical gases and vacuum

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.: 713052642

Valid from: 2015-01-15
Valid until: 2020-01-14

664215

Date, 2015-01-16

Hans-Heiner Junker

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

Digitally signed by Cojocaru Vera
Date: 2019.10.25 04:45:42 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate

mdc medical device certification GmbH
certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

design, development, production, storage and distribution of instruments and accessories for the diagnostic and therapeutic endoscopy

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	2019-03-11
Valid until	2021-01-23
Registration no.	D1033500038
Report no.	P18-01361-131193
Stuttgart	2019-03-11

Head of Certification Body

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

BSS
Better Signal Solution

BSS MEDICAL SUPPLY CO., LIMITED

Document Number : CE-DC-001 Version: A/1

EC Declaration of Conformity

Manufacturer:

BSS MEDICAL SUPPLY CO., LIMITED
No.18, Shabian Road, Torch Hi-tech Industry Zone,
Zhonggshan, China.
info@bssmedical.com

whose single Authorized Representative:

Wellkang Ltd.
Suite B, 29 Harley Street
LONDON, W1G 9QR,U.K.
info@bssmedical.com

We, the manufacturer, herewith declare that the products

Disposable ECG electrode

GMDN Code:11425

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

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

Conformity assessment procedure: Annex VII of Directive 93/43/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: BSS MEDICAL SUPPLY CO., LIMITED
Address: No.18, Shabian Road Torch Hi-tech Industry Zone, Zhongshan, China.

ZHONGSHAN2018/01/01
Place , date

Harrison Wu
Legally binding signature, Function

18-BEY-01 Adult Electrode LOT: 04192018

CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証書 ◆ CERTIFICATE ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 18 03 84065 005

Manufacturer:

Nuova GmbH
Lübecker Str. 17
23909 Ratzeburg
GERMANY

Facility(ies):

Nuova GmbH
Lübecker Str. 17, 23909 Ratzeburg, GERMANY

Product Category(ies):

Oxygen sensors

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.: 713129331

Valid from: 2018-06-18
Valid until: 2023-06-17

Date, 2018-04-18

Stefan Preiß

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

E

E-15/4

- Connector: modular jack
- Measuring range: 0-100% O_2
- Output signal: 8–12 mV
- Response time: < 16 seconds
- Warranty: 16 months
- Storage: up to 6 months

SZUTEST

EC CERTIFICATE

AT SERTİFİKA

According to Annex V of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz Yönetmeliği Ek V'e göre

Production Quality Assurance System

Üretim Kalite Güvencesi

Certificate Number: 2195-MED-1816401

Sertifika Numarası

Manufacturer: **R Vent Medikal Üretim A.Ş.**
Üretici *29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, Türkiye*

Product(s):
Ürün(ler)

(1) Steril ve Steril Olmayan Solunum Devre Sistemleri
Sterile and Non-Sterile Breathing Circuit Systems
(2) Steril ve Steril Olmayan Solunum Filtreleri
Sterile and Non-Sterile Breathing Filters
(3) Steril ve Steril Olmayan Katater Bağlantıları
Sterile and Non-Sterile Catheter Mounts

Reference Report No: MM0687-P001-R01, MM0678-P001-R02
Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe and sterile conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK V bölüm 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik ve steril koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK V, bölüm 4'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

This EC certificate is valid till 2021-06-12.

Bu AT Sertifikası 2021-06-12 tarihine kadar geçerlidir.

Issue Date/*Yayın Tarihi:* 2018-06-13

Mehmet IŞIKLAR
General Manager
Genel Müdür

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Szutest Plaza Nato Yolu Cad. Çam Sok. No:7 Ümraniye 34775 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

SERTİFİKA

Medikal Cihazlar Kalite Yönetim Sistemi

SERTİFİKA NO: 31816401

R Vent Medikal Üretim A.Ş.

29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, TÜRKİYE

EN ISO 13485:2016

Steril ve Steril Olmayan Tek Kullanımlık Solunum Sistemleri Üretimi ve Dağıtımı

Medikal Cihazlar Kalite Yönetim Sistemine yukarıda belirtilen kapsam dahilinde sahip olduğunu onaylar.

Yayın Tarihi	13.06.2018
Geçerlilik Tarihi	12.06.2021
Revizyon Tarih/No	28.01.2019 / 1

TÜRKAK BDS NO YS-B79A-A8B2

TÜRKAK
Tıbbi Cihazlar K Y S
TS EN ISO/IEC 17021
AB-0044-YS

Genel Müdür Yardımcısı

Bu belgenin doğrulanması belge üzerinde bulunan karekodların mobil cihazlara okutulması, http://public.szutest.com.tr adresinde gerekli bilgilerin girilmesi veya BDS no kullanılarak https://tbds.turkak.org.tr adresinden gerçekleştirilebilir.

