



MANAGEMENT SYSTEM CERTIFICATE

Certificate no
20373GB451260602

Final assessment report no.
20373AU04F

Effective date
2026-06-02

Expiry date
2027-03-14

This is to certify that

VascoMed GmbH

Hertzallee 1, 79589 Binzen, 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 / Part 4
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)
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)
United States:	21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

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

Place and date
Hamburg, 2026-06-02

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



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


Marcus Harder
Certification Body Operations

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

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

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DNV

Certificate no.: [20373GB452260602](#)
Place and date: [Hamburg, 2026-06-02](#)

Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of

- Ablation catheters
- Catheters for stimulation and electrophysiology diagnostics

Sites covered by this certificate and associated (partial) scopes

VascoMed GmbH, Hertzallee 1, 79589 Binzen, Germany

Design and development, and manufacturing of

- Ablation catheters
- Catheters for stimulation and electrophysiology diagnostics

VascoMed GmbH, Eulerstrasse 1, 79589 Binzen, Germany

Manufacturing and distribution of

- Ablation catheters
- Catheters for stimulation and electrophysiology diagnostics

