

Certificate Number US19/819943289



The management system of

Olsen Medical, LLC.

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

Dun & Bradstreet D-U-N-S identification number : 07-934-4210

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

See second page for the scope.

The certificate is valid from
Effective Date: 2019-07-25 until Expiry Date: 2022-07-24
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-05-26
Issue 1. Certified since 2019-07-25

Authorised by J Hall
Business Manager



Jonathan M. Hall

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MDSAP M2

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Certificate Number US19/819943289, continued

The management system of

SGS

Olsen Medical, LLC.

MDSAP (ISO 13485:2016)

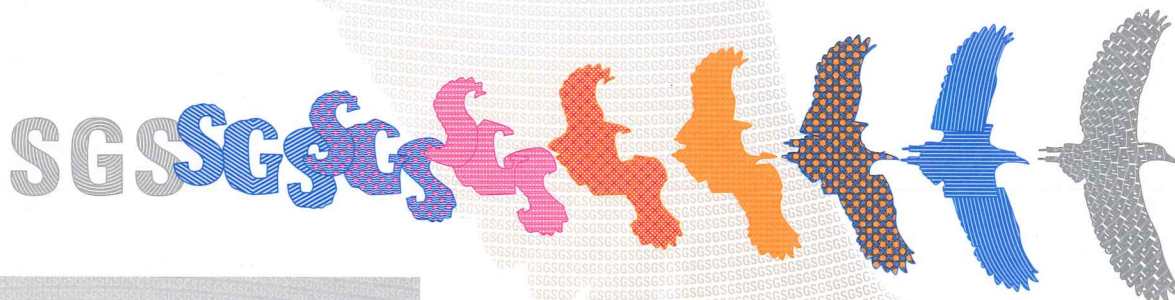
Issue 1



Detailed scope

**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.**

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM



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