

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN 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

深圳市听力医疗设备开发有限公司
中国
广东省
深圳市
龙岗区龙城街道
龙平西路4号
中天信B厂区厂房1楼、401
邮编：518172

Holds Certificate No: **MD 638744**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following 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

一次性使用环柄注射器、一次性使用医用连通器、一次性使用造影导丝、一次性使用Y型连接器套件、
高压造影注射延长管、一次性使用球囊压力泵、一次性使用穿刺针、一次性使用球囊压力泵套件、一次性使用医用连通器套件、一次性使用挠动脉止血器、一次性使用股动脉止血器、一次性使用肝素帽和一次性使用床单夹的制造。

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-02-19

Effective Date: 2019-01-04

Latest Revision Date: 2019-01-04

Expiry Date: 2021-10-18



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.