EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 761322 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 XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X 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: **2023-04-27**

Current Issue Date: **2024-01-25**

Starting Validity Date: **2024-01-25**

Expiry Date: **2028-04-26**

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

Device(s)	Risk Classification
Disposable manifold kits	Class IIa
Manifold and stopcocks	Class IIa
Disposable needles	Class IIa
Pressure lines	Class IIa
Guide Wires	Class IIa
Haemostatic valves	Class IIa
Disposable inflation device kits	Class IIa
Disposable balloon inflation devices	Class Is
Disposable angio-closure pads	Class Is
Control syringes	Class Is
Disposable TR-closure band/radiseals	Class Is
Disposable heparin caps	Class Is
Disposable towel/sheet clips	Class Is
Banded bag with elastic opening	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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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
2023-04-27	3576883	Issued
2023-09-08	30007284	Amended – change of EU Authorised Representative to CMC Medical Devices & Drugs SL
Current	30093550	Supplemented – addition of banded bag with elastic opening

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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.

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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