Version: 2.0

Date: 25/10/21

EU Declaration of Conformity
for Trocars and Cannula

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Trocars and Cannula
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Trocar series have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments into the body cavity of patients.
MDD Classification:	Class IIa, Rule 7
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIa - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:** GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

Appendix II – Product Listing/Schedule

Bladed Trocar & Cannula Sets 70, 100 and 150mm Working Lengths

Part/Catalogue Number	Description/Name	GMDN Code
EC3SSP(GT)	3mm Cannula with gas tap and pyramidal trocar, 60mm length	42412
EC3SSPT(GT)	3mm Threaded Cannula with gas tap and pyramidal trocar, 60mm length	42412
EC5DL	2 x 5mm Cannula with gas tap, 1 x retractable blade trocar 100mm length	42412
EC5DS	2 x 5mm Cannula with gas tap, 1 x retractable blade trocar, 70mm length	42412
EC5SL	5mm Cannula with gas tap and retractable blade trocar, 100mm length	42412
EC5SL-C	5mm Cannula with gas tap 100mm length, without trocar	42412
EC5SLS	5mm Smooth Cannula with gas tap retractable blade trocar, 100mm length	42412
EC5SLT	5mm Cannula with gas tap retractable blade trocar, 100mm length (threaded sleeve)	42412
EC5SS	5mm Cannula with gas tap retractable blade trocar, 70mm length	42412
EC5SS-C	5mm Cannula with gas tap 70mm length, without trocar	42412
EC5SXL-C	5mm Cannula with Gas tap, 150mm length, without Trocar	42412
EC10DL AUTO	2 x 10/11mm Cannula with gas tap and automatic reducing valve. Retractable blade trocar, 100mm length	42412
EC10SL AUTO	10/11mm Cannula with gas tap and automatic reducing valve. Retractable blade trocar, 100mm length	42412
EC10SL-C AUTO	10/11mm Cannula with gas tap and automatic reducing valve. 100mm length, without trocar	42412
EC10SLS AUTO	10/11mm cannula with gas tap and automatic reducing valve. Retractable blade trocar, 100mm length	42412
EC12DL AUTO	2 x 10/12mm Cannula with gas tap and automatic reducing valve. 1 x Retractable blade trocar, 100mm length	42412
EC12SL AUTO	10/12mm Cannula with gas tap and automatic reducing valve. Retractable blade trocar, 100mm length	42412
EC12SL-C AUTO	10/12mm Cannula with gas tap and automatic reducing valve. 100mm length, without trocar	42412
EC12SXL AUTO	10/12mm Cannula with gas tap and auto reducing valve. Retractable blade trocar, 150mm length	42412
EC12SXL-C AUTO	10/12mm Cannula with gas tap and automatic reducing valve. 150mm length, without trocar	42412

Bladeless Trocar & Cannula Sets 60, 70, 100 and 150mm Working Lengths

Part/Catalogue Number	Description/Name	GMDN Code
EC3SS-C	3mm Cannula without Gas Tap, without trocar, 60mm length	42412
EC3SSB	3mm Cannula without Gas Tap and bladeless trocar, 60mm length	42412
EC3SSB(GT)	3mm Threaded Cannula with gas tap and bladeless trocar, 60mm length	42412
EC3SSBT(GT)	5mm Balloon Cannula and optical trocar, 100mm length	42412
EC3SST(GT)-C	3mm Threaded Cannula with gas tap, without trocar, 60mm length	42412
EC5DLB	2 x 5mm Cannula with gas tap and 1 x bladeless trocar, 100mm length	42412
EC5DSB	2 x 5mm Cannula with gas tap and 1 x bladeless trocar, 70mm length	42412
EC5SLB	5mm Cannula with gas tap and bladeless trocar, 100mm length	42412
EC5SLBT	5mm Cannula with gas tap and bladeless trocar, 100mm length (threaded sleeve)	42412
EC5SSB	5mm Cannula with gas tap and bladeless trocar, 70mm length	42412
EC10DLB AUTO	2 x 10/11mm Cannula with gas tap and automatic reducing valve, 1 x bladeless trocar, 100mm length	42412
EC10SLB AUTO	10/11mm Cannula with gas tap and automatic reducing valve, bladeless trocar, 100mm length	42412

EC10SXLB AUTO	10/11mm Cannula with gas tap and automatic reducing valve, bladeless trocar, 100mm length	42412

