Certificate US19/819943289

The quality management system of

Olsen Medical, LLC

3230 Commerce Center Place, Louisville, KY, 40211, United States Of America

Facility Identification Number: F003262

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 - Full Quality Assurance System
Brazil Jurisdictions
RDC ANVISA n. 16/2013 - Good Manufacturing Practices
RDC ANVISA n. 23/2012
RDC ANVISA n. 67/2009 - Vigilance
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
Japan 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 and devices
Design, Manufacture, service and distribution of Sterile and non-sterile monopolar and bipolar forceps; Sterile and non-sterile monopolar and bipolar cables; Sterile and non-sterile electrodes; Sterile disposable irrigating bipolar forceps; Sterile disposable electrosurgical pencils and sets (including pads and holsters); Non-sterile electrosurgical handles, Sterile electrosurgical monopolar adaptors, and sterile single use irrigating cables, non-sterile vaginal speculums for the areas of general surgery.

This certificate is valid from Effective Date: 19 July 2022 until Expiry Date: 06 June 2025
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 April 2025

Issue 2. Certified since 25 July 2019.

Authorised by

L. Henderson

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