

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

质量管理体系 ISO 13485:2016

This is to certify that: Sanbor Medical Xiamen, Inc.  
兹证明 5F  
Suiwa High Technology Elec. Industry Park  
1776 Lvling Road  
Xiamen  
Fujian  
361008, China

声普医疗设备（厦门）有限公司  
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福建省  
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吕岭路1776号  
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邮编：361008

Holds Certificate No: **MD 764383**  
持有证书

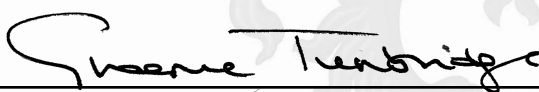
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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

Design, development and manufacture of active medical devices used for clinical analysis of in vitro fertilization cultivation and monitoring, organ delivery systems, non-sterile surgical instruments, printed circuit board assemblies, and related electronic components and plastic molding components.

用于体外受精培养的临床分析和监护的有源医疗器械、器官输送系统、非无菌手术器械、印刷电路板组装，以及相关的电子组件和塑料成型部件的设计、开发和生产。

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： 2022-06-27

Latest Revision Date 最新发证日期： 2025-06-17

Effective Date 生效日期： 2025-06-27

Expiry Date 有效期至： 2028-06-26

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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。

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