

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0521GB452250410

Final assessment report no.
0521AU38F

Effective date
2025-04-10

Expiry date
2027-11-04

This is to certify that

Primed Halberstadt Medizintechnik GmbH

Straße des 20. Juli 1, 38820 Halberstadt, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016 + AC:2018 + A11:2021

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2025-04-10

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com


Annika Chill
Certification Body

Activities and products/services covered by this certificate

Design and development, manufacturing and distribution of

- Sets for autologous transfusion
- Section Catheters
- Bacterial and viral filters
- Brachytherapy needles with goldmarker
- Colon-preparation systems
- Disinfectants
- Dilatation-sets for percutaneous tracheostomy
- Loops
- Drainage accessories
- Tracheal cannula necklaces
- 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

Sites covered by this certificate and associated (partial) scopes

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

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Primed Halberstadt Medizintechnik GmbH, Am Bahndamm 11, 38820 Halberstadt, Germany

Manufacturing of

- Suction tubes and suction connecting tubes

Primed Halberstadt Medizintechnik GmbH, Domplatz 34, 38820 Halberstadt, Germany

Distribution of

- Sets for autologous transfusion
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