Part/Catalogue Number	Description/Name	GMDN Code
EC12DLB AUTO	2 x 10/12mm Cannula with gas tap and automatic reducing valve, 1 x bladeless trocar, 100mm length	42412
EC12SLB AUTO	10/12mm Cannula with gas tap and automatic reducing valve, bladeless trocar 100mm length	42412
EC12SXLB AUTO	10/12mm Cannula with gas tap and automatic reducing valve, bladeless trocar, 150mm length	42412
EC15 SLB	15mm Cannula with gas tap and reducing valve converter, bladeless trocar 100mm length	42412

Hasson Trocar & Cannula 100mm Working Length

Part/Catalogue Number	Description/Name	GMDN Code
EC10SHL AUTO	10/11mm Hasson Trocar and Cannula with automatic reducing valve, 100mm length	42412
EC12SHL AUTO	10/12mm Hasson Trocar and Cannula with automatic reducing valve, 100mm length	42412

Optical Trocar & Cannula Sets

Part/Catalogue Number	Description/Name	GMDN Code
EC5DL-O	5mm Optical Trocar and 2 x Cannula with gas tap, 100mm length	42412
EC5SL-O	5mm Optical Trocar and Cannula with gas tap, 100mm length	42412
EC5SS-O	5mm Optical Trocar and Cannula with gas tap, 70mm length	42412
EC5SXL-O	5mm Optical Trocar and Cannula with gas tap, 150mm length	42412
EC10SL-O AUTO	10/11mm Optical Trocar and Cannula with gas tap and automatic reducing valve, 100mm length	42412
EC12SL-O AUTO	10/12mm Optical Trocar and Cannula with gas tap and automatic reducing valve, 100mm length	42412
EC12SXL-O AUTO	10/12mm Optical Trocar and Cannula with gas tap and auto reducing valve, 150mm length	42412

Trocar Cannula Reducer

Part/Catalogue Number	Description/Name	GMDN Code
EC10/12 AUTO-R	10/12mm-5mm Auto Reducing Seal	42412

Balloon Cannula & Trocar Sets

Part/Catalogue Number	Description/Name	GMDN Code
BC5SS-O	5mm Balloon Cannula and optical trocar,with retention disc, 70mm length	42412
BC5SS-C	5mm Balloon Cannula 70 mm length, without trocar	42412
BC5SL	5mm Balloon Cannula and bladed trocar, with retention disc, 100mm length	42412
BC5SL-O	5mm Balloon Cannula and optical trocar, 100mm length	42412
BC5SL-C	5mm Balloon Cannula 100mm length, without trocar	42412
BC10SLR AUTO	10mm Balloon Cannula and bladed trocar, with retention disc, 100mm length	42412
BC10SLR-C AUTO	10mm Balloon Cannula 100mm length, with retention disc, without trocar	42412
BC10SLR-O AUTO	10mm Balloon Cannula and optical trocar with retention disc, 100mm length	42412
BC12SL-C AUTO	10/12mm Balloon Cannula 100mm length, without trocar	42412
BC12SHL AUTO	10/12mm Balloon Cannula and Hasson trocar, 100mm length	42412
BC12SL-O AUTO	10/12mm Balloon Cannula and optical trocar, 100mm length	42412
BC12SLR-C AUTO	10/12mm Balloon Cannula, 100mm length with retention disc, without trocar	42412
BC12SLR-O AUTO	10/12mm Balloon Cannula and optical trocar with retenton disc, 100mm length	42412

Thoracic Trocars

Part/Catalogue Number	Description/Name	GMDN Code
TC6S	6mm Thoracic cannula with blunt trocar	63275
TC11S	11mm Thoracic cannula with blunt trocar	63275
TC13S	13mmThoracic cannula with blunt trocar	63275
TC15S	15mm Thoracic cannula with blunt trocar	63275

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

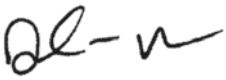
EU Declaration of Conformity
for Tissue Retrieval System

