# 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**

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### 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. | |

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### 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.<br>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.<br>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. |

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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.

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