



Certificate CN15/30833

The management system of

# Shenzhen Lifotronic Technology Co., Ltd.

Unit A, 4<sup>th</sup> 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 13 July 2021 until 12 July 2024 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 19 June 2024

Issue 9. Certified since 13 July 2015

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

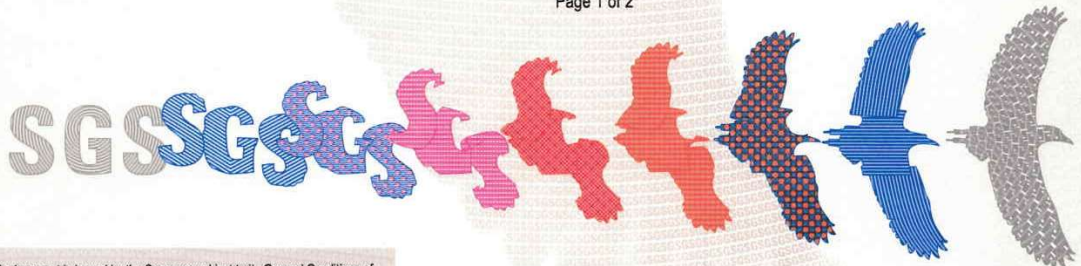


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SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

HC SGS 13485 2016 0118 M2

Page 1 of 2



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# Shenzhen Lifotronic Technology Co., Ltd.

## ISO 13485:2016 EN ISO 13485:2016



Issue 9

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 Analyzer, Specific Protein Analyzer, Lateral Flow Immunoassay Analyzer, Automated Electrochemiluminescence (ECL) Immunoassay Analyzer, Fully Automated Urine ACR Analyzer and Hemostasis Analyzer; Development and manufacture of in vitro diagnostic assay kits for determining coagulation, anemia, liver fibrosis, bone metabolism, gastric function, kidney, cardiovascular, glycometabolism, rheumatic, thyroid diseases; determining human chorionic gonadotrophin and inflammatory response.**

Additional facilities

No. 2 Zhanghua Road, Songshan Lake Park,  
Dongguan City, Guangdong Province, 523808, P.R. China



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