

# 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**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

**EN ISO 13485:2016**

This certification is subject to surveillance by MEDCERT.

**Effective date:** 2022-10-17  
**Expiry date:** 2024-11-04

Report No.: 0521IA35F  
Procedure No.: QS – 0521  
Certificate No.: 0521GB445221017

Hamburg, 2022-10-17

  
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MEDCERT Certification Body  
Marcus Harder

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

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## Appendix of certificate

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### Activities and products/services in the scope of certification

Design and development, manufacturing, final inspection and distribution of

- Sets for autologous transfusion
- Section catheters
- 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
- Redon-systems
- Oxygene cannulas
- Suction tubes and suction connecting tubes
- Speaking valves with respiration connection
- Fecal management systems
- Thoracic and trocar catheters
- Tracheostomy cannulas, stents and applicators
- Transfusion devices for blood bags
- Transmission systems
- Pump tubing systems and their accessories
- Wound foams
- Accessories for tracheal cannulas

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## Appendix of certificate

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### Locations in the scope of certification

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

Primed Halberstadt Medizintechnik GmbH  
Am Bahndamm 11  
38820 Halberstadt  
Germany

Primed Halberstadt Medizintechnik GmbH  
Domplatz 34  
38820 Halberstadt  
Germany

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