DNV

EC CERTIFICATE
Full Quality Assurance System

Certificate no.:
10000322554-PA-NA-NOR Rev. 2.0

Initial certification date:
01 November 2019

Valid Until:
27 May 2024

This is to certify that the management system of

MEDISTIM ASA
Økernveien 94, 0579, Oslo, Norway

For design, production and final product inspection/testing of:
IMAGING AND VOLUME FLOWMETER PROBES

has been assessed and found to comply with respect to:
the conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

Place and date:
Høvik, 18 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

for **Bjørg Synnøve Nesgård**
Operations Manager Medical

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

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate History		
Revision	**Description**	**Issued Date**
0.0	Recertification and replacement of certificate number (previous certificate no.242086-2017-CE-NOR-NA-PS) due to the split	01-11-2019
1.0	New production site	02-03-2020
2.0	Re issuance of Certificate in new template	18-05-2021

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Invasive Vascular ultrasound system probes	Medistim Vascular TTFM Probes: PV101011, PV100021, PV100031, PV100032, PV100041, PV100042, PV100051, PV100052, PV100061, PV100062, PV100081, PV100082, PV100101, PV100102, PV100121, PV100122, PV100141, PV100142, PV100161, PV100162 Remark: On the probe the number of reuses is marked by a suffix after the part-number, if there is no suffix this indicates 50 reuse.	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 242093-2017-CE-NOR-NA-PS Rev 3.0

Sites covered by this certificate	
Site Name	**Site Address**
Manufacturer: Medistim ASA	Økernveien 94, 0579 Oslo, Norway
Factory: Medistim ASA	Bromsveien 17, 3183 Horten, Norway

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.