



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 665498
Issued To: **Microline Surgical, Inc.**
50 Dunham Road, Suite 1500
Beverly
Massachusetts
01915
USA

In respect of:

Design, development and manufacture of active laparoscopic surgical instruments, sterile and non-sterile scissor, grasping and dissecting tips; sterile and non-sterile clip appliers, sterile ligating clips; sterile cautery forceps, sterile and non-sterile thermal ligation shears (Including power supply and footswitch).

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-06-05**

Date: **2017-06-05**

Expiry Date: **2020-07-30**

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Page 1 of 1

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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List of Significant Subcontractors

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

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Date: **2017-06-05**
Issued To: **Microline Surgical, Inc.**
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01915
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Subcontractor:	Service(s) supplied
GDM Electronic & Medical 2070 Ringwood Avenue San Jose California 95131 USA	Manufacture
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	Gamma Sterilization
Isomedix Operations, Inc. 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	ETO Sterilization

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Subcontractor:

Service(s) supplied

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

EU Representative

Parker Hannifin Corporation
Medical Systems Division - Ventrex
Business Unit
3007 Bunsen Avenue
Ventura
CA 93003
USA

Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 665498**
Date: **2017-06-05**
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USA

Date	Reference Number	Action
05 June 2017	8651082	First issue. Transfer from another Notified Body

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