



此为证书 CN15/30833 译本

下述组织

深圳普门科技股份有限公司

中国广东省深圳市南山区松白路 1008 号艺晶公司 15 栋四楼 A



的管理体系已经过审核, 并被证明符合下述要求

ISO 13485:2016 EN ISO 13485:2016

所涉及的活动范围覆盖

所涉及的活动范围显示在第二页

该证书的有效期自 2018-08-9 至 2021-07-12
并须经过符合要求的监督审核保持有效
持续认证需在 2021-06-19 之前执行
版本号 5. 初始注册日期 2015-07-13

该证书为多地址证书, 其它具体地址在后续页上列出

签署



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HC SGS 13485 2016 0118 M2

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深圳普门科技股份有限公司

ISO 13485:2016 EN ISO 13485:2016

Issue 5

所涉及的活动范围覆盖

光子治疗仪(用于伤口消炎和止痛)、结肠水疗仪(治疗便秘)、
红外治疗仪(用于肌肉和关节消炎镇痛)、脉冲磁治疗仪(用于骨
科疾病)、空气波压力治疗系统(预防静脉血栓和肺栓塞)、多功
能清创仪(用于人体伤口的超声清创)、高频振动排痰系统(用于
辅助排痰)、紫外线治疗系统(用于皮肤病辅助治疗)和医用真空
负压机(NPWT 治疗)以及糖化血红蛋白分析仪、特定蛋白分析
仪、免疫荧光分析仪、化学发光免疫分析仪的设计和制造
非灭菌硅凝胶敷料的设计和生
用于诊断肾功能、心血管病、糖代谢、风湿病、甲状腺功能,以
及诊断早孕反应和炎性反应的试剂盒的开发和生产

附属机构

深圳市南山区松白路 1008 号艺晶公司 15 栋一楼 B、C 区, 四楼
深圳市光明新区公明办事处楼村社区鲤鱼河工业区振兴路 37 号
F 栋 2 楼 B 区、G 栋 4 楼



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Certificate CN15/30833

The management system of

Shenzhen Lifotronic Technology Co., Ltd.

Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R. China



has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 9 August 2018 until 12 July 2021 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 19 June 2021 Issue 5. Certified since 13 July 2015

This is a multi-site certification. Additional site details are listed on the subsequent page.

Authorised by

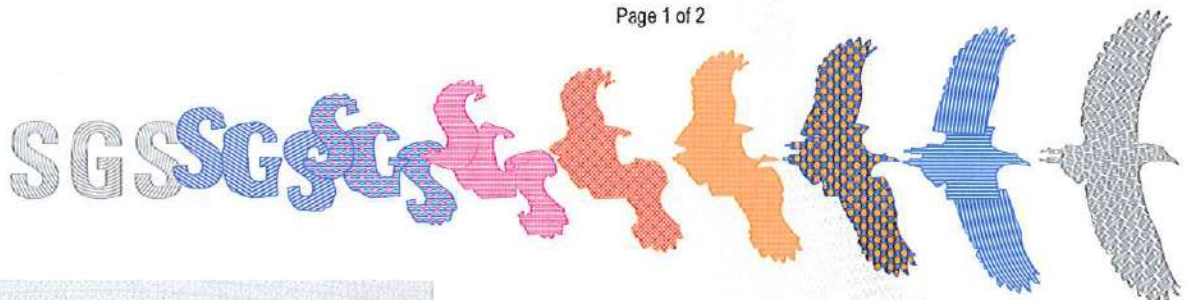


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Shenzhen Lifotronic Technology Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016



Issue 5

Detailed scope

Design and manufacture of Phototherapy Devices (for anti inflammation and pain management of wound), Hydrotherapy System (for constipation treatment), Infrared Light Therapy System (for pain management of muscle and joint), Pulse Magnetic Therapy System (for orthopaedic diseases), Air Compression Therapy System (prevent deep vein thrombosis and pulmonary embolism), Wound Clean System (for ultrasound debridement of wounds), Airway Clearance System (assistant discharge of sputum and murus), Ultraviolet Phototherapy System (for assistant treatment of skin diseases), Negative Pressure Wound Therapy Device, Hemoglobin Analyzer (HPLC) and HbA1c Analyser, Specific Protein Analyzer, Lateral Flow Immunoassay Analyzer, and Automated Electrochemiluminescence(ECL) Immunoassay Analyzer;
Design and manufacture of Non Sterile Silicone Gel Dressing;
Development and manufacture of in vitro diagnostic assay kits for determining kidney, cardiovascular, glycometabolism, rheumatic, thyroid diseases; determining human chorionic gonadotrophin and inflammatory response



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Additional facilities

4th Floor and Unit B and C of 1st Floor, Building 15, Yijing Estate,
No.1008 Songbai Road, Nanshan District, Shenzhen City,
Guangdong Province, 518055, P.R. China

4th Floor, Building G & Unit B of 2nd Floor, Building F, No. 37 Zhenxing Road, Liyuhe
Industrial Park, Loucun Community, Gongming Street, Guangming New District,
Shenzhen City, Guangdong Province, 518107, P.R. China