



DNV

# EC CERTIFICATE

## Full Quality Assurance System

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Certificate no.:  
242036-2017-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 DEVICES UTILIZING NON-IONIZING RADIATION**

has been assessed and found to comply with respect to:  
**the conformity assessment procedure described in Annex II excluding section 4 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



  
Bjørg Synnøve Nesgård  
Operations Manager Medical

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

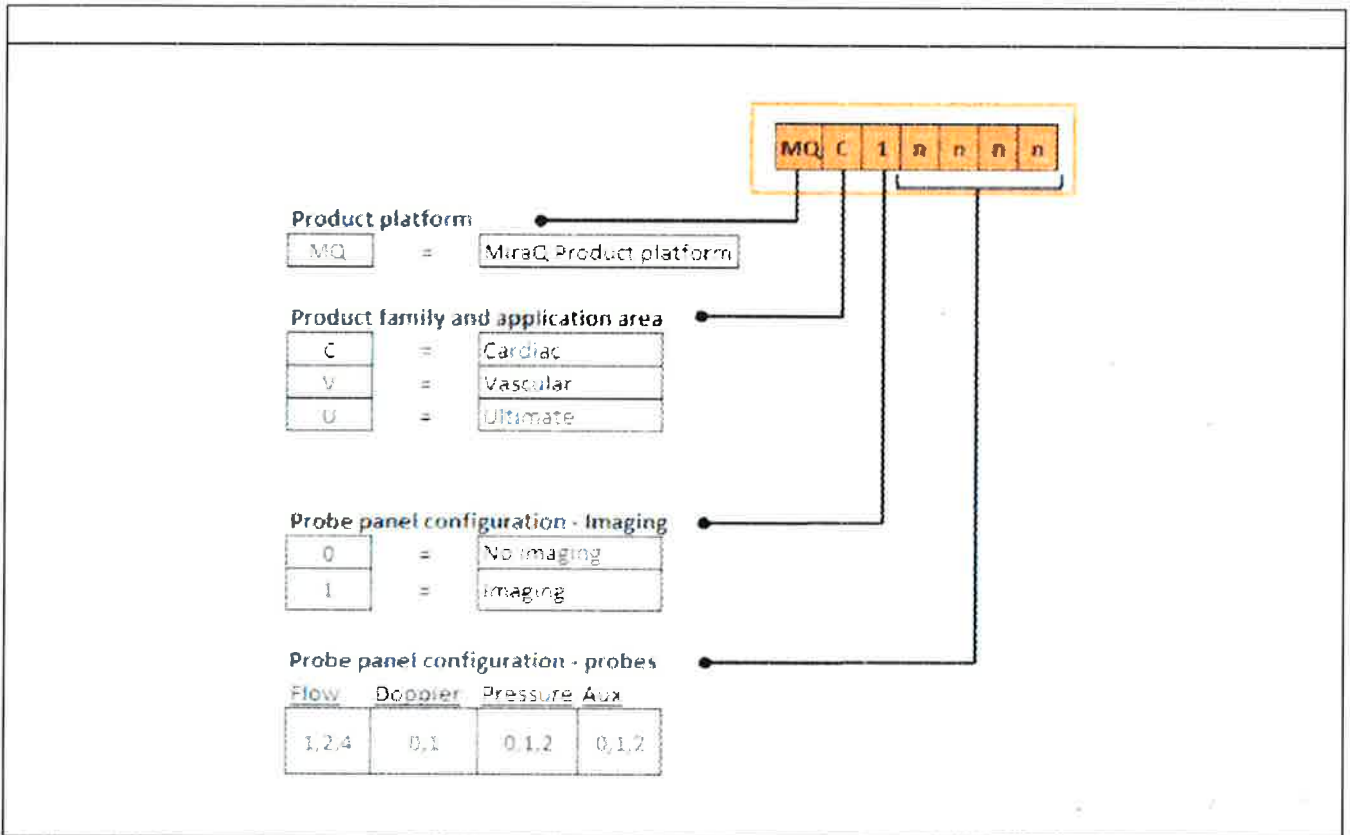
Notified Body 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

