



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0542GB451260114

Final assessment report no.
0542AU34F

Effective date
2026-01-20

Expiry date
2029-01-19

This is to certify that

Medizintechnik Promedt GmbH

Kleiner Moorweg 4, 25436 Tornesch, Germany

has introduced, applies and maintains a management system at the site(s) listed on the following page(s).

This management system has been audited and found to conform to the quality management systems 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, 2026-01-14

For the issuing office
DNV MEDCERT GmbH
Brooktorkai 18, 20457 Hamburg, Germany



Marcus Harder
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 fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. 820114 EN Rev 7 2026.01.13

MDSAP RECOGNIZED AUDITING ORGANIZATION: DNV MEDCERT GmbH
Brooktorkai 18, 20457 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com



Certificate no.: 0542GB451260114
Place and date: Hamburg, 2026-01-14

Activities and products/services covered by this certificate

Design and development, and manufacturing of

- Bloodlines
- Tubing systems for apheresis
- Infusion tubes
- Refill kits and their accessories for implantable pumps

Sites covered by this certificate and associated (partial) scopes

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

Site-specific scope

Design and development, and manufacturing of

- Bloodlines
- Tubing systems for apheresis
- Infusion tubes
- Refill kits and their accessories for implantable pumps