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31816401

R Vent Medikal Üretim A.Ş.

29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, TÜRKİYE

EN ISO 13485:2016

Manufacturing and Distribution of Sterile and Non Sterile Disposable Breathing Systems

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date	13.06.2018
Expiry Date	12.06.2021
Revision Date/No	28.01.2019 / 1

TÜRKAK BDS NO
YS-B79A-A8B2

TÜRKAK
Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021
AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

№ 09228
23 Temmuz 2018

EC CERTIFICATE

for the Quality Assurance System

DOCUMENT MARKED AND
IDENTIFIED IN PENANG
MALAYSIA BY:

17/11/17

TAN GAIK CHOON
NOTARY PUBLIC
1st Floor, 46, Rangoon Road
10400 Penang, Malaysia

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Teleflex Medical Sdn. Bhd.

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

Certified location:

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50076-Z6-00, the decision dated 2017-04-19 and is only valid in connection with the successful performance of the annual surveillance audits

This certificate is valid from 2017-06-27 to 2020-06-26

Registration No.: 50076-16-07

ASLINDAN TERCÜMESİ YAPILMISTIR

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart, 2017-04-19
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

MÜSTENNATTIR
TEKRARINA
KULLANILAMAZ.

KADIKÖY 13. NOTERI
NAZIK ASKER
BASKATIP
NURTEN ÇAKIR

Annex to the EC Certificate No. 50076-16-07

Revision status: 1

Valid from 2017-06-27 to 2020-06-26

№09228

23 Temmuz 2018

Devices/device categories included in the certificate:

Class II a:

Urology Device

- Foley/Haematuria Catheter (Latex)
- Foley / Haematuria Catheter (PVC)
- Preconnected Urological System (Latex)
- Hyperthermia Bladder Silicone Catheter
- Ureteral Connector
- Catheterization Set
- Suprapubic Catheter (PVC)
- Urodynamic Catheter
- Hydrostatic Catheter
- Silicone Catheter for Radiological Display of Urethra

Respiratory Device

- Breathing Circuits
  - Catheter Mount
  - Heat and Moisture Exchanger
  - Bacterial / Viral Filter
  - HME with Filter
  - Rebreathing bag
  - Multifit Nebuliser System
- Nasal Cannula Set
- Endotracheal Tube (with/without Stylet)

Gastrointestinal Device

- Gastrointestinal Tube
- Intestinal Decompression Tube
- Rectal Tube
- Sengstaken

Gynaecological Device

- Word Catheter

Surgical Device

- Surgical Drainage Tube
- Gas Filter

ASLINDAN TERCÜMESİ YAPILMIŞTIR

MÜSTEDNATTIR. TEK BAŞINA KULLANILMAZ.

KADIKÖY 13. NOTERİ NAZİK AKSOY BAŞKATİP NURTEN ÇAKIR

Annex to the EC Certificate No. 50076-16-07

Revision status: 1

Valid from 2017-06-27 to 2020-06-26

№09228

23 Temmuz 2018

Devices/device categories included in the certificate:

Class II b:

Urology Device

- Foley Catheter (Silicone)
- Latex Foley Catheter (Hydrogel coated)
- Preconnected Urological System (Silicone)
- Suprapubic Catheter (Silicone)
- 2 Way All Silicone Temperature Sensor Catheter
- Silicone Nephrostomy Catheter

Respiratory Device

- Tracheostomy tube and Accessories

TAN GAIK CHOON NOTARY PUBLIC PENANG MALAYSIA

MÜSTECNATTIR. TERCÜMESİ KULAZ.

