By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 616311**

Issued To: **Clear Guide Medical**
3600 Clipper Mill Road, Suite 400
Baltimore
Maryland
21211
USA

In respect of:

The design and manufacture of ultrasound guidance systems.
Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture of sterile drapes and sterile on-patient markers.

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-04-20** Date: **2020-05-01** Expiry Date: **2024-05-26**

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Supplementary Information to CE 616311

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NBOG code(s)	Device Description	Intended purpose
Class IIa		
MD 1202 MD 1111	Ultrasound guidance systems for navigation and instrument guidance, including standalone software application	NA for class IIa devices
Class Is		
MDS 7006	Sterile drape for camera	NA for class Is devices
MDS 7006	Sterile on-patient markers	NA for class Is devices

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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**
MT Promedt Consulting GmbH Altenhofstrasse 80 66386 St. Ingbert Germany	**EU Representative**
Sterigenics US, LLC 502 Prairie Mine Road Mulberry Florida 33860 USA	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
SteriPack USA (Limited) LLC 4255 South Pipkin Rd. Lakeland Florida 33811 USA	**Control of Sterilization** **Packaging**
TIDI Products, LLC 14241 Fenton Road Fenton Michigan 48430 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616311**

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Date	Reference Number	Action
20 April 2015	8179823	First Issue
09 December 2015	8431185	Amendment of scope to remove accessories and to add "Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture of sterile accessories" and addition of subcontractor CFI Medical for manufacture and ETO Sterilization
13 May 2016	8486042	Addition of subcontractor SteriPack USA (Limited) LLC for sterile manufacture
10 October 2016	8621845	Removal of Emergo Europe as EU representative Addition of MT Promedt as EU representative
21 March 2019	8862650	Traceable to NB 0086.
Current	9767527	Renewal. Added device list table. Changed subcontractor legal name from CFI to TIDI. Removed subcontractor TRICOR Systems, Inc. Added existing subcontractors Centurion Medical and Sterigenics US. Amended services supplied by subcontractors TIDI and Steripack USA to remove sterilization services. Clarified Class Is sterile device scope wording to be in line with BSI scope requirements