**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.

<b>Certificate History</b>		
<b>Revision</b>	<b>Description</b>	<b>Issued Date</b>
0.0	Replaces certificate EU1406404 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	15-09-2017
1.0	Corrected certificate history	27-09-2019
2.0	Re-certification	10-07-2019
3.0	New Production site	02-03-2020
<b>Products covered by this Certificate:</b>		
<b>Product Description</b>	<b>Product Name</b>	<b>Class</b>
Medistim MiraQ Systems	MQC0xxxx MQV0xxxx MQU0xxxx	Ila
Medistim MiraQ systems with imaging	MQC1xxxx, MQV1xxxx, MQU1xxxx	Ila

**The MiraQ model number structure**



Model name	GMDN code
MQC02000 MiraQ Cardiac System - 2 Flow	<b>61227</b>
MQC02001 MiraQ Cardiac System - 2 Flow, 1 AUX	
MQC02002 MiraQ Cardiac System - 2 Flow, 2 AUX	
MQC02010 MiraQ Cardiac System - 2 Flow, 1 Pressure	
MQC02011 MiraQ Cardiac System - 2 Flow, 1 Pressure, 1 AUX	
MQC02012 MiraQ Cardiac System - 2 Flow, 1 Pressure, 2 AUX	
MQC02020 MiraQ Cardiac System - 2 Flow, 2 Pressure	
MQC02021 MiraQ Cardiac System - 2 Flow, 2 Pressure, 1 AUX	
MQC02022 MiraQ Cardiac System - 2 Flow, 2 Pressure, 2 AUX	
MQC02100 MiraQ Cardiac System - 2 Flow, Doppler	
MQC02101 MiraQ Cardiac System - 2 Flow, Doppler, 1 AUX	
MQC02102 MiraQ Cardiac System - 2 Flow, Doppler, 2 AUX	
MQC02110 MiraQ Cardiac System - 2 Flow, Doppler, 1 Pressure	
MQC02111 MiraQ Cardiac System - 2 Flow, Doppler, 1 Pressure, 1	

AUX	
MQC02112 MiraQ Cardiac System - 2 Flow, Doppler, 1 Pressure, 2 AUX	
MQC02120 MiraQ Cardiac System - 2 Flow, Doppler, 2 Pressure	
MQC02121 MiraQ Cardiac System - 2 Flow, Doppler, 2 Pressure, 1 AUX	
MQC02122 MiraQ Cardiac System - 2 Flow, Doppler, 2 Pressure, 2 AUX	
MQC04000 MiraQ Cardiac System - 4 Flow	
MQC04001 MiraQ Cardiac System - 4 Flow, 1 AUX	
MQC04002 MiraQ Cardiac System - 4 Flow, 2 AUX	
MQC04010 MiraQ Cardiac System - 4 Flow, 1 Pressure	
MQC04011 MiraQ Cardiac System - 4 Flow, 1 Pressure, 1 AUX	
MQC04012 MiraQ Cardiac System - 4 Flow, 1 Pressure, 2 AUX	
MQC04020 MiraQ Cardiac System - 4 Flow, 2 Pressure	
MQC04021 MiraQ Cardiac System - 4 Flow, 2 Pressure, 1 AUX	
MQC04022 MiraQ Cardiac System - 4 Flow, 2 Pressure, 2 AUX	
MQC04100 MiraQ Cardiac System - 4 Flow, Doppler	
MQC04101 MiraQ Cardiac System - 4 Flow, Doppler, 1 AUX	
MQC04102 MiraQ Cardiac System - 4 Flow, Doppler, 2 AUX	
MQC04110 MiraQ Cardiac System - 4 Flow, Doppler, 1 Pressure	
MQC04111 MiraQ Cardiac System - 4 Flow, Doppler, 1 Pressure, 1 AUX	
MQC04112 MiraQ Cardiac System - 4 Flow, Doppler, 1 Pressure, 2 AUX	
MQC04120 MiraQ Cardiac System - 4 Flow, Doppler, 2 Pressure	
MQC04121 MiraQ Cardiac System - 4 Flow, Doppler, 2 Pressure, 1 AUX	
MQC04122 MiraQ Cardiac System - 4 Flow, Doppler, 2 Pressure 2 AUX	
MQV02000 MiraQ Vascular System - 2 Flow	
MQV02001 MiraQ Vascular System - 2 Flow, 1 AUX	

