



EC Certificate Full Quality Assurance System

Certificate No.: EU1406404

Date: 2015-10-29

Order No.: 263687

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 devices utilizing non-ionizing radiation
GMDN code:	See page 2 to this certificate
Models:	See page 2 to this certificate
Risk class as defined by the manufacturer:	IIb
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, with the exemption of section 4.
Date of audit:	2014-03-05/06
End of the validity:	2019-07-21
Nemko EC notification No.:	0470
Remarks:	This certificates replaces the certificate EU1406404 issued 2014-10-14

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.

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For Nemko AS

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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	Initial Certification	2014-06-27
1	Change of GMDN code	2014-10-14
2	Update of certificate	2015-10-29

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

Device Category	Model Name <small>*Complete list of Model names with "xxxx" is registered at the NB.</small>	GMDN Code
MD1202	Medistim MiraQ Systems MQC0xxxx MQV0xxxx MQU0xxxx	61227
MD1202	Medistim MiraQ systems with imaging MQC1xxxx, MQV1xxxx, MQU1xxxx	40763

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