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**

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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.	

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

First Issued: **2022-04-22** Date: **2022-05-20** Expiry Date: **2027-04-21**

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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. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas, Ipoh Perak 30020 Malaysia	**Manufacture**

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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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