

# Certificate

## The Certification 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**

**With its facilities as per attachment 1**

has introduced, applies and maintains a Quality Management System in the area of:

**Design, manufacture, final inspection and distribution of  
Medical Devices as per attachment 2 to 3**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

**EN ISO 13485:2016**

The license of certification is subject to surveillance by MEDCERT.

**This certificate is valid until: 01 April 2022**

Report No.: 0521FS32F  
Process No.: QS - 0521  
Certificate No.: 0521GB445190621

Hamburg, 21 June 2019



MEDCERT Certification Body  
(Lorenz Runge)



Deutsche  
Akkreditierungsstelle  
D-ZM-19630-04-00

**Attachment 1  
Certificate  
QS - 0521**

This attachment is valid only in connection with certificate No.: 0521GB445190621

**Facilities**

**Am Bahndamm 11  
38820 Halberstadt  
Germany**

**Am Domplatz 34  
38820 Halberstadt  
Germany**

Hamburg, 21 June 2019



---

MEDCERT Certification Body  
(Lorenz Runge)

**Attachment 2  
Certificate  
QS - 0521**

This attachment is valid only in connection with certificate No.: 0521GB445190621

- **Anuscope**
- **Sets for autologous transfusion**
- **Bacterial and viral filters**
- **Dosage systems for bladder-instillation**
- **Brachytherapy catheters**
- **Brachytherapy needles with goldmarker**
- **Colon-preparation systems**
- **Disinfectants**
- **Dilatation-sets for percutaneous tracheostomy**
- **Feeding tube, tubes of small intestine and suction tubes**
- **Loops**
- **Infusion and drainage accessories**
- **Intra uterine pessaries (IUP)**
- **Tracheal cannula necklaces**
- **Articles for general hospital supplies**
- **Artificial noses (HME) with and without O2-connector and their accessories**
- **Laser catheters and their accessories for laser application**

Hamburg, 21 June 2019



---

MEDCERT Certification Body  
(Loretz Runge)

**Attachment 3  
Certificate  
QS - 0521**

This attachment is valid only in connection with certificate No.: 0521GB445190621

- **Urine bags**
- **Gingivodental orthopaedic devices**
- **Ventilation tubes**
- **Pessaries**
- **Redon-systems**
- **Oxygene cannulas**
- **Suction tubes and suction connecting tubes**
- **Speaking valves with respiration connection**
- **Fecal management system**
- **Overdentures**
- **Thoracic and trocar catheters**
- **Tracheostomy cannulas, stents and applicators**
- **Transfusion devices for blood bags**
- **Transmission systems**
- **Pump tubing systems and their accessories**
- **Wound foams**
- **Compilation of blood collection sets**

Hamburg, 21 June 2019



---

MEDCERT Certification Body  
(Loretz Runge)