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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 666820**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

In respect of:

Manufacture of sterile electro-cautery lubricating device, sterile vascular loops, sterile vascular booties for use with sutures and sterile and non-sterile silicone clamp covers for jaws of surgical clamps.
Those aspects of Annex V associated with securing and maintaining sterile conditions of K-Wire and Pin Covers, cautery tip cleaners, disposable biopsy valves, irrigation cannulas, endoscopic polyp trap devices and surgical skin markers.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-03-31** Date: **2020-03-05** Expiry Date: **2024-05-11**

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Supplementary Information to CE 666820

Issued To:

Key Surgical LLC
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
NBOG Code	Device or generic device group	---
MD 0106	Sterile and Non-sterile Silicone Clamp covers	---
MD 0106	Sterile electro-cautery lubricating device	---
MD 0106	Sterile Vascular Booties	---
MD 0106	Surgical Vascular Loops	---
Class Is		
NBOG Code	Device or generic device group	---
MD 0106	Cautery Tip Cleaners	---
MD 0106	Surgical Skin markers	---
MD 0106	Cautery Tip Cleaners	---
MD 0106	K-wire and pin covers	---
MD 0303	Irrigation Cannulas	---
MD 0106	Disposable Biopsy Valves	---
MD 0106	Endoscopic polyp removal devices	---

First Issued: **2017-03-31** Date: **2020-03-05** Expiry Date: **2024-05-11**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Subcontractor:	Service(s) supplied
Degania Silicone Limited Degania Bet 1513000 Israel	**Manufacture**
Dongguan Tondaus Meditech Co. Ltd. 3rd Floor, 27 Guantai Road Chiling Community, Houjie Town Dongguan Guangdong 523900 China	**Packaging**
F&M Plastics 503 Simmon Dr. Osceola Wisconsin 54020 USA	**Manufacture**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Subcontractor:	**Service(s) supplied**
Goals Sterilization Co., Ltd. East of Renkangtang South of 07 provincial road, Xinfeng Town Nanhu District 314005 Jiaxing, Zhejiang China	**ETO Sterilization**
Guangzhou Kaiheng K&S Co. LTD. Kaiheng Technology Garden No. 148 Changan Guangshan Highway 510520 Guangzhou China	**Gamma Irradiation**
In2Healthcare Room A 21F Gaylord Commercial Build 114-118 Lockhart Road Wanchai Hong Kong	**Finished Device Supplier**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Subcontractor:	Service(s) supplied
Interlock Medizintechnik GmbH Zum Windpark 1 Lensahn 23738 Germany	**Packaging**
Medical Device Safety Service (MDSS) Schiffgraben 41 30175 Hannover Germany	**EU Representative**
Medplus Inc. 4th Floor, Building C-4 Gaosha Industrial Zone ZhongCun, Panyu District Guangzhou Guangdong Province 511495 China	**Packaging**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Subcontractor:	Service(s) supplied
Purple Surgical Manfacturing Ltd Culmhead Business Centre, Culmhead Taunton Somerset TA3 7DY United Kingdom	**Manufacture** **Packaging**
Shenzhen Gray Irradiation 4th Building No. 33 Zhenxing Road Loucun Community, Gongming Street Guangming New District, Shenzhen Guangdong 518107 China	**E Beam Sterilization**
Shenzhen JPY Ion-Tech Co., Ltd. No. 68, Buxin Dongsheng Rd. Luohu District 518019 Shenzhen China	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Subcontractor:	Service(s) supplied
Sterigenics UK Limited Plot 13a Seymour Link Road Markham Vale, Chesterfield S43 3FG United Kingdom	**Gamma Sterilization**
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Gamma Sterilization**
Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 01454 Radeberg Germany	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Subcontractor:	**Service(s) supplied**
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**Gamma Sterilization**
UShare Medical Inc. 445 AnJi Zhong Road SanZao Town 519040 Zhuhai China	**ETO Sterilization** **Packaging**
Wilson Instruments (SHA) Co., Ltd. 25D, He Yi Business Plaza No. 420, Jiang Ning Rd. Shanghai 200041 China	**Packaging**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Date	Reference Number	Action
31 March 2017	8666542	First issue. Transfer from another notified body.
31 March 2017	8941313	Removal of non-sterile vascular loops and non-sterile vascular booties; administrative update to remove suppliers, Custom Manufacturing and Nilymed; change of name to "Key Surgical LLC".
14 February 2019	8780875	Traceable to NB 0086.
15 April 2019	8941313	Administrative update to change manufacturer's name from Key Surgical, Inc. to Key Surgical LLC Removal of devices from scope: Non-sterile Vascular loops, Non-sterile vascular booties and Light handle covers Addition of following devices to scope: Disposable biopsy valves, Irrigation cannula and Endoscopic polyp trap devices Administrative removal of crucial suppliers: Custom Manufacturing and Nilymed Addition of Sub-contractors: Hefei C&P Nonwoven, Yong Chang Sterilization, Dongguan Tondaus Meditech Co. Ltd., Interlock Medizintechnik GmbH, Synergy Health Radeberg GmbH, Medplus Inc., Guangzhou Kaiheng K&S Co. LTD., Wilson Instruments (SHA) Co., Ltd., Goals Sterilization Co., Ltd. and UShare Medical Inc. Removal of sub-contractor, GRI Medical & Electronic and Dongguan City Kapok Stationery Co. Ltd.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 666820**