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Tissue Retrieval System
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The LaproSurge Tissue Retrieval System is indicated for use as a receptacle for the collection and extraction of tissues, organ and calculi during general and laparoscopic surgery procedures.
MDD Classification:	Class IIa, Rule 7
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIa - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:**GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed  **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
EP001	4" x 6.5" (10 x 16cm) Endo Pouch with memory wire (volume 200ml) for use with a 10/12mm trocar	45130
EP002	6" x 7" (15 x 18cm) Endo Pouch with memory wire (volume 680ml) for use with a 10/12mm trocar	45130
MRB002	Mini endo pouch with 5mm delivery system and detachable bag 6.5" x 2.5" (16.5cm x 6cm), volume 120ml	45130
RB001	Non-detachable endo pouch tissue retrieval system 4" x 6.5" (10cm x 16cm) 255ml volume for use with a 10/12mm trocar	45130
RB001-T	Non-detachable tapered endo pouch tissue retrieval system 4" x 6.5" (10com x 16cm) 200ml volume for use with a 10/12mm trocar	45130
RB002	Detachable endo pouch tissue retrieval system with detachable bag 4" x 6.5" (10 x 16cm) 255ml volume, for use with a 10/12mm trocar	45130
RB002-T	Detachable tapered endo pouch tissue retrieval system with detachable bag 4" x 6.5" (10cm x 16cm) 200ml volume, for usewith a 10/12mm trocar	45130
RB003	Non-detachable large endo pouch tissue retrieval system 6" x 7" (15cm x 18cm) 680ml volume for use with a 10/12mm trocar	45130
RB004	Detachable large endo pouch tissue retrieval system with detachable bag, 6" x 7" (15cm x 18cm) 680ml volume for use with a 10/12mm trocar	45130
RB006	Detachable extra large endo pouch tissue retrieval system with detachable bag, 7.5" x 9" (19cm x 23cm) 1500ml, for use with a 15mm trocar	45130
RB008	Detachable extra large endo pouch tissue retrieval system with detachable bag, 7.5" x 9" (19cm x 23cm) 1500ml volume, for use with a 12mm trocar	45130

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity

for Suction Irrigation and Irrigation/Aspiration probes without Diathermy

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Suction Irrigation and Irrigation/Aspiration probes without Diathermy
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Suction Irrigation set is a sterile multifunctional instrument which achieve up to 3 functions in one, Suction, Irrigation and Coagulation. Single packed accessories are available as following: Monopolar L hook, Spatula, probes.
MDD Classification:	Class IIa, Rule 7
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIa - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:** GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 25th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
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EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems
EN ISO 60601-2-2:2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
MD001-5	Trumpet Valve with 5mm x 330mm probe with holes with Dual Spike Tubing Set	60793
MD002-5	Trumpet Valve with 5mm x 330mm probe with holes with Single Spike Tubing Set	60793
MD001-45	Trumpet Valve with 5mm x 450mm probe with holes with Dual Spike Tubing Set	60793
MD001-3	Trumpet Valve with 3mm x 330mm probe with holes with Dual Spike Tubing Set	60793
MD001-3S	Trumpet Valve with 3mm x 230mm probe with holes with Dual Spike Tubing Set	60793
HDP002(S)	10mm Suction Irrigation Probe 330mm length, for use with MD001 series only	60793
HDP003(S)	10mm Suction Irrigation Probe 450mm length, for use with MD001 series only	60793
HDP004(S)	5mm Suction Irrigation Probe 450mm length, for use with MD001 series only	60793
HDP001-3	3mm Suction Irrigation Probe 330mm length, for use with MD001 series only	60793
HDP001-3S	3mm Suction Irrigation Probe 230mm length, for use with MD001 series only	60793

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity

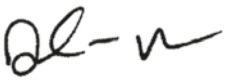
for Suction Irrigation and Irrigation/Aspiration probes with Diathermy

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC , and the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices.

The undersigned declares that the products described in this document meet the European Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Suction Irrigation and Irrigation/Aspiration probes with Diathermy
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Suction Irrigation set is a sterile multifunctional instrument which achieve up to 3 functions in one, Suction, Irrigation and Coagulation. Single packed accessories are available as following: Monopolar L hook, Spatula, and Electrode probes.
MDD Classification:	Class IIb, Rule 9
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIb - Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive **Certificate:** GB19/964570

Name David Campbell **Position** CEO, LaproSurge Ltd

Signed  **Place** **Hertfordshire, UK**

Date 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile

	barrier systems and packaging systems
EN ISO 60601-2-2:2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
HDP-HE(S)	5mm L-Hook-Electrode 330mm length, monopolar, for use with MD001 series only	58039
HDP-SE (S)	5mm Spatula Electrode 330mm length, monopolar, for use with MD001 series only	58039
MD001-HE	Trumpet Valve with 5mm L-Hook Electrode with Dual Spike Tubing Set	60793

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity
for Smoke Venting Filter

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Smoke Venting Filter
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Clearflow™ is a passive flow filter system used in laparoscopic surgery to evacuate smoke, particulates and aerosolized pathogens from the abdominal cavity without loss of pneumoperitoneum.
MDD Classification:	Class Is, Rule I
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class Is - [EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V] **Certificate: GB19/964561**

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th October 2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
PVF001	ClearFlow™ passive automatic laparoscopic smoke venting filter (standard)	44979
PVF002	ClearFlow™ Ultra for use with lasr/ultrasonics (hydrophillic)	44979

