

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, irrigation cannulas, 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, Senior Vice President - Medical Devices

First Issued: 2017-03-31

Date: 2021-05-18

Expiry Date: 2024-05-11

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

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	K-wire and pin covers	---
MD 0303	Irrigation Cannulas	---

First Issued: **2017-03-31**

Date: **2021-05-18**

Expiry Date: **2024-05-11**

...making excellence a habit™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.



EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 666820**
 Date: **2021-05-18**
 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.

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 666820**
 Date: **2021-05-18**
 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.
05 May 2020	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.

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 666820**
 Date: **2021-05-18**
 Issued To: **Key Surgical LLC**
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Date	Reference Number	Action
18 May 2021	3445572	Removal of scope expression covering endoscopic poly trap devices and disposable biopsy valves; Removal of subcontractors: UShare Medical Inc., Wilson Instruments (SHA) Co., Ltd., Medplus Inc., Guangzhou Kaiheng K&S Co. LTD., Interlock Medizintechnik GmbH, Goals Sterilization Co., Ltd.; Addition of sub-contractors: Guangzhou Furui High-energy Technology Co., Ltd., Isomedix Operations, Inc. North Facility (Libertyville, IL), Isomedix Operations, Inc (Libertyville, IL); SteriPack Medical Poland Sp. Z o.o. Administrative correction of services provided for Synergy Health Radeberg GmbH
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
07 January 2026	30592098	Addition of critical subcontractor

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

07 January 2026
Key Surgical LLC
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 666820	93/42/EEC Annex V	30592098	Addition of critical subcontractor

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices



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

30 April 2024

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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9, 1066 EP
Amsterdam, The Netherlands

bsigroup.com
bsigroup.nl
T: +31 20 346 0780





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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9, 1066 EP
Amsterdam, The Netherlands

bsigroup.com
bsigroup.nl
T: +31 20 346 0780

Page 2 of 3



Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

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 <i>Electro-cautery lubricating device</i>	Class IIa	N/A	MDD Certificate 666820 Expiry date = May 11, 2024 NB# 2797
Irrigation <i>Cannulas</i>	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

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.



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	Dec 31, 2028	Not applicable
Cautery Tip Cleaners	CE 666820	2024-05-11	BSI NB# 2797	BSI NB# 2797	Dec 31, 2028	Not applicable
Irrigation Cannulas	CE 666820	2024-05-11	BSI NB# 2797	BSI NB# 2797	Dec 31, 2028	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)