EC Certificate Full Quality Assurance System: Certificate US19/819943659

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile disposable and non-sterile reusable monopolar and bipolar forceps; Sterile disposable and non-sterile reusable electrodes; Sterile disposable irrigating bipolar forceps; Sterile disposable electrosurgical pencil sets; Sterile electrosurgical monopolar suction coagulators.

Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions
• Sterile monopolar and bipolar cables
• Sterile cleaning pads for cleaning tips of ES devices
• Sterile Single Use Holsters for holding electrosurgical electrodes during procedures.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 31 August 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 07 June 2001
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MC 201832

Authorised by

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