

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****...making excellence a habit.™**

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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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| 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). |