

Certificate Number US19/819943430

The quality management system of



Kirwan Surgical Products LLC

180 Enterprise Drive, Marshfield, MA, 02050, United States

Facility identification number : F004229

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 (excluding Part 1.6) – Full Quality Assurance Procedure (including design)

Brazil:

RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68 / PMD Act

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

Design and Development, Production and Distribution of Sterile and Non-Sterile Electrosurgical Handpieces, Bipolar Coagulators and Handpieces with Cords for the areas of surgery.

This certificate is valid from

Effective Date: 2021-10-20 until Expiry Date: 2024-03-30

and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-03-07

Issue 2. Certified since 2019-10-16

Authorised by L Henderson
Business Manager

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