

# 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**

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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
<b>Class IIa</b>		
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	---
<b>Class Is</b>		
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	---

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Production Quality Assurance

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## List of Significant Subcontractors

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

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

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**Subcontractor:**

**Service(s) supplied**

Guangzhou Furui High-energy  
Technology Co., Ltd.  
2nd Da Yong East Road Nansha District  
511458 Guangzhou  
People's Republic of China

**Radiation (Gamma Sterilization)**

In2Healthcare  
Room A 21F Gaylord Commercial Build  
114-118 Lockhart Road  
Wanchai  
Hong Kong

**Finished Device Supplier**

Isomedix Operations, Inc.  
North Facility  
1880 Industrial Drive  
Libertyville  
Illinois  
60048  
USA

**Radiation (Gamma Sterilization)**

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	<b>Radiation (Gamma Sterilization)</b>
Medical Device Safety Service (MDSS) Schiffgraben 41 30175 Hannover Germany	<b>EU Representative</b>
Purple Surgical Manufacturing Ltd Culmhead Business Centre, Culmhead Taunton Somerset TA3 7DY United Kingdom	<b>Manufacture Packaging</b>

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**Subcontractor:**

**Service(s) supplied**

Shenzhen Gray Irradiation  
 4th Building No. 33 Zhenxing Road  
 Loucun Community, Gongming Street  
 Guangming New District, Shenzhen  
 Guangdong  
 518107  
 China

**Radiation (E Beam Sterilization)**

Shenzhen JPY Ion-Tech Co., Ltd.  
 No. 68, Buxin Dongsheng Rd.  
 Luohu District  
 518019 Shenzhen  
 China

**Radiation (Gamma Sterilization)**

Sterigenics UK Limited  
 Plot 13a  
 Seymour Link Road  
 Markham Vale, Chesterfield  
 S43 3FG  
 United Kingdom

**Radiation (Gamma Sterilization)**

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	<b>Radiation (Gamma Sterilization)</b>
SteriPack Medical Poland Sp. Z o.o. Leg, ul. Japonska 1 55-220 Jelcz-Laskowice Poland	<b>Packaging</b>
Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany	<b>Radiation (E Beam Sterilization)</b>

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**Subcontractor:**

**Service(s) supplied**

Synergy Health Sterilisation UK Ltd  
Brunel Close  
Drayton Fields Industrial Estate  
Daventry  
NN11 8RB  
United Kingdom

**Radiation (Gamma Sterilization)**

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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.
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.

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Date	Reference Number	Action
Current	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