Certificate CN21/968401

The management system of

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.
Wickimed Supply Company Limited

Tang Jiao XingWang Street, LiLin Town, ZhongKai Hi Tech Zone, HuiZhou, GuangDong, 516035, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities
Design and Manufacture of Non sterile reusable electrosurgical pencil with electrode, Sterile single use electrosurgical pencil with electrode, Sterile single use electrode, Sterile single use bipolar forceps, Grounding pad, Sterile single use laparoscopic trocar, Sterile single use specimen retrieval bag, Sterile single use veress needle, Sterile single use suction irrigation tubing set.
Manufacture of Sterile single use tip cleaner, Sterile single use surgical smoke evacuation pencil, Non sterile single use syringe without needle.
Manufacture of Cable used in active medical devices (non-implantable).
Provision of Contract Ethylene Oxide Processing service for single use medical device.

This certificate is valid from 13 September 2024 until 01 December 2027 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 01 December 2006

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by
Liz Moran
Business Manager

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Certificate CN21/968401, continued

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.
Wickimed Supply Company Limited

ISO 13485:2016
EN ISO 13485:2016

Issue 4

Sites

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.
Tang Jiao XingWang Street, LiLin Town, ZhongKai Hi Tech Zone, HuiZhou, GuangDong, 516035, P.R. China

Design and Manufacture of Non sterile reusable electrosurgical pencil with electrode, Sterile single use electrosurgical pencil with electrode, Sterile single use electrode, Sterile single use bipolar forceps, Grounding pad, Sterile single use laparoscopic trocar, Sterile single use specimen retrieval bag, Sterile single use veress needle, Sterile single use suction irrigation tubing set.
Manufacture of Sterile single use tip cleaner, Sterile single use surgical smoke evacuation pencil, Non sterile single use syringe without needle.
Manufacture of Cable used in active medical devices (non-implantable).
Provision of Contract Ethylene Oxide Processing service for single use medical device.

Wickimed Supply Company Limited
Room 317, 3/F, Genplas Industrial Building, 56 Hoi Yuen Road, Kwun Tong, Kowloon, Hong Kong

Order receipt management in support of Design and Manufacture of Non sterile reusable electrosurgical pencil with electrode, Sterile single use electrosurgical pencil with electrode, Sterile single use electrode, Sterile single use bipolar forceps, Grounding pad, Sterile single use laparoscopic trocar, Sterile single use specimen retrieval bag, Sterile single use veress needle, Sterile single use suction irrigation tubing set, Manufacture of Sterile single use tip cleaner.

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.
5th Floor, Building D, No. 3 Nandi Road, Yingguang Village, Lilin Town, Zhongkai High-Tech Zone, Huizhou, Guangdong, 516035, P.R. China

EO sterilization management in support of Design and Manufacture of Sterile single use electrosurgical pencil with electrode, Sterile single use electrode, Sterile single use bipolar forceps, Sterile single use laparoscopic trocar, Sterile single use specimen retrieval bag, Sterile single use veress needle, Sterile single use suction irrigation tubing set. Manufacture of Sterile single use tip cleaner, Sterile single use surgical smoke evacuation pencil, Provision of Contract Ethylene Oxide Processing service for single use medical device.

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