

The management system of

XcellLance Medical Technologies Pvt. Ltd.

W-239, Rabale MIDC, TTC Industrial Area
Rabale, Navi Mumbai - 400 701, India

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

Electrosurgical Unit (Diathermy) for cutting and Coagulation of body tissues,
CO2 Insufflator with OR without smoke evacuation feature,
Suction Irrigation Pump with OR without suction feature
Reusable Bipolar Laparoscopic Handles with various end effectors and cables,
Reusable Monopolar Laparoscopic Handles with various end effectors and cables

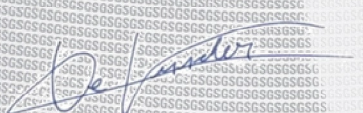
Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 18 May 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 19 February 2015

Certification is based on reports numbered IN/MUM 235606

Authorised by


Global Medical Devices Head of Notified Body

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



SGS

Certificate IN15/92699

The management system of

XcelLance Medical Technologies Pvt. Ltd.

W-239, Rabale MIDC, TTC Industrial Area,
Rabale, Navi Mumbai - 400 701, India

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 09 February 2021 until 18 February 2024
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 11 October 2023

Issue 3. Certified since 19 February 2015

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



0005



This document is issued by the Company subject to its General Conditions of Certification Services 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 <http://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.

XcellLance Medical Technologies Pvt. Ltd.

ISO 13485:2016
EN ISO 13485:2016



Issue 3

Detailed scope

Design, Development, Manufacture, Sale, Installation and Servicing
of Electro medical devices and accessories namely Electrosurgical
Generators (Diathermy), Argon Plasma Coagulator, CO2 Insufflators,
LED Light source, OT/surgical light, Suction Irrigation System.
Design, Development, Manufacture and Sale of Footswitch,
Bipolar Laparoscopic Handles with various end effectors and cables,
Monopolar Laparoscopic Handles with various end effectors
and cables, Laparoscopic Grasper with various end effectors.
Monopolar Pencil with various electrodes for open surgery.
Procurement and Sale of Surgical Table with Accessories,
Electrosurgical Monopolar, Bipolar,
Saline Resection and Vessel sealing accessories



0005