

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.

Certified location:

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

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50076-Z5-00, the decision dated 05.05.2014 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 11.10.1996

Date of the last recertification: 27.06.2014

This certificate is valid until: 26.06.2017

Certificate registration No.: 50076-16-06

DEKRA Certification GmbH
Stuttgart, 05.05.2014

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

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid.

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



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
- Preconnected Urological System (IPAS)
- Ureteral Connector
- Catheterization Set
- Suprapubic Catheter (PVC)
- Urodynamic Catheter
- Hydrostatic Catheter
- Kidney Transplant Catheter
- Silicone Catheter for Radiological Display of Urethra

Respiratory Device

- Humid Heat Vented Water Feed Set
- Catheter Mount
- Ventilation Breathing Circuits and Anaesthetic Breathing Circuits
- Heat and Moisture Exchanger
- Bacterial / Viral Filter
- HME with Filter
- Rebreathing bag
- Multifit Nebuliser System
- Suction Catheter
- Nasal Cannula Set
- Endotracheal Tube (with/without Stylet)
- Laryngeal Tube

Gastrointestinal Device

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

Gynaecological Device

- Word Catheter

Surgical Device

- Surgical Drainage Tube
- Gas Filter

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
- Silicone Ureterocutaneostomy Catheter

Respiratory Device

- Tracheostomy tube and Accessories