

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0521GB448260910

Final Assessment Report no.
0521AU40F

Effective date
2026-09-10

Expiry date
2031-06-18

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, 2026-09-10

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Brooktorkai 18, 20457 Hamburg, Germany



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

BS-MDR-096

Dr. Ralf Reimer-Guénon
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

NOTIFIED BODY 0482: DNV MEDCERT GmbH
Brooktorkai 18, 20457 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com



DNV

Certificate no.: 0521GB448260910
Place and date: Hamburg, 2026-09-10

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	Initial Issue
0521GB448260630	2026-06-30	Renewal Addition in class IIa of MDA 0308 EMDN A0601 acc. to WO-012867 and WO-012866; adjustment of base date acc. to WO-014791





DNV

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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
MDA 0308	A0601	SURGICAL DRAINAGE SYSTEMS
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

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.

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.

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 valve 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
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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
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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.