

EC DECLARATION OF CONFORMITY


We, Vessix Vascular, Inc., 26052 Merit Circle, Suite 106, Laguna Hills CA, 92653 USA, declare under our sole responsibility that the products to which this declaration relates are in conformity with the following standard(s) or other normative document(s):

Directives 93/42/EEC Council Directive Concerning Medical Devices Jun 14, 1993
 2007/47/EC Council Directive Concerning Medical Devices M5 Sep 5, 2007

Conformity Assessment Route (Annex) Annex II, Full Quality System
UMDNS CODE 17566 Catheters Angioplasty, Radio-Frequency Thermal

Product	Model Number(s)		Class-Rule
Vessix Vascular Renal Denervation System*	Description	Model # (UPN)	Class IIb – Annex 9, Rule 6 & 9
	Vessix™ Renal Denervation Catheter - 4mm	H749RDNC0400	
	Vessix™ Renal Denervation Catheter - 5mm	H749RDNC0500	
	Vessix™ Renal Denervation Catheter - 6mm	H749RDNC0600	
	Vessix™ Renal Denervation Catheter - 7mm	H749RDNC0700	
	Vessix™ RF Generator System - English	H749RDNS0100	
Vessix™ RF Generator System Refurbished - English	H749RDNSPS01R00		
Manufacturer (Name and Address) Vessix Vascular, Inc. 26052 Merit Circle, Suite 106 Laguna Hills, CA 92653 USA		Notified Body Notified Body Number: 0086 (BSI)	European Representative: Boston Scientific International SA 55 Avenue des Champes Pierruex 92729 Nanterre Cedex France

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.



 Vessix Vascular, Inc.
 Rinda Sama - Director of Operations and Quality

 Laguna Hills, California 92653; USA
 Place of Issue

 5/6/2013
 Date of Issue

* Vessix System includes Class I products listed in Attachment 1.

Attachment 1

Listing of Vessix System Accessories
(Non-Sterile Class I)

The following Class I products are used as part of the Vessix System and meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Accessory Description	Model # (UPN)
Vessix™ Cart System	H749RDNS0200
Vessix™ Patient Extension Cable	H749RDNSPA2300
Vessix™ Power Supply/Brick	H749RDNSPA2400
Vessix™ Power Cord – UK	H749RDNA0200
Vessix™ Power Cord – Europe	H749RDNA0300
Vessix™ Power Cord – Denmark	H749RDNA0400
Vessix™ Power Cord – Switzerland	H749RDNA0500
Vessix™ Power Cord - Italy	H749RDNA1200