

# 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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