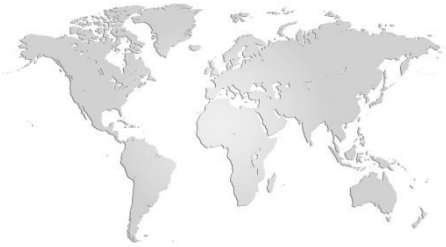
EC CERTIFICATE

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

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

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
  - Pezzer
  - 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
  - Brillant & Silflate Catheters

- Foley Catheter Latex (Hydrogel Coated)
  - 2 Way Foley Catheter (Sympacath/ Aquaflate 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

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart

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