MQV02002 MiraQ Vascular System - 2 Flow, 2 AUX	
MQV02010 MiraQ Vascular System - 2 Flow, 1 Pressure	
MQV02011 MiraQ Vascular System - 2 Flow, 1 Pressure, 1 AUX	
MQV02012 MiraQ Vascular System - 2 Flow, 1 Pressure, 2 AUX	
MQV02020 MiraQ Vascular System - 2 Flow, 2 Pressure	
MQV02021 MiraQ Vascular System - 2 Flow, 2 Pressure, 1 AUX	
MQV02022 MiraQ Vascular System - 2 Flow, 2 Pressure, 2 AUX	
MQV02100 MiraQ Vascular System - 2 Flow, Doppler	
MQV02101 MiraQ Vascular System - 2 Flow, Doppler, 1 AUX	
MQV02102 MiraQ Vascular System - 2 Flow, Doppler, 2 AUX	
MQV02110 MiraQ Vascular System - 2 Flow, Doppler, 1 Pressure	
MQV02111 MiraQ Vascular System - 2 Flow, Doppler, 1 Pressure, 1 AUX	
MQV02120 MiraQ Vascular System - 2 Flow, Doppler, 2 Pressure	
MQV02121 MiraQ Vascular System - 2 Flow, Doppler, 2 Pressure, 1 AUX	
MQV02122 MiraQ Vascular System - 2 Flow, Doppler, 2 Pressure, 2 AUX	
MQV04000 MiraQ Vascular System - 4 Flow	
MQV04001 MiraQ Vascular System - 4 Flow, 1 AUX	
MQV04002 MiraQ Vascular System - 4 Flow, 2 AUX	
MQV04010 MiraQ Vascular System - 4 Flow, 1 Pressure	
MQV04011 MiraQ Vascular System - 4 Flow, 1 Pressure, 1 AUX	
MQV04012 MiraQ Vascular System - 4 Flow, 1 Pressure, 2 AUX	
MQV04020 MiraQ Vascular System - 4 Flow, 2 Pressure	
MQV04021 MiraQ Vascular System - 4 Flow, 2 Pressure, 1 AUX	
MQV04022 MiraQ Vascular System - 4 Flow, 2 Pressure, 2 AUX	
MQV04100 MiraQ Vascular System - 4 Flow, Doppler	
MQV04101 MiraQ Vascular System - 4 Flow, Doppler, 1 AUX	
MQV04102 MiraQ Vascular System - 4 Flow, Doppler, 2 AUX	

