

EC Design-Examination Certificate

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

No.**CE 742557**

Issued To:

**Volcano Corporation
3721 Valley Centre Drive, Suite 500
San Diego
California
92130
USA**

In respect of:

Visions Ultrasound Catheters

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-26**Date: **2021-05-03**Expiry Date: **2022-08-15**

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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 certificate was issued electronically and is bound by the conditions of the contract.

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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Catalogue Number	Device Name	Intended purpose per IFU	Classification
88901	Visions Ultrasound Catheter PV. 035	<p>The Visions PV .035 Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels.</p> <p>The Visions PV .035 Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.</p>	Class III

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Certificate History

Date	Reference Number	Action
26 February 2021	3316864	First issue. New Certificate for same Legal Manufacturer traceable to 'old address' certificate CE 589210.
Current	3413176	Approval of new ETO sterilization cycle parameters (cycle #56 using 3M 8XL Sterilizer) at Philips de Costa Rica S.R.L. (Coyol, Alajuela, Costa Rica) and reduction of Positive PCD Controls. Correction to expiration date.

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