EC Certificate
Full Quality Assurance System

Certificate No.: EU1410412 Date: 2016-06-27

Order No.: 293525

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Manufacturer:	Medistim ASA Økernveien 94 N-0579 Oslo Norway
Device categorie(s):	MD1202, Imaging and volume flowmeter probes
GMDN code:	17190, 61226
Models:	See page 2 and 3 to this certificate
Risk class as defined by the manufacturer:	III
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, incl. section 4.
Date of audit:	2014-03-05 and 2014-03-06
End of the validity:	2019-11-01
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Ragnar Stranger Christiansen
For Nemko AS

Nemko Norway
Nemko AS, Gaustadalléen 30, P.O. Box 73 Blindern, 0314 Oslo, Norway
TEL +47 22 96 03 30 FAX +47 22 96 05 50 EMAIL info@nemko.com
ENTERPRISE NUMBER NO974404532

EC Certificate
Full Quality Assurance System

Certificate No.: EU1410412 Date: 2016-06-27

Order No.: 293525

Manufacturer: Medistim ASA
Økernveien 94
N-0579 Oslo
Norway

Factory: Medistim ASA
Moloveien 10
N-3187 Horten
Norway

Certificate History:

Revision	Description	Issue Date
0.0	Re-certification	2014-10-24
1.0	Correction of a misprint in the field for Standards/provisions. Section 4 of Annex II of the EC-Directive 93/42/EEC, is included.	2014-12-02
2.0	Adding new devices	2015-09-22
3.0	Adding new device	2015-09-23
4.0	Adding new variant	2016-05-19
5.0	**Removed suffix form variants**	**2016-06-27**

The certificate referred to above, includes the following devices/models:

Coronary and Peripheral Probes, GMDN code: 61226:

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.

Medistim QuickFit TTFM Probes:

PQ101011, PQ101012, PQ100021, PQ100022,
PQ100031, PQ100032, PQ100041,
PQ100042, PQ100051, PQ100052,
PS101011, PS101012, PS100021,
PS100022, PS100031, PS100032,
PS100041, PS100042, PS100051,
PS100052, PS100071, PS100072

EC Certificate
Full Quality Assurance System

Certificate No.: EU1410412 Date: 2016-06-27

Order No.: 293525

Medistim Vascular TTFM Probes:

PB100021, PB100022, PB100031, PB100032, PB100041, PB100042,

PB100051, PB100052, PB100061, PB100062, PA100041,

PA100071, PA100072, PA100081, PA100082, PA100101, PA100102,

PA100121, PA100122, PA100142, PA100161, PA100211, PA100271

PV101011, PV100021, PV100031, PV100031, PV100032,

PV100041, PV100042, PV100051,

PV100052, PV100061, PV100062,

PV100081, PV100082, PV100082, PV100101,

PV100102, PV100121, PV100121,

PV100122, PV100141, PV100142, PV100161, PV100162

Medistim Doppler Probe:

PD110752

Medistim Cardiac Output TTFM Probes, GMDN code: 17190:

PR100251, PR100301, PR100351

Medistim Ultrasound Imaging probe, GMDN code: 61226:

EL100015

Nemko Norway
Nemko AS, Gaustadalléen 30, P.O. Box 73 Blindern, 0314 Oslo, Norway
TEL +47 22 96 03 30 FAX +47 22 96 05 50 EMAIL info@nemko.com
ENTERPRISE NUMBER NO974404532