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity
for Monopolar Laparoscopic Scissors, Graspers & Dissectors

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Monopolar Laparoscopic Scissors, Graspers & Dissectors
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	This device is intended to be used in laparoscopic operation. Probe intends to grasp, manipulate, cut, and cauterize soft tissue and organs or take samples from the body of patient during the surgical procedures requiring the use of Monopolar electrosurgery.
MDD Classification:	Class IIb, Rule 9
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIb - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:** GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th May 2024

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This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems
EN ISO 60601-2-2:2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
LG001-T	5mm Atraumatic Grasper with ratchet rotatable, 330mm working length, double action jaws, monopolar	58039
LG002-T	5mm Clinch Grasper with ratchet rotatable, 330mm working length, double action jaws, monopolar	58039
LG003-T	5mm Claw Grasper with ratchet rotatable, 330mm working length, double action jaws, monopolar	58039
LG004-T	5mm Babcock Grasper with ratchet rotatable, 330mm working length, double action jaws, monopolar	58039
LG005-3	3mm Curved Dissector rotatable, 310mm working length, double action jaws, monopolar	58039
LG005-3S	3mm Curved Dissector, short rotatable, 230mm working length, double action jaws, monopolar	58039
LG005-T	5mm Curved Dissector Rotatable, 330mm working length, double action jaws, monopolar	58039
LG006-3	3mm Johan Grasper rotatable, 310mm working length, double action jaws, monopolar	58039
LG006-3S	3mm Johan Grasper rotatable, 230mm working length, double action jaws, monopolar	58039
LG006-T	5mm Johan Grasper with ratchet rotatable, 330mm working length, double action jaws, monopolar	58039
LG007-T	5mm Johan Grasper with ratchet rotatable, 330mm working length, single action 22mm jaws, monopolar	58039
LG008-T	5mm Johan Grasper with ratchet rotatable, 345mm working length, single action 40mm jaws, monopolar	58039
LG009-T	5mm Johan Grasper with ratchet rotatable, 450mm working length, single action 40mm jaws, monopolar	58039
LS001	5mm Curved Scissors 330mm length, 17mm blade, monopolar	58039
LS003	5mm fully insulated curved (Metzenbaum) sharp tip scissors, 330mm length, 17mm blades, monopolar	58039
LS006	5mm Curved Scissors 330mm working length, 17mm blade monopolar	58039
LS006-3	3mm Curved Scissors, 310mm working length, 10mm blade, monopolar	58039
LS006-3S	3mm Curved Scissors, 230mm working length, 10mm blade, monopolar	58039
LS006-C	5mm Curved Scissors 330mm working length, 17mm blade with 4mm monopolar cable	58039
LS007	5mm Curved Scissors 330mm working length, 12mm blade, monopolar	58039
LS008	5mm Long Curved Scissors 450mm working length,17mm blade, monopolar	58039

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity
for LaproClose (Trocar Site Closure Device)

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	LaproClose (Trocar Site Closure Device)
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	LaproSurge trocar site closure device is a sterile and single use product. It incorporates a cone shaped needle introducer or 15 cm needle with retractable jaws. The device has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites. The device must be used with a suture of appropriate size to close the incision site.
MDD Classification:	Class IIa, Rule 6
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIa - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:** GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing

EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
TSC001	LaproClose trocar site closure device with 10/12mm guide	61143
TSC002	LaproClose trocar site closure device (NEEDLE ONLY)	61143
TSC003	LaproClose trocar site closure device with 15mm guide	61143

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version:2.0

Date: 24/10/21

EU Declaration of Conformity
for Insufflation Tubing

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Insufflation Tubing
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Insufflation Tubing Set is for use to insufflate the abdominal cavity in order to create working space for endoscopic procedure, and it contains a filter for filtration of the insufflation gas.
MDD Classification:	Class IIa, Rule 3
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIa - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:** GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
FT001	Filtered insufflation tubing set with luer lock to luer lock (0.02 micron)	60738
FT004	Filtered insufflation tubing 15mm O.D. luer lock (0.02 micron)	60738

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 24/10/21

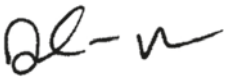
EU Declaration of Conformity
for Insufflation Needle

