

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

质量管理体系 ISO 13485:2016

This is to certify that: **Sunny Medical Device (Shenzhen) Co., Ltd.**  
兹证明  
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  
914403007488755871  
中国  
广东省  
深圳市  
龙岗区  
中天信B厂区厂房1楼、401  
邮编: 518172

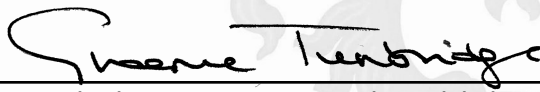
Holds Certificate No: **FM 659381**  
持有证书

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

并运行符合 ISO 13485:2016 要求的质量管理体系, 认证范围如下:

Please see scope page.

For and on behalf of BSI:  
BSI代表:

  
Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期: 2016-09-19

Effective Date 生效日期: 2024-10-19

Latest Revision Date 最新发证日期: 2024-08-21

Expiry Date 有效期至: 2027-10-18

Page: 1 of 2



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. 此证书的所有权属于BSI并受合同条款的约束

An electronic certificate can be authenticated [online](#). 可以 [在线](#) 查询电子证书的有效性。

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +86 10 8507 3000.

打印的证书可以通过网站 <http://www.bsi-global.com/ClientDirectory> 或者致电 +86 10 8507 3000 查询。

The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration ([www.cnca.gov.cn](http://www.cnca.gov.cn))

本证书信息亦可在国家认证认可监督管理委员会官方网站 ([www.cnca.gov.cn](http://www.cnca.gov.cn)) 上查询。

The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

信息查询及联系方式: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | 电话: +31 20 3460 780 BSI集团荷兰有限公司, 注册地荷兰, 注册号 33264284 | BSI集团控股有限公司成员

China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部(北京): 北京市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

Certificate No.

**FM 659381**

持有证书:

## 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, disposable towel/sheet clips and banded bag with elastic opening.

Design and development, manufacture and sterilization of disposable invasive blood pressure transducer.

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、一次性使用床单夹和C臂罩的制造。 一次性使用有创血压传感器的设计、开发和制造。



Original Registration Date 首次发证日期: 2016-09-19

Effective Date 生效日期: 2024-10-19

Latest Revision Date 最新发证日期: 2024-08-21

Expiry Date 有效期至: 2027-10-18

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. 此证书的所有权属于BSI并受合同条款的约束

An electronic certificate can be authenticated [online](#). 可以 [在线](#) 查询电子证书的有效性。

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +86 10 8507 3000.

打印的证书可以通过网站 <http://www.bsi-global.com/ClientDirectory> 或者致电 +86 10 8507 3000 查询。

The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration ([www.cnca.gov.cn](http://www.cnca.gov.cn))

本证书信息亦可在国家认证认可监督管理委员会官方网站 ([www.cnca.gov.cn](http://www.cnca.gov.cn)) 上查询。

The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

信息查询及联系方式: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | 电话: +31 20 3460 780 BSI集团荷兰有限公司, 注册地荷兰, 注册号 33264284 | BSI集团控股有限公司成员

China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。