

EC Certificate - Full Quality Assurance System

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

No. CE 580056
Issued To: **Rhythmia Medical Inc**
111 S. Bedford Street Suite 205
Burlington
Massachusetts
01803
USA

In respect of:

Design and Manufacture of Rhythmia Mapping System and Catheter

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: **14 December 2012**

Date: **28 May 2014**

Expiry Date: **13 December 2017**

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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:

Certificate No: **CE 580056**
 Date: **28 May 2014**
 Issued To: **Rhythmia Medical Inc**
111 S. Bedford Street Suite 205
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Massachusetts
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Subcontractor:	Service(s) supplied
Alden Products, Inc. 117 North Main Street Brockton MA 02301 USA	Manufacture
Boston Scientific Corporation 47900 Bayside Parkway Fremont CA 94538 USA	Labelling Packaging
Boston Scientific International S.A. 55 avenue des Champs Pierreux TSA 51101 92729 Nanterre Cedex France	EU Representative

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Nothern Digital, Inc. (NDI) 103 Randall Drive Waterloo Ontario N2V 1C5 Canada	Manufacture
Professional Contract Sterilization, Inc. 40 Myles Standish Boulevard Taunton MA 02780 USA	Sterilization
TE Connectivity, Inc. 10025 SW Freeman Court Wilsonville OR 97070 USA	Manufacture
Tech Device Corporation 650 Pleasant Street Watertown MA 02780 USA	Manufacture

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 580056
Date: 28 May 2014
Issued To: Rhythmia Medical Inc
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Date	Reference Number	Action
14 December 2012	7758035	First Issue
30 April 2013	7985968	Update scope to include Rhythmia Mapping System. Change of EU Representative and addition of Alden Products, Inc. and Northern Digital, Inc. (NDI) significant subcontractors.
28 May 2014	8163768	Addition of significant subcontractor Boston Scientific Corporation in Fremont, CA, USA with the services "Packaging and Labelling" supplied.