

EU Quality Management System Certificate

Certificate no.
0521GB448250613

Final Assessment Report no.
0521AU38F

Effective date
2025-06-13

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, 2025-06-13



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

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


Lorenz Runge
Certification Body Operations

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

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.dnv.com



Certificate no.: 0521GB448250613
Place and date: Hamburg, 2025-06-13

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
0521GB448240709	2024-07-09	Addition of MDN 1202 EMDN A060102 and removal of reference to additional certificate under Class IIb
0521GB448250410	2025-04-10	Correction of Typos and Addition of class IIa MDN 1201 (EMDN R010580 acc. to WO-011262) and MDN 1201 (EMDN R010501 / EMDN A060101 acc. to WO-013624 / WO-013625)
0521GB448250602A	2025-06-02	Addition of class IIa MDN 1201 (EMDN R010601 / EMDN R010603 acc. to WO-014440) and MDS 1011 (acc.to WO-014443)

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

Procedure packs according to Article 22, section 3

For procedure packs placed on the market in sterile condition, 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
MDS 1011	N/A	Devices in systems or procedure packs

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 1201	R010580	TRACHEOSTOMY AND LARYNGECTOMY CANNULAS – ACCESSORIES
MDN 1201	A060101	VACUUM AND GRAVITY DRAINAGE SYSTEMS
MDN 1201	R010501	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
MDN 1201	R010601	CIAGLIA TRACHEOSTOMY KITS
MDN 1201	R010603	GRIGGS TRACHEOSTOMY KITS
MDN 1202	A060204	THORACENTESIS AND PARACENTESIS 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 NASAL CANNULAS
MDN 1214	R040101	ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS
MDN 1214	R040102	ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS 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 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