MQV04110 MiraQ Vascular System - 4 Flow, Doppler, 1 Pressure	
MQV04111 MiraQ Vascular System - 4 Flow, Doppler, 1 Pressure, 1 AUX	
MQV04112 MiraQ Vascular System - 4 Flow, Doppler, 1 Pressure, 2 AUX	
MQV04120 MiraQ Vascular System - 4 Flow, Doppler, 2 Pressure	
MQV04121 MiraQ Vascular System - 4 Flow, Doppler, 2 Pressure, 1 AUX	
MQV04122 MiraQ Vascular System - 4 Flow, Doppler, 2 Pressure 2 AUX	
MQU02000 MiraQ Ultimate System - 2 Flow	
MQU02001 MiraQ Ultimate System - 2 Flow, 1 AUX	
MQU02002 MiraQ Ultimate System - 2 Flow, 2 AUX	
MQU02010 MiraQ Ultimate System - 2 Flow, 1 Pressure	
MQU02011 MiraQ Ultimate System - 2 Flow, 1 Pressure, 1 AUX	
MQU02012 MiraQ Ultimate System - 2 Flow, 1 Pressure, 2 AUX	
MQU02020 MiraQ Ultimate System - 2 Flow, 2 Pressure	
MQU02021 MiraQ Ultimate System - 2 Flow, 2 Pressure, 1 AUX	
MQU02022 MiraQ Ultimate System - 2 Flow, 2 Pressure, 2 AUX	
MQU02100 MiraQ Ultimate System - 2 Flow, Doppler	
MQU02101 MiraQ Ultimate System - 2 Flow, Doppler, 1 AUX	
MQU02102 MiraQ Ultimate System - 2 Flow, Doppler, 2 AUX	
MQU02110 MiraQ Ultimate System - 2 Flow, Doppler, 1 Pressure	
MQU02111 MiraQ Ultimate System - 2 Flow, Doppler, 1 Pressure, 1 AUX	
MQU02112 MiraQ Ultimate System - 2 Flow, Doppler, 1 Pressure, 2 AUX	
MQU02120 MiraQ Ultimate System - 2 Flow, Doppler, 2 Pressure	
MQU02121 MiraQ Ultimate System - 2 Flow, Doppler, 2 Pressure, 1 AUX	
MQU02122 MiraQ Ultimate System - 2 Flow, Doppler, 2 Pressure, 2 AUX	
MQU04000 MiraQ Ultimate System - 4 Flow	
MQU04001 MiraQ Ultimate System - 4 Flow, 1 AUX	
MQU04002 MiraQ Ultimate System - 4 Flow, 2 AUX	
MQU04010 MiraQ Ultimate System - 4 Flow, 1 Pressure	
MQU04011 MiraQ Ultimate System - 4 Flow, 1 Pressure, 1 AUX	

<p>MQU04012 MiraQ Ultimate System - 4 Flow, 1 Pressure, 2 AUX</p> <p>MQU04020 MiraQ Ultimate System - 4 Flow, 2 Pressure</p> <p>MQU04021 MiraQ Ultimate System - 4 Flow, 2 Pressure, 1 AUX</p> <p>MQU04022 MiraQ Ultimate System - 4 Flow, 2 Pressure, 2 AUX</p> <p>MQU04100 MiraQ Ultimate System - 4 Flow, Doppler</p> <p>MQU04101 MiraQ Ultimate System - 4 Flow, Doppler, 1 AUX</p> <p>MQU04102 MiraQ Ultimate System - 4 Flow, Doppler, 2 AUX</p> <p>MQU04110 MiraQ Ultimate System - 4 Flow, Doppler, 1 Pressure</p> <p>MQU04111 MiraQ Ultimate System - 4 Flow, Doppler, 1 Pressure, 1 AUX</p> <p>MQU04112 MiraQ Ultimate System - 4 Flow, Doppler, 1 Pressure, 2 AUX</p> <p>MQU04120 MiraQ Ultimate System - 4 Flow, Doppler, 2 Pressure</p> <p>MQU04121 MiraQ Ultimate System - 4 Flow, Doppler, 2 Pressure, 1 AUX</p> <p>MQU04122 MiraQ Ultimate System - 4 Flow, Doppler, 2 Pressure 2 AUX</p>	
<p>MQC12000 MiraQ Cardiac System - 1 Imaging, 2 Flow</p> <p>MQC12001 MiraQ Cardiac System - 1 Imaging, 2 Flow, 1 AUX</p> <p>MQC12002 MiraQ Cardiac System - 1 Imaging, 2 Flow, 2 AUX</p> <p>MQC12010 MiraQ Cardiac System - 1 Imaging, 2 Flow, 1 Pressure</p> <p>MQC12011 MiraQ Cardiac System - 1 Imaging, 2 Flow, 1 Pressure, 1 AUX</p> <p>MQC12012 MiraQ Cardiac System - 1 Imaging, 2 Flow, 1 Pressure, 2 AUX</p> <p>MQC12020 MiraQ Cardiac System - 1 Imaging, 2 Flow, 2 Pressure</p> <p>MQC12021 MiraQ Cardiac System - 1 Imaging, 2 Flow, 2 Pressure, 1 AUX</p> <p>MQC12022 MiraQ Cardiac System - 1 Imaging, 2 Flow, 2 Pressure, 2 AUX</p> <p>MQC12100 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler</p> <p>MQC12101 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 1 AUX</p> <p>MQC12102 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 2 AUX</p> <p>MQC12110 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 1 Pressure</p> <p>MQC12111 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 1 Pressure, 1 AUX</p> <p>MQC12112 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 1 Pressure, 2 AUX</p>	<p><b>40763</b></p>

