EC Certificate Production Full Quality Assurance System: Certificate GB19/964561



The management system of

LaproSurge Limited

5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire, WD18 0FN, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions

For the following products

Sterile smoke venting filter Sterile laparoscopic camera sleeves Sterile disposable monopolar cables

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

This certificate is valid from 01 April 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 01 October 1999.

Certification is based on reports numbered GB/PC/ 06917

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

LPMD5008 - Certificate CE1639 AnnexV EN Rev. 02

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The management system of

LaproSurge Limited

5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire, WD18 0FN, UK

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 Laparoscopic Instruments for single use:

Sterile Monopolar Laparoscopic Scissors, Graspers & Dissectors

Sterile Disposable Diathermy Electrodes

Sterile Bipolar disposable Maryland Forceps

Sterile suction Irrigation sets with irrigation/aspiration probes

with or without Diathermy

Sterile Insufflation Needle

Sterile Tissue retrieval system

Sterile Insufflation tubing

Sterile Endoscopic Anti-Fog Solution with pad

Sterile Trocar & Cannula and Trocar Site Closure Device

Sterile Disposable laparoscopic Blunt Tipped Dissectors

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 01 April 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 01 October 1999.

Certification is based on reports numbered GB/PC 06917

Authorised by

Global Medical Devices Head of Notified Body

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The management system of

SGS

LaproSurge Limited

5b Fishers Industrial Estate Wiggenhall Road WD18 0FN Watford Hertfordshire United Kingdom

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The design, manufacture and distribution of sterile single-use equipment for endoscopic and laparoscopic procedures. The sales and distribution of sterile single-use and non-sterile reusable equipment for endoscopic and laparoscopic procedures.

This certificate is valid from 20 November 2023 until 08 November 2026 and remains valid subject to satisfactory surveillance audits. Issue 5. Certified since 08 November 2017

Last certificate expiry date 08 November 2023 Recertification audit date 02 August 2023

Jordhan M. Hall

Authorised by Jonathan Hall Global Head - Certification Services

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





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Certificate GB17/873441

The management system of

LaproSurge Ltd

SGS

Unit 5B Fishers Industrial Estate Wiggenhall Road Watford WD18 0FN United Kingdom

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

The sales and distribution of sterile single-use and non-sterile reusable equipment for endoscopic and laparoscopic procedures.

This certificate is valid from 08 November 2023 until 08 November 2026 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 08 November 2017

Jorothan M. Hell

Authorised by Jonathan Hall Global Head - Certification Services

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







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