



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0521GB452241104

Final assessment report no.
0521AU38F

Effective date
2024-11-05

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, 2024-11-04

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



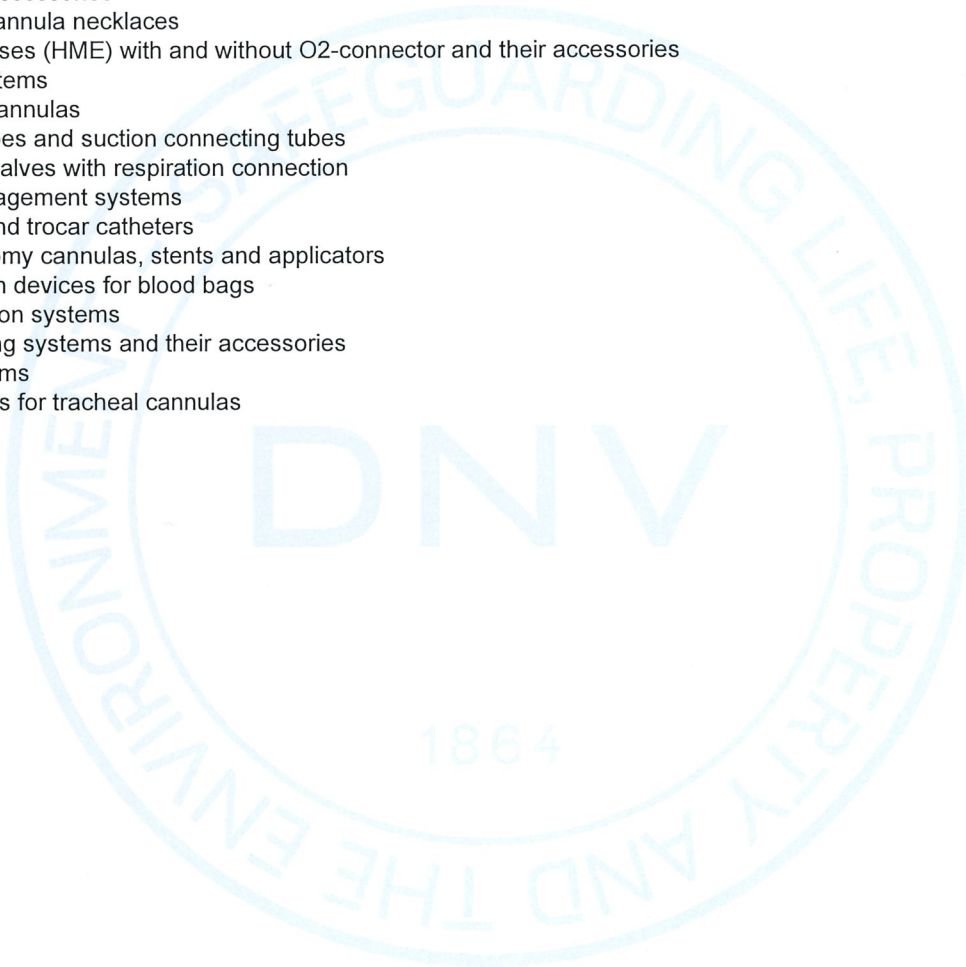
Lorenz Runge
Certification Body

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

Activities and products/services covered by this certificate

Design and development, and manufacturing 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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- Accessories for tracheal cannulas

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

Oversight on all matters related to the management process of

- Sets for autologous transfusion
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