



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000512922-PA-MDSAP-DNK

Initial certification date:
2020-04-12

Expiration Date:
2026-04-11

This is to certify that the management system of

MEDISTIM ASA

Økernveien 94, 0579 Oslo, Norway

REP F005915

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

A. Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

A. Medical Devices Regulations – Part 1- SOR 98/282

Japan:

A. MHLW Ministerial Ordinance 169, Article 4 to Article 68
B. PMD Act (as applicable)

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D

This certificate is valid for the following scope:

The design, development, manufacturing, distribution, and servicing of diagnostic ultrasound systems for the areas of cardiovascular, vascular and transplant surgery.

The design, development, manufacturing, and distribution of diagnostic ultrasound probes for the areas of cardiovascular, vascular and transplant surgery.

Place
Høvik

Effective Date:
2023-04-12



DNV is an MDSAP authorised
auditing organization



For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Yury Sumtsov
Certificate Authorizer

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

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

All our Certificates are in blockchain system and as a first step you can validate the certificate details by scanning the QR code on the Certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.



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Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Medistim ASA F005915	Økernveien 94, 0579 Oslo, Norway	Management, Research and Development, QA and Regulatory Affairs
Medistim ASA F005917	Bromsveien 17, 3183 Horten, Norway	Manufacture, Distribution, Servicing and Procurement

