



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0542GB451230224

Final assessment report no.
0542AU29F

Effective date
2023-02-24

Expiry date
2025-01-27

This is to certify that the management system of
Medizintechnik Promedt GmbH
Kleiner Moorweg 4, 25436 Tornesch, Germany
Facility ID: F005743
With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard
ISO 13485:2016 and the following country-specific requirements

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
Brazil: RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2022-02-24

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

DNV MEDCERT is an MDSAP
authorised auditing organisation

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

Markus Bianchi
Director Certification Body

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

820114 EN Rev 5 2022.11.16

AUTHORISED UNIT: 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, www.dnv.com

Activities and products/services covered by this certificate

Design and development, and manufacture of

- Bloodlines
- Tubing systems for apheresis
- Connection tubes
- Infusion tubes
- Irrigation sets
- Grip plates for syringes
- Thorax drain containers
- Thorax drain-tubes
- Thorax drain systems
- Refill kits and their accessories for implantable pumps

Sites covered by this certificate

Medizintechnik Promedt GmbH, Kleiner Moorweg 4, 25436 Tornesch, Germany
Facility ID: F005743

Site-specific scope

Design and development, and manufacture of

- Bloodlines
- Tubing systems for apheresis
- Connection tubes
- Infusion tubes
- Irrigation sets
- Grip plates for syringes
- Thorax drain containers
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