



Certificate

Full Quality Assurance

No. CE 578640



Issued to:

Vessix Vascular, Inc.
26052 Merit Circle, Suite 106
Laguna Hills
California
92653
USA

In respect of:

The design, development and manufacture of RF Generators and Sterile Balloon Catheters with mounted RF Electrodes for percutaneous renal artery nerve denervation for the treatment of hypertension and the treatment of peripheral vascular diseases.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **9 Dec 2011**

Date: **17 Apr 2013**

Expiration Date: **12 Feb 2014**

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

...making excellence a habit.™



List of Significant Subcontractors

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

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Subcontractor**Service(s) supplied**

Life Science Outsourcing, Inc.
830 Challenger Street
Brea
CA 92821
USA

Manufacture

Boston Scientific International S.A
55 Avenue des Champs Pierruex
92729 Nanterre Cedex
France

EU Representative

Nutek Corporation
1005 Whipple Road
Hayward
CA 94544
USA

Sterilization

Lucas Medical
1751 S. Douglas Road
Anaheim, CA 92806
USA

Manufacture



History of Quality Assurance Certificate

Certificate No: CE 578640
Issue Date: 17 Apr 2013
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Date	Reference Number	Action
09 December 2011	7729391	First Issue. Transfer from another Notified Body.
27 April 2012	7818497	FQA extension to scope; tech file review and addition of V2 Renal Denervation System.
17 April 2013	7982948	Change of EU Authorized Representative to Boston Scientific International in France and the addition of Life Science Outsourcing to the list of significant subcontractors.