# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

| Certificate no. | Final Assessment Report no. | Effective date | Expiry date |
|---|---|---|---|
| 0521GB448260630 | 0521AU39F | 2026-06-30 | 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, 2026-06-30**

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**
**Brooktorkai 18, 20457 Hamburg, Germany**

**Markus Bianchi**
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 fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820111 EN Rev 9 2026.03.23

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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, Domplatz 34, 38820 Halberstadt, Germany

Primed Halberstadt Medizintechnik GmbH, Am Bahndamm 11, 38820 Halberstadt, Germany

## Preceding certificate

| Certificate no. | Issue date | Identification of changes |
|---|---|---|
| 0521GB448230725 | 2023-07-25 | Addition of MDN 1202, Class Is, Class IIa MDN 1202 G020301and 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 Is MDN 1201 (acc. to WO-014643) |
| 0521GB448251028 | 2025-10-28 | Correction preceding “Identification of changes” (addition of class IIa MDN 1202 EMDN A060204 (acc.to WO-013627), removal of MDS 1011, addition of class IIb MDN 1104 EMDN Z110103 and addition in class IIb MDN 1201 EMDN R010501 and R010502 of Intended Purpose (acc.to WO-015528) and R010503 of Intended Purpose (acc. to WO-015526) |

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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 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 LARYNGECTOMY 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 |

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## Class IIb medical devices

| Category | EMDN code | Medical devices/groups of medical devices |
|---|---|---|
| MDN 1201 | R010501 | TRACHEOSTOMY AND LARYNGECTOMY CANNULAS AND KITS, UNCUFFED |

**Intended purpose**

PRIMED® tracheostomy tubes for neonates and children are used to keep a tracheostoma open and allow the patient to breathe.

**Intented purpose**

Tracheostomy tubes are used to hold open a tracheostoma and permit the patient to breathe. Some versions allow phonation and, as a result, speech.

**Intended purpose**

PRIMEDIBUTTON® stoma buttons hold the tracheostoma open and counteract the tissue's tendencies to shrink.

**Intended purpose**

PRIMEDISILK® laryngectomy tubes are tracheostomy tubes made of silicone (silicone cannulas) which are particularly suitable for use in laryngectomized patients - especially when a normal tracheostomy tube is no longer required. They are used to hold open a tracheostoma and permit the patient to breathe. Some versions allow phonation and, as a result, speech.

**Intended purpose**

SILVER tracheostomy tubes stabilise the tracheostoma and keep it open, thereby facilitating breathing. Silver tracheostomy tubes with a voice function / silver speaking value can be used in patients with a completely or partially preserved larynx. They enable tracheostomized patients to speak.

**Intended purpose**

The Tracheo-Safe is a tracheostoma stent for holding open the tracheostoma. It provides access to bronchial toilet and is used during de-cannulation.

| | | |
|---|---|---|
| MDN 1201 | R010502 | TRACHEOSTOMY AND LARYNGECTOMY CANNULAS AND KITS, CUFFED |

**Intended purpose**

PRIMED® tracheostomy tubes for neonates and children are used to keep a tracheostoma open and allow the patient to breathe.

**Intended purpose**

Tracheostomy tubes are used to hold open a tracheostoma and permit the patient to breathe. Some versions allow phonation and, as a result, speech.

| | | |
|---|---|---|
| MDN 1201 | R010503 | TRACHEOSTOMY INNER CANNULAS |

**Intended purpose**

Inner cannulas are used to hold the tracheostomy tube open so that the lumen is not blocked by secretions. In combination with the corresponding tracheostomy tube, the inner cannulas help to hold the tracheostoma open and enable the patient to breathe. Versions with phonation openings are used in combination with a sieved outer cannula to allow the respiratory air to flow through the upper airways and thus permit phonation and speech.

## Class IIb implantable WET medical devices

WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.

| Category | EMDN code | Medical devices/groups of medical devices |
|---|---|---|
| MDN 1104 | Z110103 | BRACHYTHERAPY RADIATION INSTRUMENTS |

**Intended purpose**

Needles for the interstitial placement of gold markers in the prostate.

**Intended purpose**

The gold marker serve as prostate localization devices for the purpose of radiation therapy.