The management system of

Lily Medical Corporation

No.28-2, Shun Jeau Diann, Chunan Town, Miaoli County, 35056, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

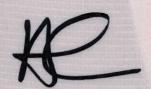
For the following activities

1. Design and manufacture of sterile and non-sterile products including intravascular administration set (infusion sets, volume metric administration sets, infusion accessories, extension tubings), urine collector and accessories (urodynamic bags), blood access device and accessories (blood tubing lines, fistula needles), tracheobronchial suction catheter (suction catheters, suction catheter kits), irrigating syringe (irrigation sets), venous blood pressure manometer (CVP manometers), urological catheter and accessories (silicon foley catheter, ureteral catheters), tracheostomy tube and tube cuff (tracheostomy tube) and Spinal fluid manometer. 2. Design and manufacture of non-sterile products including heat and moisture condenser (artificial noses) and nonpowered single patient portable suction apparatus (suction liner bags).

3. Providing commercial Ethylene Oxide Sterilization, validation service for medical device in accordance with EN ISO11135: 2014 requirements.

This certificate is valid from 05 January 2022 until 21 August 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 6. Certified since 21 August 2012 Expiry date of last certificate: 31 December 2021 End date of last recertification audit: 01 October 2021

Authorised by



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

21HC 13485 2016 0421

Page 1 of 1











This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. titention is drawn to the limitations of liability, indemnification and jurisdictional nmon is drawn to the limitations of nations, more manufactured that is easier than the entire that the state of this document may be to !!/www.sgs.com/en/certified-clients-and-products/certified-client unauthorized alteration, forgery or falsification of the content or a jof this document is unlawful and offenders may be prosecuted to