

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 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 20 May 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 5. 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

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.