ASLINDAN TERCÜMESİ YAPILMIŞTİR

DEKRA Certification GmbH Stuttgart Handwerkstraße 15

DEKRA

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-10-05
Notified Body ID-number: 0124

KADIKÖY 13. NOTERLİĞİ BAŞKATİP NURTEN CANDAN

T.C.
KADIKÖY 13. NOTERLİĞİ
Rıhtım Cd. Sevket Bey Işhanı
No:12/2 Kadıköy-İstanbul
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TERCÜME 23 Temmuz 2018 № 09228

BELGE MALEZYA, PENANG'DA
AŞAĞIDAKİ NOTER TARAFINDAN
MÜHÜRLENMİŞ VE UYGUNLUĞU ONAYLANMIŞTIR:
(Noterin İmzası) 17/11/17
TAN GAIK CHOON
NOTER
1st Floor, 46, Rangoon Road
10400 Penang, Malezya

ASLI GİBİDİR

DEKRA

EC SERTİFİKASI

Direktif 93/42/EEC, Ek II'ye uygun olarak, bölüm (4) hariç Kalite Güvence Sistemi için

Avrupa Birliği Yetkili Kurumu olarak, DEKRA Certification GmbH, işbu belge ile aşağıda belirtilen şirketin

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Teleflex Medical Sdn. Bhd.

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malezya

Onaylı adresi:

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malezya

(PENANG, MALEZYA NOTERİ
TAN GAIK CHOON'UN
SOĞUK DAMGASI)

93/42/EEC sayılı direktifin ek II'sine uygun olarak ilişikte listelenmiş bulunan medikal cihazlar için bir kalite güvence sistemi uygulamakta olduğunu tasdik eder. Bu onay 50076-Z6-00 numaralı tekrar sertifikasyon denetim raporu, 19-04-2017 tarihli karar sonuçlarına dayanmaktadır ve sadece yıllık değerlendirme denetimlerinde başarılı performans ile bağlantılı olarak geçerlidir.

İşbu sertifika 27-06-2017 tarihinden 26-06-2020 tarihine kadar geçerlidir.

Tescil No: 50076-16-07

(Dekra kaşesi)

(İmza)
Ruth Delbeck-Bayer
DEKRA Certification GmbH;
Stuttgart, 19-04-2017

Yetkili Kurum No: 0124

ZLG

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für Gesundheitsschutz
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Medizinprodukten
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T.C.
KADIKÖY 13. NOTERİ
NOTER YAKIP

№09228

23 Temmuz 2018

50076-16-07 numaralı EC Sertifikasına Ek

Revizyon Durumu: 1

27-06-2017 tarihinden 26-06-2020 tarihine kadar geçerli

Sertifikaya dahil olan ürünler/ürün kategorisi:

Sınıf II a:

Üroloji Ürünleri

- Foley/Hematüri Kateter (Lateks)
- Foley/ Hematüri Kateter (PVC)
- Ön Bağlantılı Ürolojik Sistem (Lateks)
- Hipertermi Mesane Silikon Kateteri
- Üreteral Konnektör
- Katheterizasyon Seti
- Suprapubik Kateter (PVC)
- Ürodinamik Kateter
- Hidrostatik Kateter
- Üretra Radyolojik Görüntüleme için Silikon Kateter

Solunumla ilgili Ürünler

- Solunum Devreleri
  - Kateter Mount
  - Isı ve Nem Değiştirici
  - Bakteriyel / Viral Filtre
  - Filtreli HME
  - Solunum Torbası
  - Multifit Nebülizatör Sistemi
- Nazal Kanül Seti
- Endotrakeal Tüp (Stileli/Stilesiz)

Sindirim Sistemi Ürünleri

- Gastrointestinal Tüp
- Intestinal Dekompresyon Tüpü
- Rektal Tüp
- Sengstaken

Jinekoloji Ürünleri

- Word Kateter

Cerrahi Ürünler

- Cerrahi Drenaj Tüpü
- Gaz Filtresi

(PENANG, MALEZYA NOTERİ
TAN GAIK CHOON'UN
MÜHRÜ VE PARAFI)

№09228

23 Temmuz 2018

50076-16-07 numaralı EC Sertifikasına Ek

Revizyon Durumu: 1

27-06-2017 tarihinden 26-06-2020 tarihine kadar geçerli

Sertifikaya dahil olan ürünler/ürün kategorisi:

Sınıf II b:

Üroloji Ürünleri

- Foley Kateter (Silikon)
- Lateks Foley Kateter (Hidrojel Kaplı)
- Ön Bağlantılı Ürolojik Sistem (Silikon)
- Suprapubik Kateter (Silikon)
- 2 Yollu Tam Silikon Sıcaklık Sensör Kateteri
- Silikon Nefrostomi Kateteri

Solunumla ilgili Ürünler

- Trakeostomi Tüpü ve Aksesuarları

(PENANG, MALEZYA NOTERİ
TAN GAIK CHOON'UN
MÜHRÜ VE PARAFI)

(İmza)
Ruth Delbeck-Bayer
DEKRA Certification GmbH;
Stuttgart, 05-10-2017
Yetkili Kurum No: 0124