LaproSurge Ltd
Unit 5B Fishers Industrial Estate
Wiggenhall Road
Watford Hertfordshire
WD18 0FN
UK

23/05/2024

Confirmation Letter Reference: CLNB1639 - GBPC 06917

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

LaproSurge Ltd
Unit 5B Fishers Industrial Estate
Wiggenhall Road
Watford Hertfordshire
WD18 0FN
UK
SRN: GB-MF-000018684

Authorised Representative:
Advena Limited
Tower Business Centre, 2nd Floor
Tower Street
Swatar
BKR 4013
Malta.
SRN: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB identification
Sterile smoke venting filter, sterile laparoscopic camera sleeves, sterile disposable monopolar cables. 506018996PVF-SmoVen3X	Class Is	Sterile smoke venting filter	N/A	GB19/964561; NB1639
Sterile Monopolar Laparoscopic Scissors, Graspers & Dissectors 506018996LG/LS-MonopolMA	Class IIb	Sterile Monopolar Lapraroscopic Scissors, Graspers & Dissectors.	N/A	GB19/964570; NB1639
Sterile Disposable Diathermy Electrodes 506018996HE/SE-DiaEleAB	Class IIb	Sterile Disposable Diathermy Electrode		GB19/964570; NB1639
Sterile Bipolar disposable Maryland Forceps 506018996BPM-BiForFS	Class IIb	Sterile Bipolar disposable Maryland forceps		GB19/964570; NB1639
Sterile suction Irrigation sets with irrigation/aspiration probes with or without Diathermy -506018996MDHDP-SuIrrWiOE2 -506018996MDHDP-SucirrWithDF	Class IIb	-Sterile Suction Irrigation sets with irrigation/aspiration probes with Diathermy - Sterile Suction Irrigation sets with irrigation/aspiration probes with or without Diathermy		GB19/964570; NB1639

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile Insufflation Needle 506018996VN-InsNee6N	Class IIa	Sterile Insufflation Needle	N/A	GB19/964570; NB1639
Sterile Tissue retrieval system 506018996EP/RB-TisRetTR	Class IIa	Sterile Tissue Retrieval System:	N/A	GB19/964570; NB1639
Sterile Insufflation tubing 506018996FT-InsTubYV	Class IIa	Sterile Insufflation tubing	N/A	GB19/964570; NB1639
Sterile Endoscopic Anti-Fog Solution with pad 506018996FG-AntiFogKV	Class IIa	Sterile Endoscopic Anti-Fog Solution with pad	N/A	GB19/964570; NB1639
Sterile Trocar & Cannula and Trocar Site Closure Device 506018996EC-TroCanP9	Class IIa	Sterile Trocar & Cannula	N/A	GB19/964570; NB1639

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
23/05/2024	Version 1	Initial issue