Certificate US01/52676

SCS

The management system of

Olsen Medical, LLC.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

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 pencil sets (including pads and holsters); Non-sterile electrosurgical handles, Sterile electrosurgical monopolar suction coagulators, Non-sterile extension/adaptor cables and Non-sterile monopolar adaptors, and sterile single use irrigating cables, non-sterile vaginal speculums.

This certificate is valid from 06 June 2022 until 06 June 2025 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 16. Certified since 07 June 2001

Authorised by



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