Date: **2020-03-05**

Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Date	Reference Number	Action
08 May 2019	9756763	Renewal Removal of devices from scope – sterile anti-fogging solution, disposable instrument pads, disposable needle counters Administrative update for activity for subcontractor Dongguan Tondaus Meditech Co. Ltd. to packaging Removal of Batrik Medical Manufacturing Inc., Hefei C & P Nonwoven, Yong Chang Sterilization and Zhonghong (DG) Abrasives Co. Ltd. as subcontractors.
Current	3106667	Extension of Scope to include sterile electro-cautery lubricating device. Addition of subcontractors – Purple Surgical Manufacturing Ltd, Synergy Health Sterilisation UK Ltd and Sterigenics UK Limited.

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Key Surgical LLC
8101 Wallace Road
Eden Prairie, MN 55344 USA

30 April 2023

Notified Body Confirmation Letter
Reference: EU2023-607/ 855453

To whom it may concern,

Confirmation 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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Key Surgical LLC
8101 Wallace Road
Eden Prairie, MN 55344
USA

SRN Number (if available): US-MF-000029021

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for 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; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 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 BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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 (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
Electro Lube Sterile *Electro-cautery lubricating device*	Class IIa	N/A	MDD Certificate 666820 Expiry date = May 11, 2024 NB# 2797
Irrigation *Cannulas*	Class I device placed on the market in sterile condition	N/A	MDD Certificate 666820 Expiry date = May 11, 2024 NB# 2797
Cautery Tip Cleaner	Class I device placed on the market in sterile condition	N/A	MDD Certificate 666820 Expiry date = May 11, 2024 NB# 2797

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	Action
2024/5/07	Initial issue

KEYSURGICAL

a STERIS company

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Key Surgical LLC
Manufacturer address and contact details	8101 Wallace Road Eden Prairie, MN 55344 USA
Single Registration Number (SRN) (if available)	US-MF-000029021

Authorised Representative name (if applicable)	MDSS GmbH
Authorised Representative address and contact details	Schiffgraben 41, 30175 Hannover, Germany
Single Registration Number (SRN) (if available)	DE-AR-000005430

Notified body name (if applicable)	BSI
Notified body number (if applicable)	2797
Directive Certificate number to which this confirmation is made	MD 666820
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	May 11, 2024
End date of extended validity/transition period	Dec 31, 2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the attached **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate covering the listed device was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

☑ Expired *after* 20 March 2023 and

☑ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made and submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

☑ A QMS in accordance with Article 10(9) MDR is in place.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name	Key Surgical LLC
Location & Date	Eden Prairie, MN 55344 USA, May 11, 2024
Signature, Print Name, Title	Steve Deline, MS RAS
	Sr. Manager, Regulatory Affairs
Contact Details (at least email)	steve_deline@steris.com
Signature	

KEYSURGICAL

a STERIS company

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile Electro-cautery lubricating device	CE 666820	2024-05-11	BSI NB# 2797	BSI NB# 2797	2023	Not applicable
Cautery Tip Cleaners	CE 666820	2024-05-11	BSI NB# 2797	BSI NB# 2797	2023	Not applicable
Irrigation Cannulas	CE 666820	2024-05-11	BSI NB# 2797	BSI NB# 2797	2023	Not applicable

[2] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)