

# 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



**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	Ila
Endoscopic instruments	Stone extraction Balloons SU	Ila
	Scissors RU	Ila
	Cytology Brushes SU	Ila
	Spray Catheters SU/RU	Ila
	Suture Punches RU	Ila
	Foreign Body Retrievers / Polyp Retrievers SU/RU	Ila
	Biopsy Forceps SU/RU	Ila
	Multi Band Ligation Device SU	Ila
Needle systems	Fibrin Application Needles SU/RU	Ila
	FNA Systems for ultrasound endoscopy SU	Ila
	Transbronchial Aspiration Needles SU	Ila
	Injection Needles SU/RU	Ila
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



# 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



**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)



A handwritten signature in black ink, appearing to be "J. A.", is written over a horizontal line.

Head of Certification Body

# 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**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# 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**

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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**Dublin Road**  
**Athlone**  
**Co. Westmeath**  
**Ireland**

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

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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Date: **28 August 2015**  
Issued To: **Teleflex Medical  
IDA Business and Technology Park  
Dublin Road  
Athlone  
Co. Westmeath  
Ireland**

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

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# 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**

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

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# 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**

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

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# 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 Rüsck, 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

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# 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.



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



**Date,** 2015-01-16

Hans-Heiner Junker

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

Page 1 of 1

# 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

A handwritten signature in black ink, appearing to be "J. A.", written over a light blue horizontal line.

Head of Certification Body





## 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,  
Zhongshan, 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



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

18-BEY-01 Adult Electrode LOT: 04192018



No.18, Shabian Road, Torch Hi-tech Industry Zone, Zhongshan, China  
+86 760 85280100 www.bssmedical.com info@bssmedical.com

**BSS-----Nothing Less Than Perfect!**



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<sub>2</sub>
- Output signal: 8-12 mV
- Response time: < 16 seconds
- Warranty: 16 months
- Storage: up to 6 months

## 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):** (1) Steril ve Steril Olmayan Solunum Devre Sistemleri  
Ürün(ler) 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 İSİKLAR  
General Manager  
Genel Müdür

## 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



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.

## 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



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>.

No 09228  
23 Temmuz 2018

# EC CERTIFICATE

## for the Quality Assurance System

DOCUMENT MARKED AND IDENTIFIED IN PENANG MALAYSIA BY:

*Tan Gai Choon* 17/11/17

TAN GAI 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:

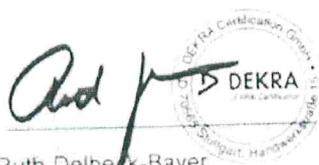
Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia



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



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

ASLINDAN  
TERCÜMESİ  
YAPILMIŞTIR



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



MÜSTERHATTIR  
TEKİR NAKİNA  
KULLANILMAZ.

KADIKÖY 13. NOTERİ  
NAZİK 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

Devices/device categories included in the certificate:

№ 09228

23 Temmuz 2018

## 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

MÜSTEDİNATTIR.  
TEK BAŞIRA  
KULLANILMAZ.

KADIKÖY 13. NOYERİ  
NAZİK ARÇEN  
BAŞKATIŞ  
NURTEN ÇAKIR



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

Revision status: 1

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

Devices/device categories included in the certificate:

No 09228

23 Temmuz 2018

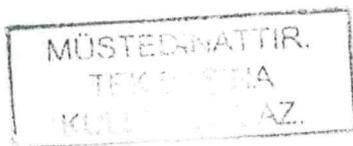
## Class II b:

### 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

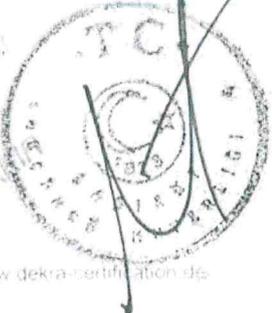


ASLINDAN  
TERCÜMESİ  
YAPILMIŞTIR



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2018-10-05  
Notified Body ID-number: 0124

KADIKÖY 13 NOTER  
HAZIK KESER  
BAŞKATIP  
NURTEN ÇAĞRI



TERCÜME

23 Temmuz

№ 09228  
2018

Y.C.  
KADIKÖY 13. NOTERLİĞİ  
Rıhtım Cd. Sevket Bıy İşhanı  
No:12/2 Kadıköy-İstanbul  
Tel: 345 54 85 - 418 13 48  
Fax: 338 43 13

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

## 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

**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 ilişkide 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



Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
tarafından  
görevlendirilmiştir.  
ZLG-BS-295.10.02

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

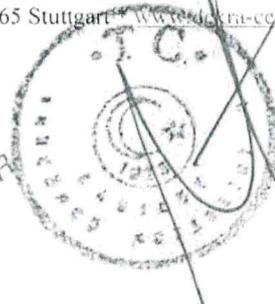
Sayfa 1/1

ECE

Tercüme Bürosu

Translation - Übersetzung - Traduction  
Rıhtım Cd. E. Şişli Sk. Bayraktar Hanı  
Tel: 345 54 85 - Fax: 348 41 98  
Kadıköy / İstanbul / T.C. No: 23351342540

KADIKÖY 13. NOTERİ  
10/11/17  
19/04/2017  
NOTERİN İMZASI  
MURTELİN ÇAKIR



№ 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)
- Ürokinamik 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
- İntestinal 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)

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

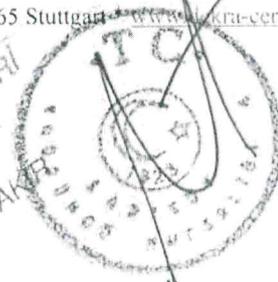
Sayfa 1/2

**ECE**

Tercüme Bürosu

Translation - Übersetzung - Traduction  
Rıhtım Cad. Başçavuş Sok. Bayraklar Hanı  
Tel: 348 41 00 04 Fax: 348 41 96  
Kadıköy Y.B. No: 23251342548

KADIKÖY 13. NOTERİ  
MAZİK ASKER  
BAŞKATIP  
NURTEN ÇAKIR



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

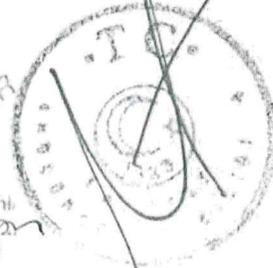
Sayfa 2/2

**ECE**

**Tercüme Bürosu**

Translation - Übersetzung - Traduction  
Rihtim Cad. Bayravsuz Sk. Bayraktar Hanı  
Tel: 348 20 00 Fax: 348 41 98  
Kadıköy / İstanbul / Türkiye No: 23951342548

KADIKÖY 13. NOTERİ  
NAZİK ASKER  
BAŞKATİP  
BURTEN ÇAKIR



İşbu belgenin aslına uygun olarak  
..... Lisansından  
..... Çıkarışının  
tarafından yapıldığını onaylıyorum.

İşbu çeviri büromuz yerini  
tercüman .....  
tarafından tercüme edildiğini  
onaylıyorum.