

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, Senior Vice President Medical Devices

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

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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.

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Supplementary Information to CE 666820

Issued To: **Key Surgical LLC**
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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**

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List of Significant Subcontractors

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

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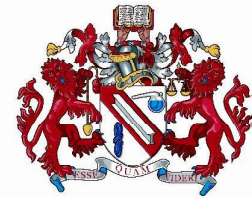
Subcontractor:	Service(s) supplied
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	Gamma Sterilization
UShare Medical Inc. 445 AnJi Zhong Road SanZao Town 519040 Zhuhai China	ETO Sterilization Packaging
Wilson Instruments (SHA) Co., Ltd.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

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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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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.