EU Quality Management System Certificate

Certificate no.:	Final Assessment Report No.:	Effective date:	Expiry date:
0521GB448230823	0521AU35F	2023-08-23	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 Chapter I 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, 2023-08-23

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
Chief Certification

The certificate is only valid when provided entirely with all of its pages. To verify the vailidity of this certificate, contact info@medcert.de

Certificate no.: 0521GB448230823
Place and date: Hamburg, 2023-08-23

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
MDN 1202	Is	Non-active, non-implantable devices for administration, channelling and removal of substances, including devises 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 1202	G020301	Rectal Tubes
MDN 1202	A060203	Pleural Drainages with valve and kits

Class IIb medical devices

For placing on the market of class IIb medical devices covered by this certificate, an additional EU Type Examination Certificate according to Annex X of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

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

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.