

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 787253 R000

Manufacturer: Myocardial Solutions, Inc.

Address:

4819 Emperor Blvd.
Suite 140
Durham
North Carolina
27703
USA

Single Registration Number: US-MF-000018411

EU Authorised Representative: Emergo Europe

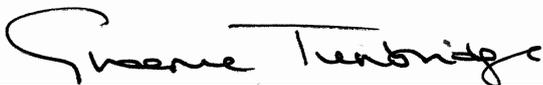
Address:

Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-11-24**

Current Issue Date: **2025-11-24**

Starting Validity Date: **2025-11-24**

Expiry Date: **2030-11-23**

...making excellence a habit.™

Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 787253 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Magnetic Resonance Imaging (MRI) Instrument – Medical Device Software	Class IIa



First Issue Date: **2025-11-24**

Current Issue Date: **2025-11-24**

Starting Validity Date: **2025-11-24**

Expiry Date: **2030-11-23**

...making excellence a habit.™

Page 2 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 787253 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3875177	Issued



First Issue Date: **2025-11-24**

Current Issue Date: **2025-11-24**

Starting Validity Date: **2025-11-24**

Expiry Date: **2030-11-23**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.