

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 657862  
**Issued To:** **Myocardial Solutions, Inc.**  
**808 Aviation Parkway**  
**Suite 700**  
**Morrisville**  
**North Carolina**  
**27560**  
**USA**

In respect of:

**Design, development and manufacture of software for the quantification of cardiac MRI images.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-12-20**

Date: **2019-11-26**

Expiry Date: **2021-12-19**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 657862

Issued To:

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NBOG Code(s)	Device Description	Intended purpose
<b>Class IIa</b>		
MD 1111	Software for analysis of cardiac MRI images for quantification of cardiac function	N/A for Class IIa

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Page 2 of 2

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**27560**  
**USA**

**Subcontractor:**

**Service(s) supplied**

Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**EU Representative**

Myocardial Solutions Egypt  
7 Asmaa fahmi St.  
off Nabil Elwaqad Ard ElGolf  
Cairo  
Egypt

**Manufacture**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 657862**  
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Date	Reference Number	Action
20 December 2016	8570157	First Issue.
18 February 2019	8877581	Traceable to NB 0086.
Current	3055551	Change of legal manufacturer's address from Suite 117 Morrisville North Carolina 27560 to 808 Aviation Parkway, Suite 700 Morrisville, NC 27560 on the 30th June 2019. Change of address of the subcontractor Myocardial Solutions, Egypt from 12 Mohammed Bayomi St., behind Almazah Central, Cairo Egypt to 7 Asmaa fahmi St. off Nabil Elwaqad Ard ElGolf, Cairo Egypt. Change of address EU representative from Emergo Europe Molestraat 15 2513BH The Hague, The Netherlands To Emergo Europe B.V. Prinsessegracht 20 2514 AP The Hague, The Netherlands. Addition of product table.

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Page 1 of 1

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