MQC12120 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 2 Pressure	
MQC12121 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 2 Pressure, 1 AUX	
MQC12122 MiraQ Cardiac System - 1 Imaging, 2 Flow, Doppler, 2 Pressure, 2 AUX	
MQC14000 MiraQ Cardiac System - 1 Imaging, 4 Flow	
MQC14001 MiraQ Cardiac System - 1 Imaging, 4 Flow, 1 AUX	
MQC14002 MiraQ Cardiac System - 1 Imaging, 4 Flow, 2 AUX	
MQC14010 MiraQ Cardiac System - 1 Imaging, 4 Flow, 1 Pressure	
MQC14011 MiraQ Cardiac System - 1 Imaging, 4 Flow, 1 Pressure, 1 AUX	
MQC14012 MiraQ Cardiac System - 1 Imaging, 4 Flow, 1 Pressure, 2 AUX	
MQC14020 MiraQ Cardiac System - 1 Imaging, 4 Flow, 2 Pressure	
MQC14021 MiraQ Cardiac System - 1 Imaging, 4 Flow, 2 Pressure, 1 AUX	
MQC14022 MiraQ Cardiac System - 1 Imaging, 4 Flow, 2 Pressure, 2 AUX	
MQC14100 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler	
MQC14101 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 1 AUX	
MQC14102 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 2 AUX	
MQC14110 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 1 Pressure	
MQC14111 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 1 Pressure, 1 AUX	
MQC14112 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 1 Pressure, 2 AUX	
MQC14120 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 2 Pressure	
MQC14121 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 2 Pressure, 1 AUX	
MQC14122 MiraQ Cardiac System - 1 Imaging, 4 Flow, Doppler, 2 Pressure 2 AUX	
MQV12000 MiraQ Vascular System - 1 Imaging, 2 Flow	
MQV12001 MiraQ Vascular System - 1 Imaging, 2 Flow, 1 AUX	
MQV12002 MiraQ Vascular System - 1 Imaging, 2 Flow, 2 AUX	
MQV12010 MiraQ Vascular System - 1 Imaging, 2 Flow, 1 Pressure	
MQV12011 MiraQ Vascular System - 1 Imaging, 2 Flow, 1 Pressure, 1 AUX	
MQV12012 MiraQ Vascular System - 1 Imaging, 2 Flow, 1 Pressure, 2 AUX	
MQV12020 MiraQ Vascular System - 1 Imaging, 2 Flow, 2 Pressure	



MQV12021 MiraQ Vascular System - 1 Imaging, 2 Flow, 2 Pressure, 1 AUX	
MQV12022 MiraQ Vascular System - 1 Imaging, 2 Flow, 2 Pressure, 2 AUX	
MQV12100 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler	
MQV12101 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 1 AUX	
MQV12102 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 2 AUX	
MQV12110 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 1 Pressure	
MQV12111 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 1 Pressure, 1 AUX	
MQV12112 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 1 Pressure, 2 AUX	
MQV12120 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 2 Pressure	
MQV12121 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 2 Pressure, 1 AUX	
MQV12122 MiraQ Vascular System - 1 Imaging, 2 Flow, Doppler, 2 Pressure, 2 AUX	
MQV14000 MiraQ Vascular System - 1 Imaging, 4 Flow	
MQV14001 MiraQ Vascular System - 1 Imaging, 4 Flow, 1 AUX	
MQV14002 MiraQ Vascular System - 1 Imaging, 4 Flow, 2 AUX	
MQV14010 MiraQ Vascular System - 1 Imaging, 4 Flow, 1 Pressure	
MQV14011 MiraQ Vascular System - 1 Imaging, 4 Flow, 1 Pressure, 1 AUX	
MQV14012 MiraQ Vascular System - 1 Imaging, 4 Flow, 1 Pressure, 2 AUX	
MQV14020 MiraQ Vascular System - 1 Imaging, 4 Flow, 2 Pressure	
MQV14021 MiraQ Vascular System - 1 Imaging, 4 Flow, 2 Pressure, 1 AUX	
MQV14022 MiraQ Vascular System - 1 Imaging, 4 Flow, 2 Pressure, 2 AUX	
MQV14100 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler	
MQV14101 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 1 AUX	
MQV14102 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 2 AUX	
MQV14110 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 1 Pressure	
MQV14111 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 1 Pressure, 1 AUX	
MQV14112 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 1 Pressure, 2 AUX	
MQV14120 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 2 Pressure	

