

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt
Germany

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

Medical devices as per attachment 1

The compliance of the Quality Assurance System with the below mentioned
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II excluding section 4

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 31 March 2021

Report No.: 0521PS29F

Process No.: QS - 0521

Certificate No.: 0521GB410171204

Hamburg, 04 December 2017



MEDCERT Certification Body
(Dr. Andreas Schich)

MEDCERT Identification No.: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Attachment 1
EC-Certificate of Conformity
QS - 0521

This attachment is valid only in connection with certificate No: 0521GB410171204

- **Sets for autologous transfusion**
- **Bacterial-and viral filters**
- **Brachytherapy catheters**
- **Brachytherapy needles with goldmarker**
- **Disinfectants**
- **3-way stopcocks**
- **Feeding tubes, tubes for small intestine and suction catheters**
- **Loops**
- **Intra uterine pessaries (IUP)**
- **Artificial noses (HME) with O2-connector and their accessories**
- **Nasal splints**
- **Ventilation tubes**
- **Dilation sets for percutaneous tracheostomy**
- **Pessaries**
- **Pump tubing systems and their accessories**
- **Redon-systems**
- **Oxygene cannulas**
- **Speaking valves with respiration connection**
- **Fecal management systems**
- **Thoracic and trocar catheters**
- **Tracheostomy cannulas, stents and -applicators**
- **Transfusion devices for blood bags**
- **Urine drainage systems**
- **Wound Foams**

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