

# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
0521GB448251028

Final Assessment Report no.  
0521AU39F

Effective date  
2025-10-28

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 & development, manufacturing and final product inspection/testing of  
**Medical devices/groups of medical devices at locations as 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, 2025-10-28



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
BS-MDR-096

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

A handwritten signature in blue ink, appearing to read 'Annika Chill'.  
Annika Chill  
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](mailto:medcert-info@dnv.com)

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

820111 EN Rev 7 2025.10.20

NOTIFIED BODY 0482: DNV MEDCERT GmbH  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, [www.dnv.com](http://www.dnv.com)

Certificate no.: [0521GB448251028](#)  
Place and date: [Hamburg, 2025-10-28](#)

## 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

## Preceding certificate

| <b>Certificate no.</b> | <b>Issue date</b> | <b>Identification of changes</b>   |
|------------------------|-------------------|--|
| 0521GB448230725        | 2023-07-25        | Addition of MDN 1202, Class Ia, 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)   |
| 0521GB448250613        | 2025-06-13        | Addition of class Ia MDN 1201 (acc. to WO-014643)  |

## 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 condition.

| Category | Medical devices/groups of medical devices |
|----------|---|
| MDS 1011 | 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 1201 | Is    | Non-active non-implantable devices for anaesthesia, emergency and intensive care  |
| 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, CUZZED   |
| 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