

EC CERTIFICATE

for the Quality Assurance System

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-Z7-00, the decision dated 2019-06-26 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-06-26 to 2024-05-26

Registration No.: 50076-16-08

A handwritten signature in black ink, appearing to read "Ruth Delbeck-Bayer".

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-26
Notified Body ID-number: 0124



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

Annex to the EC Certificate No. 50076-16-08

Valid from 2019-06-26 to 2024-05-26

Revision status of the annex: 0 dated 2019-06-26

Devices/device categories included in the certificate:

Class II a:

Urology Device

- Foley /Heamaturia Catheter (Latex)
 - 2 Way Foley Catheter
 - 3 Way Foley Catheter
 - Preconnected Urological System
- Foley Catheter (PVC)
 - 2 Way Foley Catheter (Simplastic)
 - 3 Way Foley Catheter (Simplastic)
- Hyperthermia Bladder Silicone Catheter
- Urodynamic Catheter
- Suprapubic Catheter (PVC)

Respiratory Device

- Breathing Circuit
 - Catheter Mount
 - Heat & Moisture Exchanger (HME)
 - HME with Catheter Mount
 - Bacterial/Viral Filter
 - Bacterial/ Viral Filter with Catheter Mount
 - HME Filter
 - HME Filter with Catheter Mount
 - Rebreathing Bag
 - Multimask
- Endotracheal Tube with / without stylet
- Nasal Cannula
 - Nasal Cannula Set
 - Comfort Flo Plus Cannula

Gastrointestinal Device

- Rectal Tube

Gynecological Device

- Drainage Catheter
 - Word Catheter

Surgical Device

- Surgical Drainage Catheters
 - Pezzet
 - Malecot
- Laparoscopy Filter

Annex to the EC Certificate No. 50076-16-08

Valid from 2019-06-26 to 2024-05-26

Revision status of the annex: 0 dated 2019-06-26

Devices/device categories included in the certificate:

Class II b:

Urology Device

- Foley Catheter Silicone
 - 2 Way Foley Catheter
 - 3 Way Foley Catheter
 - Preconnected Urological System
 - Brilliant & Silflite Catheters
- Foley Catheter Latex (Hydrogel Coated)
 - 2 Way Foley Catheter (Sympacath/ Aquaflite Sympacath)
 - 3 Way Foley Catheter (Sympacath)
- Nephrostomy Catheter with/ without Stylet
- Suprapubic Catheter (Silicone)
- 2 Way Silicone Temperature Sensor Catheter

Respiratory Device

- Tracheostomy Tube
 - Crystal Clear Tracheostomy Tube

Ruth Delbeck-Bayer



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DEKRA Certification GmbH, Stuttgart, 2019-06-26
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