

Certificate

The certification body

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

herewith certifies that the company

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

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

**Design and development, manufacture, final inspection and distribution of
Medical Devices as listed in the appendix**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-04-24

Expiry date: 2022-04-01

Report No.: 0521PS33F

Procedure No.: QS – 0521

Certificate No.: 0521GB445200424

Hamburg, 2020-04-24


MEDCERT Certification Body
(Lorenz Runge)

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certification body

Appendix of certificate

Procedure No.: QS – 0521

Certificate No.: 0521GB445200424

List of locations included in the scope of certificate

**Am Bahndamm 11
38820 Halberstadt
Germany**

**Domplatz 34
38820 Halberstadt
Germany**

– End of list –

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Appendix of certificate

Procedure No.: QS – 0521

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List of products included in the scope of certificate

- **Sets for autologous transfusion**
- **Section Catheter**
- **Bacterial and viral filters**
- **Brachytherapy catheters**
- **Brachytherapy needles with goldmarker**
- **Colon-preparation systems**
- **Disinfectants**
- **Dilatation-sets for percutaneous tracheostomy**
- **Loops**
- **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**
- **Gingivodental orthopaedic devices**
- **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**

– End of list –

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