MQV14121 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 2 Pressure, 1 AUX	
MQV14122 MiraQ Vascular System - 1 Imaging, 4 Flow, Doppler, 2 Pressure 2 AUX	
MQU12000 MiraQ Ultimate System - 1 Imaging, 2 Flow	
MQU12001 MiraQ Ultimate System - 1 Imaging, 2 Flow, 1 AUX	
MQU12002 MiraQ Ultimate System - 1 Imaging, 2 Flow, 2 AUX	
MQU12010 MiraQ Ultimate System - 1 Imaging, 2 Flow, 1 Pressure	
MQU12011 MiraQ Ultimate System - 1 Imaging, 2 Flow, 1 Pressure, 1 AUX	
MQU12012 MiraQ Ultimate System - 1 Imaging, 2 Flow, 1 Pressure, 2 AUX	
MQU12020 MiraQ Ultimate System - 1 Imaging, 2 Flow, 2 Pressure	
MQU12021 MiraQ Ultimate System - 1 Imaging, 2 Flow, 2 Pressure, 1 AUX	
MQU12022 MiraQ Ultimate System - 1 Imaging, 2 Flow, 2 Pressure, 2 AUX	
MQU12100 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler	
MQU12101 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 1 AUX	
MQU12102 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 2 AUX	
MQU12110 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 1 Pressure	
MQU12111 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 1 Pressure, 1 AUX	
MQU12112 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 1 Pressure, 2 AUX	
MQU12120 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 2 Pressure	
MQU12121 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 2 Pressure, 1 AUX	
MQU12122 MiraQ Ultimate System - 1 Imaging, 2 Flow, Doppler, 2 Pressure, 2 AUX	
MQU14000 MiraQ Ultimate System - 1 Imaging, 4 Flow	
MQU14001 MiraQ Ultimate System - 1 Imaging, 4 Flow, 1 AUX	
MQU14002 MiraQ Ultimate System - 1 Imaging, 4 Flow, 2 AUX	
MQU14010 MiraQ Ultimate System - 1 Imaging, 4 Flow, 1 Pressure	
MQU14011 MiraQ Ultimate System - 1 Imaging, 4 Flow, 1 Pressure, 1 AUX	
MQU14012 MiraQ Ultimate System - 1 Imaging, 4 Flow, 1 Pressure, 2 AUX	
MQU14020 MiraQ Ultimate System - 1 Imaging, 4 Flow, 2 Pressure	
MQU14021 MiraQ Ultimate System - 1 Imaging, 4 Flow, 2 Pressure, 1 AUX	

<p>MQU14022 MiraQ Ultimate System - 1 Imaging, 4 Flow, 2 Pressure, 2 AUX</p> <p>MQU14100 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler</p> <p>MQU14101 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 1 AUX</p> <p>MQU14102 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 2 AUX</p> <p>MQU14110 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 1 Pressure</p> <p>MQU14111 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 1 Pressure, 1 AUX</p> <p>MQU14112 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 1 Pressure, 2 AUX</p> <p>MQU14120 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 2 Pressure</p> <p>MQU14121 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 2 Pressure, 1 AUX</p> <p>MQU14122 MiraQ Ultimate System - 1 Imaging, 4 Flow, Doppler, 2 Pressure 2 AUX</p>	
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<b>Sites covered by this certificate</b>	
<b>Site Name</b>	<b>Site Address</b>
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.