Certificate US19/819943289

The quality management system of

Olsen Medical LLC

6945 Southbelt Dr SE, Caledonia, MI 49316, United States of America
Facility number: F003262

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
Canada: Medical Devices Regulations (SOR/98-282) Part 1 - General
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, Manufacture, 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 2025-06-06 until Expiry date 2028-06-06 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 2019-07-25

L. Henderson

Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.