

Certificate US19/819943430

The quality management system of

# Kirwan Surgical Products LLC

180 Enterprise Drive, Marshfield, MA 02050, United States Of America  
Facility number: F004229

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

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 - Field Actions; RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Devices Regulations (SOR/98-282) Part 1 - General

Japan: Japan PMD Act (as applicable), MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)

USA: 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 Development, Production, Servicing, and Distribution of Sterile and Non-sterile Electro-surgical Handpieces, Bipolar Coagulators and Handpieces with Cords for the areas of surgery.

This certificate is valid from Effective date 2025-07-21 until Expiry date 2027-03-30 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2019-10-16



Authorised by

Lynn Henderson

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - [www.sgs.com](http://www.sgs.com)

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at [www.SGS.com](http://www.SGS.com).



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

