DNV

# EC CERTIFICATE
# Full Quality Assurance System

Certificate no.:
242086-2017-CE-NOR-NA-PS Rev. 4.0

Initial certification date:
15 September 2017

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**

pp **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 | Replaces certificate EU1410412 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460) | 15-09-2017 |
| 1.0 | Deleting Medistim Cardiac Output TTFM Probes: PR100251, PR100301, PR100351 | 03-05-2018 |
| 2.0 | Recertification & following devices are removed and replaced into their own certificates: Medistim Vascular TTFM Probes, Medistim Doppler Probe, Medistim Ultrasound Imaging Probe | 01-11-2019 |
| 3.0 | New Production site | 02-03-2020 |
| 4.0 | 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 QuickFit TTFM Probes:<br>PS101011, PS101012, PS100021, PS100022,<br>PS100031, PS100032, PS100041, PS100042,<br>PS100051, PS100052, PS100071, PS100072<br>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 reuses | III* |

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 242091-2017-CE-NOR-NA-PS Rev 2.0

**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.