

# 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:

## **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

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Devices/device categories included in the certificate:

## **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



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