By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 618251**

Issued To: **Med-Logics, Inc.**
1627 Enterprise St.
Athens
Texas
75751
USA

In respect of:

The design and manufacture of microkeratomes and sterile microkeratome blades; and of lens removal and anterior vitrectomy devices and associated sterile single use accessories. Those aspects of Annex II related to securing and maintaining sterility of vacuum tubing and PVA eye spears.

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 2797):

Albert Roossien, Regulatory Lead

First Issued: **2014-09-30** Date: **2019-02-20** Expiry Date: **2023-11-01**

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NBOG Code	Device Name	Intended purpose per IFU	Classification
MD1105	ML7 Microkeratome	The ML7 Microkeratome is used to perform lamellar keratoplasty procedures. This procedure is performed by refractive surgeons to create a thin circular corneal cap.	IIa
MD0106	ML7000 Series Blades	The ML7000 Series Blades are designed to be replacements for OEM disposable blades, uniquely configured for each make and model of OEM microkeratome. These blades fit into the drive mechanism of the OEM microkeratome (i.e. the blade fits into the microkeratome head and accepts a drive pin from the microkeratome handpiece, which oscillates the blade). The microkeratome head translates across the eye mated to a vacuum ring, which also fixates the eye. The microkeratome, with blade, is used to perform a lamellar keratectomy. This procedure is most commonly performed as a preliminary step in the LASIK procedure.	IIa
MD1105	CataPulse Console	The CataPulse® is intended to be used on a crystalline lens (cataract) that is grade 3+ or less, unless a femtosecond laser is used to break up the grade 4+ cataract.	IIb

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NBOG Code	Device Name	Intended purpose per IFU	Classification
MD0102	CataPulse Lens Removal Kit	The CataPulse Lens Removal Handpiece Set is indended to be used with the CataPulse Console to remove the crystalline lens from the eye.	IIa
MD0106	CataPulse Vit Cutter Kit	The CataPulse Anterior Vitrectomy Disposable Set is intended to be used with the CataPulse Console to remove unwanted vitreous from the capsule of the eye	IIa
MD0102	CataPulse Cannulas	The CataPulse Cannulas are intended to be used with the CataPulse Console and the CataPulse Lens Removal Handpiece Set to remove the crystalline lens and cortex from inside the eye. crystalline lens (cataract) that is grade 3+ or less, unless a femtosecond laser is used to break up the grade 4+ cataract.	IIa

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NBOG Code	Device Name	Intended purpose per IFU	Classification
MDS7006	ML100 Cleantouch PVA Eye Spears	The CleanTouch PVA products are designed and intended to be used to absorb moisture on a variety of surfaces, including the human eye. The CleanTouch PVA eye spears have a plastic handle and are designed to be used to absorb excess fluids and manipulate tissue on the human eye.	Is
MDS7006	ML8000 Series Tubing	The ML8000 Series Sterile Tubing sets are designed to be replacements for OEM disposable tubing sets uniquely configured for each model and make of OEM microkeratome. These tubing sets attach the keratome vacuum ring to the console (vacuum source) of the OEM microkeratome system.	Is

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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**
Centurion Medical Products Corporation 301 Catrell Drive Howell Michigan 48843 USA	**ETO Sterilization**
M Devices Group/E C Rep Ltd. Healthcare Education Centre Portland Street Southport PR8 1HU United Kingdom	**EU Representative**
Sterigenics US, LLC 3125 Wichita Court Fort Worth Texas 76140 USA	**Gamma Irradiation**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 618251**

Date: **2019-02-20**

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Date	Reference Number	Action
30 September 2014	8196281	First Issue. Transfer from another notified body.
12 July 2016	8562621	Addition of PVA eye spears to the certification scope and Sterigenics US, LLC, 3125 Wichita Court, Fort Worth, Texas 76140, USA as a significant subcontractor for Gamma Irradiation.
26 March 2018	8907612	Extension to scope to add lens removal and anterior vitrectomy devices and associated sterile single use accessories.
29 October 2018	8918091	Certificate Renewal.
Current	8622894	Traceable to NB 0086.