

EU Quality Management System Certificate

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

MDR 803378 R000

Manufacturer: Sunny Medical Device (Shenzhen) Co., Ltd

Address:

1/F and 401 Zhongtianxin Building B
Longgang District
Shenzhen
Guangdong
518172
China

Single Registration Number: CN-MF-000022722

EU Authorised Representative: CMC Medical Devices & Drugs SL

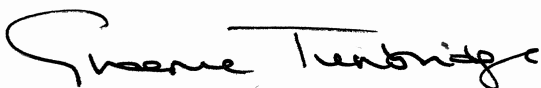
Address:

C/ Horacio Lengo N18
CP 29006
Málaga
Spain

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: **2025-05-05**

Current Issue Date: **2025-05-05**

Starting Validity Date: **2025-05-05**

Expiry Date: **2030-05-04**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Disposable invasive blood pressure transducer	Monitoring central venous pressure, arterial pressure, pulmonary artery pressure, left atrial pressure etc. and to provide objective evidence for clinical diagnosis, therapy and prognosis



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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
Current	3576883	Issued



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