EC Certificate Full Quality Assurance System: Certificate IN19/818843701

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

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

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

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