

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

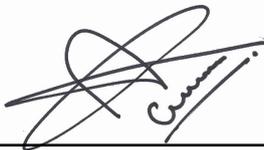
No. CE 542904
Issued To: **Volcano AtheroMed Inc.**
1530 O'Brien Drive
Suite A
Menlo Park
California
94025
USA

In respect of:

The manufacture of Atherectomy Systems and Guidewires for peripheral vascular disease.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2009-04-02**

Date: **2019-03-28**

Expiry Date: **2024-04-01**

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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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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Lake Region Medical Ltd Butlersland New Ross Co. Wexford Ireland	Manufacture
Parter Sterilization Services, LLC 17115 Kingsview Avenue Carson California 90746 USA	ETO Sterilization
Volcano Europe BVBA/SPRL Excelsiorlaan 41 B-1930 Zaventem Belgium	EU Representative

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 542904**
 Date: **2019-03-28**
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Date	Reference Number	Action
02 April 2009	7283447	First Issue.
30 April 2010	7522488	Added Parter Sterilization Services, LLC to the Significant Subcontractor list.
09 November 2013	8016140	Extension to scope to include Guidewires and the addition of Neometrics Inc as the related subcontractor.
19 March 2014	8125686	Certificate Renewal. Correction to the building number for the subcontractor Parter Sterilization Services.
19 August 2014	8206970	Updated Company Name to Volcano AtheroMed Inc. and EU Representative to Volcano Europe following Acquisition of Atheromed by Volcano. Removed Hantel Technologies, Inc. from the Significant Subcontractor list.
23 December 2016	8660497	Volcano AtheroMed Inc.'s address updated. Neometrics Inc. and Dravon Medical Inc. removed from the list of significant subcontractors while Vention Medical Design and Development, Inc. was added.
11 February 2019	7780618	Traceable to NB 0086.

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Date	Reference Number	Action
Current	9734900	Certificate renewal. Updated scope replacing the word "artery" with "vascular". Removed significant subcontractor Vention Medical and added Lake Region Medical Ltd.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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