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Insufflation Needle
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Insufflation Needle is used with insufflation tubing to insufflate abdominal cavity in order to create working space for endoscopic procedure. The Insufflation Needle, available in 120mm and 150mm lengths, has applications in gynaecological laparoscopy and other laparoscopic procedures.
MDD Classification:	Class IIa, Rule 6
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIa - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:** GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed  **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems
ISO594-1:1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements
ISO594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
VN001	Insufflation Needle 120mm length (Box of 25)	12750
VN002	Insufflation Needle 150mm length (Box of 25)	12750
VN120	Insufflation Needle 120mm length (Box of 12)	12750
VN150	Insufflation Needle 150mm length (Box of 12)	12750

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 08/04/21

EU Declaration of Conformity
for Disposable Monopolar Cable

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Disposable Monopolar Cable
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The monopolar cables are designed for use with monopolar surgical device and electrosurgical generator with monopolar electrosurgical feature in endoscopic surgery.
MDD Classification:	Class Is, Rule 1
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class Is - [EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V] **Certificate: GB19/964561**

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems
EN ISO 60601-2-2:2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
MC001	Disposable Monopolar Cable	47143

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	08/04/21	Second issue
3.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
4.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity
for Diathermy Electrodes

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Diathermy Electrodes
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Laparoscopic Instruments are intended for use in general and gynaecologic endoscopic procedures for transection, dissection, and coagulation of tissue.
MDD Classification:	Class IIb, Rule 9
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIb - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] Certificate: GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

EN ISO 60601-2-2:2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
HE002	5mm L-Hook-electrode 330mm length, monopolar, rated δ 3.6kVp	58039
HE002-45	5mm L-Hook-electrode 450mm length, monopolar	58039
HE002-C	5mm L-Hook electrode with cable 330mm length, monopolar with 4mm monopolar cable	58039
HE003	3mm L-Hook electrode, 330mm length monopolar	58039
HE003-S	3mm L-Hook-electrode, 230mm length, monopolar	58039
SE002	5mm Spatula Electrode 330mm length, monopolar	58039
SE002-C	5mm Spatula Electrode with Cable, 330mm length, monopolar with 4mm monopolar cable	58039
SE002-45	5mm Spatula Electrode 450mm length, monopolar	58039

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity
for Camera Sleeve

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Camera Sleeve
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Laparoscopy Camera Sleeve is a sterile, single use product for use in a variety of endoscopic procedures to provide a sterile for endoscopic camera systems.
MDD Classification:	Class Is, Rule I
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class Is - [EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V] **Certificate: GB19/964561**

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24 May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
CS001	Camera Sleeve (sterile)	12535

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date:25/10/21

EU Declaration of Conformity
for Bipolar disposable Maryland forceps

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Bipolar disposable Maryland forceps
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Bipolar disposable Maryland forceps are a sterile and single-use instrument to be used in a variety of laparoscopic procedures to dissect tissue.
MDD Classification:	Class IIb, Rule 9
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIb - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:**GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Signed **Date** 24th May 2024

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems
EN ISO 60601-2-2:2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
BPM001(10)	Bipolar disposable Maryland forceps 5mm, Rotable, with bipolar cable with moulded 28mm plug	57944

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued

Version: 2.0

Date: 25/10/21

EU Declaration of Conformity
for Endoscopic Anti-Fog Solution with pad

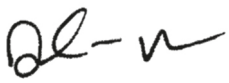
European Communities Council Directive 93/42/EEC as amended by 2007/47/EC, and the a Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Endoscopic Anti-Fog Solution with pad
Legal Manufacturer:	LaproSurge Limited, 5b Fishers Industrial Estate, Wiggenhall Road, Watford, Hertfordshire WD18 0FN, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Anti Fog is for use on endoscopic camera scopes to prevent fogging on the lens caused by condensation during use. The Anti Fog can provide clear visualization for endoscopic procedures. The solution is used for endoscopic procedures through body orifices as well as for surgical invasive procedures.
MDD Classification:	Class IIa, Rule 7
Notified Body:	SGS Belgium NV, Notified Body **1639** SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Class IIa - [Full Quality Assurance in accordance with Annex II (excluding Section 4) of the Medical Device Directive] **Certificate:**GB19/964570

Name David Campbell **Position** CEO LaproSurge Ltd

Place **Hertfodshire, UK**

Signed  **Date** 25th October 2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols for the labelling of medical devices
EN ISO 10993-1:2009 / AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and Testing

EN ISO 11137-1:2015	Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for material, sterile barrier systems and packaging systems

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
FG002	ClearVue™ endoscopic de-mister solution with self-adhesive pad	45225

Version History

Version	Compiled by	Date	Description
1.0	Denise Lane	01/03/20	First Issue
2.0	Denise Lane	25/10/2021	Added Notified body certificate number and place with reference to the Article 120(3) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3.0	Denise Lane	24/05/2024	Review after SGS Extension letter issued