

# EU Quality Management System Certificate

Certificate no.  
0521GB448240709

Final Assessment Report no.  
0521AU35F

Effective date  
2024-07-09

Expiry date  
2026-11-04

This is to certify that the quality system of

## **Primed Halberstadt Medizintechnik GmbH**

**Straße des 20. Juli 1, 38820 Halberstadt, Germany**

SRN: DE-MF-000004967

For design, production, and final product inspection/testing of  
**Medical devices/groups of medical devices listed on the following pages**

Has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX,  
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

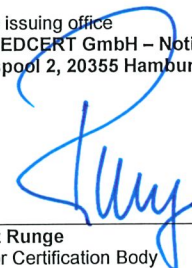
Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date  
**Hamburg, 2024-07-09**

For the issuing office  
**DNV MEDCERT GmbH – Notified Body 0482  
Pilatuspool 2, 20355 Hamburg, Germany**



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-096



**Lorenz Runge**  
Director 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](mailto:Medcert-Info@dnv.com)



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### Preceding certificate

Certificate no.	Issue date	Identification of changes
0521GB448230725	2023-07-25	Addition of MDN 1202, Class Is, Class IIa MDN 1202 G020301 and A060203 and Class IIb MDN 1201 R010501 and R010502
0521GB448230823	2023-08-23	Addition of Class IIa MDN 1214 R900602, R040201, MDN 1202 A060101 and Class IIb MDN 1201 R010503
0521GB448231026	2023-10-26	Addition of MDN 1214 EMDN R030102 and MDN 1202 EMDN A060102 and removal of reference to additional certificate under Class IIb

### Sites covered by this certificate

- Primed Halberstadt Medizintechnik GmbH, Straße des 20. Juli 1, 38820 Halberstadt, Germany
- Primed Halberstadt Medizintechnik GmbH (Verwaltung), Domplatz 34, 38820 Halberstadt, Germany
- Primed Halberstadt Medizintechnik GmbH, Am Bahndamm 11, 38820 Halberstadt, Germany





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## Products covered by this certificate

### Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

Category	Class	Medical devices/groups of medical devices
MDN 1202	Is	Non-active, non-implantable devices for administration, channelling and removal of substances, including devices for dialysis

### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1214	R040102	Ventilation filters, antibacterial and antiviral, moisturizer
MDN 1214	R040101	Antibacterial and Antiviral Respiratory Filters
MDN 1214	R900602	Phonation valves for tracheostomy
MDN 1214	R040201	Tracheostomy humidifiers
MDN 1214	R030102	Air/oxygen masks and nasal cannulas
MDN 1202	G020301	Rectal Tubes
MDN 1202	A060203	Pleural Drainages with valve and kits
MDN 1202	A060101	Vacuum and gravity drainage systems
MDN 1202	A060102	Surgical drainage connection medical tubes

### Class IIb medical devices, excluding implantable non-WET\*

Category	EMDN code	Medical devices/groups of medical devices
MDN 1201	R010501	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
MDN 1201	R010502	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
MDN 1201	R010503	TRACHEOSTOMY INNER CANNULAS

#### Intended purpose

Tracheostomy tubes are used to keep open a tracheostoma and enable the patient to breathe. Some versions allow phonation and, as a result, speech.

\* WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.