

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Sunny Medical Device
(Shenzhen) Co., Ltd.
1/F and 401
Zhongtianxin Building B
Longgang District
Shenzhen
Guangdong
518172
China

Facility ID Number: F000428

Holds Certificate No:

MDSAP 693001

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

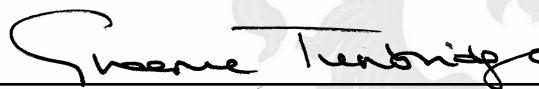
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-10-19

Effective Date: 2024-10-19

Expiry Date: 2027-10-18



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 693001**

Registered Scope:

The manufacture and sterilization of control syringes, manifold and stopcocks, guide wires, haemostatic valves, pressure lines, disposable balloon inflation devices, disposable needles, disposable inflation device kits, disposable manifold kits, disposable TR-Closure Band/Radiseals, disposable angio-closure pads, disposable heparin caps and disposable towel/sheet clips.



Original Registration Date: 2018-10-19

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.