

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.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of cables for use with Electrophysiology Catheters.

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):



Gary E Slack, Senior Vice President Medical Devices

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

Date: **2021-05-04**

Expiry Date: **2024-05-26**

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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

Issued To:

Vanguard AG
Landsberger Str. 266
Berlin
12623
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Number	Device Name	Intended Purpose per IFU
Class III products under the scope of CE 652101		
---	Remanufactured Vanguard Fixed Loop Diagnostic Catheters SJB & EB SJD Remanufactured Vanguard Variable Loop Diagnostic Catheters SJC & EB SJE	See CE 666374
---	Remanufactured Vanguard Ablation Catheter uni BWA/Vanguard Ablation Catheter uni DS BWP Remanufactured Vanguard Ablation Catheter bi BWB/Vanguard Ablation Catheter bi DS BWQ Remanufactured Vanguard Irrigated Ablation Catheter uni BWG /Vanguard Irrigated Ablation Catheter NAV uni BWI Remanufactured Vanguard Irrigated Ablation Catheter SF uni BWR/Vanguard Irrigated Ablation Catheter SF NAV uni BWT	See CE 652103

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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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Number	Device Name	Intended Purpose per IFU
Class III products under the scope of CE 652101		
---	Remanufactured Vanguard Irrigated Ablation Catheter bi BWH/Vanguard Irrigated Ablation Catheter NAV bi BWJ Remanufactured Vanguard Irrigated Ablation Catheter SF bi BWS/Vanguard Irrigated Ablation Catheter SF NAV bi BWU	See CE 652103
---	Remanufactured Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN/Vanguard Variable Loop Diagnostic Catheter NAV eco BWO Remanufactured Vanguard Steerable Diagnostic Catheter ID BWAB, bi BWAC, bi ID BWAD	See CE 717745
---	Remanufactured Vanguard Ablation Catheter uni LT G BTA, uni LT BTB, uni G BTC, uni BTD	See CE 717746

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Number	Device Name	Intended Purpose per IFU
Class III products under the scope of CE 652101		
---	Remanufactured Vanguard Irrigated Ablation Catheter NAV uni ST BWV/Vanguard Irrigated Ablation Catheter NAV bi ST BWW Remanufactured Vanguard Irrigated Ablation Catheter SF NAV uni ST BWX/Vanguard Irrigated Ablation Catheter SF NAV bi ST BWY	See CE 721173
---	Remanufactured Vanguard Irrigated Ablation Catheter Uni SJG/Vanguard Irrigated Ablation Catheter Bi SJH Remanufactured Vanguard Irrigated Ablation Catheter SE Uni SJI/Vanguard Irrigated Ablation Catheter SE BI SJJ	See CE 713013

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Number	Device Name	Intended Purpose per IFU
Class IIb products under the scope of CE 652101		
44755	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.
Class Is products under the scope of CE 652101		
MD0106	Electrophysiology catheter cables	---

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List of Significant Subcontractors

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

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Date: **2021-05-04**
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Landsberger Str. 266
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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: **2021-05-04**
 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.
05 February 2019	8768383	Traceable to NB 0086.
17 October 2019	3076475	Adapted product table. Added: Remanufactured Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN/Vanguard Variable Loop Diagnostic Catheter NAV eco BWO.
8 April 2020	3060361	Certificate Renewal; Clarification to add Class Is scope and products to product table inadvertently omitted when product table was first added; Removed "with related accessories each" from main scope.
16 February 2021	3101971	Increase the total number of remanufacturing cycles to 2 for the ETS+ and ETM+ models and standardize the cleaning procedure for all Vanguard Ultrasonic Shears.

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Date	Reference Number	Action
05 April 2021	3319222 3405979	Added Vanguard Remanufactured Steerable Diagnostic Catheters ID BWAB, bi BWAC, bi ID BWAD and Remanufactured Ablation Catheters uni LT G BTA, uni LT BTB, uni G BTC, uni LTD.
Current	3372902	Added two new Class III certificates for models Vanguard Irrigated Ablation Catheter NAV uni ST BWV/NAV bi ST BWW/SF NAV uni ST BWX/SF NAV bi ST BWY and Vanguard Irrigated Ablation Catheter Uni SJG/Bi SJH/SE Uni SJI/SE BI SJJ.

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