

EC Certificate - Full Quality Assurance System

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

No. **CE 652101**
Issued To: **Vanguard AG**
Landsberger Str. 266
Berlin
12623
Germany

In respect of:

The design, development, manufacturing, and final inspection of remanufactured irrigated and non-irrigated sterile diagnostic and ablation catheters for electrophysiology and ultrasonic cutting and coagulating devices with related accessories each.

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2016-09-14**

Date: **2019-02-05**

Expiry Date: **2021-09-13**

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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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Supplementary Information to CE 652101

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NBOG Codes	Description	Intended Purpose
Class III		
MD0106	Remanufactured Ablation Catheters (irrigated and non-irrigated)	See CE 652103
MD0106	Remanufactured Diagnostic Catheter (fixed and variable loop)	See CE 666374
Class IIb		
MD1104	Soft-tissue ultrasonic surgical system	The Vanguard Ultrasonic Shears are intended for use to aid the separation and coagulation of soft tissue in combination with the accessories and supplementary equipment listed.

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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.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

Certificate No: **CE 652101**
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Landsberger Str. 266
Berlin
12623
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Subcontractor:

Service(s) supplied

Vanguard AG
Landsberger Str. 219
Berlin
12623
Germany

Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 652101**
 Date: **2019-02-05**
 Issued To: **Vanguard AG**
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Certificate History

Date	Reference Number	Action
14 September 2016	8504684	First Issue.
07 February 2018	8733468	Extension to scope for ultrasonic cutting, coagulating devices and related accessories.
03 January 2019	9629348	Added additional Ultrasonic Shear Model Numbers; reformatted table and added existing Class III devices.
Current	8768383	Traceable to NB 0086.

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