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 accessories.

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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **20 April 2015** Date: **10 October 2016** Expiry Date: **19 April 2020**

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

List of Significant Subcontractors

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

Certificate No:	**CE 616311**
Date:	**10 October 2016**
Issued To:	**Clear Guide Medical** **3600 Clipper Mill Road, Suite 400** **Baltimore** **Maryland** **21211** **USA**

Subcontractor:	**Service(s) supplied**
CFI Medical 14241 N. Fenton Road Fenton Michigan 48430-1541 USA	**ETO Sterilization** **Manufacture**
MT Promedt Altenhofstrasse 80 66386 St. Ingbert Germany	**EU Representative**
SteriPack USA (Limited) LLC 4255 South Pipkin Rd. Lakeland Florida 33811 USA	**Sterile Manufacture**

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Subcontractor:	**Service(s) supplied**
TRICOR Systems, Inc. 1650 Todd Farm Drive Elgin Illinois 60123 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