

# EU Quality Management System Certificate

Certificate no.:  
0521GB448231026

Final Assessment Report No.:  
0521AU35F

Effective date:  
2023-10-26

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  
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, 2023-10-26**

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 [info@medcert.de](mailto:info@medcert.de)

  
**Lorenz Runge**  
Chief Certification

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

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](http://www.med-cert.com), [www.dnv.com](http://www.dnv.com)

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### 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



## 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 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 1202	G020301	Rectal Tubes
MDN 1202	A060203	Pleural Drainages with valve and kits
MDN 1202	A060101	Vacuum and gravity drainage systems

### 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
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.