

Certificate CN19/41020

The quality management system of

Guangzhou Longest Science & Technology Co., Ltd.

5 & 6F, Building B4, No. 11, Kaiyuan Avenue, Science City, Guangzhou Hi-tech Industrial Development Zone, 510530, Guangzhou, Guangdong Province, China

Facility Identification Number: F002982

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Australia:

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil Jurisdictions

RDC ANVISA n. 16/2013 - Good Manufacturing Practices

RDC ANVISA n. 23/2012

RDC ANVISA n. 67/2009 - Vigilance

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

United States:

21 CFR Part 803 - Medical Device Reporting

21 CFR Part 806 - Reports of Corrections and Removals

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing

21 CFR Part 820 - Quality System Regulation

For the following activities

Design and manufacture of Electrical Extracorporeal Shock Wave Therapy Device,
Compression Therapy Device, Portable Electro Stimulation Therapy Device,
Active Passive Trainer for Upper and Lower Limbs

This certificate is valid from Effective Date: 21 March 2022 Expiry Date: 28 January 2025 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 23 November 2024.

Issue 3. Certified since 24 March 2019.

Authorised by



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