By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 579978**

Issued To: **Veniti, Inc.**
1610 Des Peres Road, Suite 385
St. Louis
Missouri
63131
USA

In respect of:

The design, development and manufacture of venous stent systems

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):

Gary Fenton, Global Assurance Director

First Issued: **11 October 2013** Date: **12 July 2014** Expiry Date: **10 October 2018**

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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 579978**
Date:	**12 July 2014**
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Subcontractor:	**Service(s) supplied**
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	**EU Representative**
Nitinol Device and Components, Inc. 47533 Westinghouse Drive Fremont California 94539 USA	**Manufacture**
STERIS Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
Veniti, Inc. 4025 Clipper Court Fremont California 94538 USA	**Control of Sterilization** **Design** **Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
11 October 2013	7756309	First Issue
12 July 2014	8177227	Venous ablation system removed from the scope. Stellartech Research Corporation removed from the list of subcontractors. Updated address of Veniti (Fremont).