

# EU Quality Management System Certificate

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

## MDR 751424 R000

**Manufacturer:** Mercury Medical

**Address:**

11300 49th Street North  
Clearwater  
Florida  
33762  
USA

**Single Registration Number:** US-MF-000002015

**EU Authorised Representative:** Emergo Europe B.V.

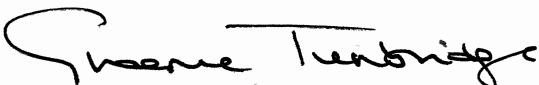
**Address:**

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 Medical Devices

First Issue Date: **2022-04-22**

Current Issue Date: **2023-05-24**

Starting Validity Date: **2023-05-24**

Expiry Date: **2027-04-21**

...making excellence a habit.™

# EU Quality Management System Certificate

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

## MDR 751424 R000

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

Device(s)	Risk Classification
Respiratory and Anaesthesia Devices	Class IIa
Manometers	Class Im

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.



First Issue Date: **2022-04-22**

Current Issue Date: **2023-05-24**

Starting Validity Date: **2023-05-24**

Expiry Date: **2027-04-21**

...making excellence a habit.™

# EU Quality Management System Certificate

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

## MDR 751424 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
2022-04-22	3449990	Issued
2022-05-20	3693539	Supplemented – Addition of Class Im Manometers. Amended – Addition of subcontractor Plaxtron Industrial (M) Sdn. Bhd.
2023-02-23	3854983	Amended - change of address of EU Authorised Representative to Emergo Europe, Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands. Amended – removal of subcontractors page.
Current	30000120	Supplemented – Device names replaced by the device category for Class IIa devices in the device schedule table following addition of T-Piece Resuscitators to scope.

First Issue Date: **2022-04-22**

Current Issue Date: **2023-05-24**

Starting Validity Date: **2023-05-24**

Expiry Date: **2027-04-21**

...making excellence a habit.™