Notified Body Confirmation Letter Reference: C686690

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Medistim ASA
Økernveien 94,
0579 Oslo
Norway
SRN Number: NO-MF-000002741

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 2024/05/31

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

André Fernandes
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Flow measurement probes Medistim QuickFit TTFM Probes*: PS101011 PS101012 PS100021 PS100022 PS100031 PS100032 PS100041 PS100042 PS100051 PS100052 PS100071 PS100072 Basic UDI-DI: 7070554TTFMPROBESNC	Class III	Not Applicable	242086-2017-CE-NOR-NA-PS Rev 4.0 242091-2017-CE-NOR-NA-PS Rev 2.0 DNV Product Assurance AS NB 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Flow measurement probes Medistim Vascular TTFM Probes*: PV101011 PV100021 PC100031 PV100032 PV100041 PV100042 PV100051 PV100052 PV100061 PV100062 PV100081 PV100082 PV100101 PV100102 PV100121 PV100122 PV100141 PV100142 PV100161 PV100162 Basic UDI-DI: 7070554TTFMPROBESNC	Class III	Not Applicable	10000322554-PA-NA-NOR Rev 2.0 242093-2017-CE-NOR-NA-PS Rev 3.0 DNV Product Assurance AS NB 2460
Medistim Ultrasound Imaging Probe (L15 probe) EL 1000015/ Basic UDI-DI: 7070554IMAGINGPROBESES	Class III	Not Applicable	10000322610-PA-NA-NOR Rev 2.0 242115-2017-CE-NOR-NA-PS Rev 2.0 DNV Product Assurance AS NB 2460
Medistim MiraQ Systems MQC0xxxx MQV0xxxx MQU0xxxx	Class IIa	Not Applicable	242036-2017-CE-NOR-NA-PS Rev 4.0

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Medistim MiraQ Systems with Imaging MQC1xxxx MQV1xxxx MQU1xxxx Basic UDI-DI: 7070554MIRAQSYSTEMSAE			DNV Product Assurance AS NB 2460
Medistim Doppler Probe PD110752 Basic UDI-DI: 7070554PDPROBES94	Class III	Not Applicable	10000322573-PA-NA-NOR Rev 2.0 242113-2017-CE-NOR-NA-PS Rev 2.0 DNV Product Assurance AS NB 2460

*On the probes the number of reuses is marked by a suffix after the part number, if there is no suffix this indicates 50 reuses.

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/25	C686690	Initial issue
2024/04/29	C686690	Updated the Model number of Doppler Probe and Flow Measurement vascular Probes

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe