Certificate CN17/30568

The quality management system of

Famidoc Technology Co., Ltd.

No. 212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town, Dongguan, Guangdong Province, 523853, P.R. China

Facility number: F001063

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System; Therapeutic Goods (Medical Devices) Regulations 2002
Canada: Medical Devices Regulations – Part 1 SOR 98/282
Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68; PMD Act
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, manufacture and distribution of Infrared Thermometers, Digital Clinical Thermometers, Upper Arm Electronic Blood Pressure monitor, and Electrical Stimulators for relief of pain and Muscle Re-education for treatment of patients with muscular atrophy.

This certificate is valid from Effective date 2022-12-16 until Expiry date 2025-07-25 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2017-06-26

Authorised by
Geofrey De Visscher
Head of NB1639

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com