

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



Ruth Delbeck-Bayer

DEKRA Certification GmbH, Stuttgart, 2019-06-26

Notified Body ID-number: 0124

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