

# EU Quality Management System Certificate

Certificate no.  
0521GB448250410

Final Assessment Report no.  
0521AU38F

Effective date  
2025-04-10

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, 2025-04-10

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

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. 820111 EN Rev. 5 2023.11.28

NOTIFIED BODY 0482: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com



**DNV**

Certificate no.: [0521GB448250410](#)  
Place and date: [Hamburg, 2025-04-10](#)

### Preceding certificate

Certificate no.	Issue date	Identification of changes
0521GB448230725	2023-07-25	Addition of MDN 1202, Class Is, Class Ila MDN 1202 G020301 and A060203 and Class Ilb MDN 1201 R010501 and R010502
0521GB448230823	2023-08-23	Addition of Class Ila MDN 1214 R900602, R040201, MDN 1202 A060101 and Class Ilb 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 Ilb
0521GB448240709	2024-07-09	Addition of MDN 1202 EMDN A060102 and removal of reference to additional certificate under Class Ilb

### Sites covered by this certificate

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

## 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
MDN 1214	Is	General non-active non-implantable devices used in health care and other non-active non-implantable devices

### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1202	A060204	THORACENTES AND PARACENTESI DRAINAGES AND KITS
MDN 1202	A060203	PLEURAL DRAINAGES WITH VALVE AND KITS
MDN 1202	A060102	SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
MDN 1202	A060101	VACUUM AND GRAVITY DRAINAGE SYSTEMS
MDN 1202	G020301	RECTAL TUBES
MDN 1214	R030102	AIR/ OXYGEN MASKS AND CANNULAS
MDN 1214	R040101	ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS
MDN 1214	R040102	ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTER HUMIDIFIERS
MDN 1214	R040201	TRACHEOSTOMY HUMIDIFIERS
MDN 1214	R900602	PHONATION VALVES FOR TRACHEOSTOMY

### Class IIb medical devices

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