

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 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: **2019-05-08**

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

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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 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	---

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