

# 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.

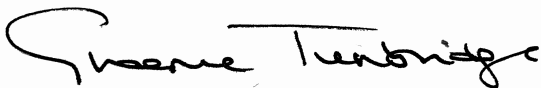
**Address:**

Prinsessegracht 20  
2514 AP The Hague  
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 and Class IIb implantable devices an 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 Issued: **2022-04-22**

Date: **2022-05-20**

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 |
|--|---------------------|
| Cardiopulmonary Resuscitation (CPR) Bags | 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 Issued: **2022-04-22**

Date: **2022-05-20**

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   |
| Current    | 3693539          | Supplemented – Addition of Class Im Manometers.<br>Amended – Addition of subcontractor Plaxtron Industrial (M) Sdn. Bhd. |



First Issued: **2022-04-22**

Date: **2022-05-20**

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

...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.

# EU Quality Management System Certificate

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

## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

### MDR 751424 R000

Date: 2022-05-20

| Critical Subcontractor/Crucial Supplier | Service(s) supplied |
|---|---------------------|
|---|---------------------|

|  |             |
|--|-------------|
| Plaxtron Industrial (M) Sdn. Bhd.<br>Plot 28, Kawasan Perusahaan Jelapang II<br>Zon Perdagangan Bebas,<br>Ipoh<br>Perak<br>30020<br>Malaysia | Manufacture |
|--|-------------|



...making excellence a habit.™