



CERTIFICATE OF REGISTRATION

This is to certify that

Medistim ASA

Økernveien 94 Oslo 0579 Norway

D-U-N-S: 51-952-1751

Refer to Attachment to Certificate of Registration dated April 15, 2020 for additional certified sites operates a

Quality Management System

which complies with the requirements of

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

Australia:

- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

Brazil:

- RDC ANVISA n. 16/2013 - Good Manufacturing Practices
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009 - Vigilance

Canada:

- Medical Device Regulations SOR/98-282, Part 1

Japan:

- MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68
- Japan PMD Act (as applicable)

United States:

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

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

Certificate No.: CERT-0127427

File No.: 1051872

Issue Date: 2020-04-15

Original Certification Date: 2020-04-12

Certification Effective Date: 2020-04-12

Certificate Expiry Date: 2023-04-11

Heather Mahon

Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an authorized
MDSAP auditing organization.



Registered by:

QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.

To verify that this certificate is current, please refer to the SAI Global On-Line Certification Register:

https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_register/



ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0127427 issued on April 15, 2020

File No.		Effective Date
1051872	Medistim ASA Økernveien 94 Oslo 0579 Norway D-U-N-S: 51-952-1751 Management, Research and Development, Quality Assurance and Regulatory Affairs	April 12, 2020
1054593	Medistim ASA Bromsveien 17 Horten, Oslo 3183 Norway D-U-N-S: 73-056-1912 Operations/Production, Servicing and Procurement	April 12, 2020