

EC Certificate - Full Quality Assurance System

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

No.**CE 85990****Issued To:**

**Volcano Corporation
2870 Kilgore Road
Rancho Cordova
California
95670
USA**

In respect of:

The design, development and manufacture of ultrasonic imaging catheters, ultrasonic imaging electronic systems, intravascular ultrasonic imaging balloon catheters, intravascular pressure and flow measuring guide wires, microcatheters, intravascular pressure and flow measuring electronic systems, guide wires, pull back devices and implantable vena cava filters with delivery system.

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **25 June 2004**

Date: **01 June 2015**

Expiry Date: **24 June 2019**

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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 85990**
 Date: **01 June 2015**
 Issued To: **Volcano Corporation**
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Subcontractor:	Service(s) supplied
Lake Region Medical 45 Lexington Drive Laconia New Hampshire 03246 USA	Manufacture
Sterigenics Costa Rica S.R.L. Zona Franca PROPARK Calle Principia, Edificio 10 El Coyol Alajuela Costa Rica	ETO Sterilization
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles CA 90058 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Volcano Corporation 3721 Valley Centre Drive, Suite 500 San Diego CA 92130 USA	Design Development
Volcano Corporation VOLCARICA S.R.L., Coyol Free Zone & Business Park B37, Alajuela Costa Rica	ETO Sterilization Manufacture
Volcano Europe SA/NV Excelsiorlaan 41 Zaventem B-1930 Belgium	EU Representative

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Certificate History

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Date	Reference Number	Action
25 June 2004		First Issue Transferred from RWTUV, Certificate No. 04 207-2074/03
21 March 2005		Change of company name
28 July 2006		Reissue to include Doppler flow measuring guidewires and electronic systems within the scope
11 May 2009	7215023	Certificate Renewal and addition of EU Representative
27 May 2010	7536390	Addition of TACTX as a significant subcontractor and extension to scope adding "intravascular ultrasonic imaging balloon catheters".
1 May 2012	7803070	Extension to scope adding "Microcatheters" Update of significant subcontractors: Addition of San Diego, CA site (Design and Development); addition of Billerica, MA site (Design, Development and Manufacture)
21 December 2012	7917634	Update of significant subcontractors: Addition of Volcano's Costa Rica manufacturing facility "Volcarica" as a significant subcontractor (Manufacturer and in-house ETO Sterilization)
27 June 2013	7947875	Extension to scope: addition of Aspiration Catheters to scope

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19 May 2014	8079742	Extension to scope: addition of implantable vena cava filters. Deletion of TactX as a significant subcontractor. Deletion of the Volcano Billerica MA facility as a significant subcontractor. Addition of Accellent as a significant subcontractor. Updated the manufacturers corporate address at its San Diego facility.
24 June 2014	8165113	Certificate Renewal. Scope changes for clarification purposes and to remove Aspiration Catheters, Patient Cables and Sterile Covers.
01 June 2015	8335812	Addition of Sterigenics Costa Rica S.R.L in Costa Rica as a significant subcontractor.

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