

# EC Design-Examination Certificate

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

**No.** **CE 652103**  
Issued To: **Vanguard AG**  
**Landsberger Str. 266**  
**Berlin**  
**12623**  
**Germany**

In respect of:

**See certificate scope page.**

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: **2016-09-14**

Date: **2021-04-16**

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 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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Certificate No: CE 652103

## Certificate Scope:

**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**

**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**

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Vanguard Ablation Catheter uni BWA/DS BWP		
<p><b>Indications for Use per IFU</b></p> <p>The Vanguard Ablation Catheter uni BWA/DS BWP is designed for temporary intercardiac ECG conductance and stimulation (mapping) of the heart within the scope of electrophysiological examinations, in conjunction with compatible connection cables from the Biosense Webster, Inc. and suitable devices for electrophysiological mapping. It can also be used in conjunction with a suitable high frequency generator (RF generator) for cardiac ablation procedures. The Vanguard Ablation Catheter uni DS BWP is to be used for ablation with a Stockert EP Shuttle RF generator.</p>		
<p><b>Classification</b></p> <p>Class III Non-Implantable</p>		
Catalog Number	Device Name	Model, Type
33396	Vanguard Ablation Catheter uni BWA	A-Type 6F 92cm 4p 2-5-2 TC
33397	Vanguard Ablation Catheter uni BWA	A-Type 6F 92cm 4p 2-5-2 TR
33398	Vanguard Ablation Catheter uni BWA	B-Type 6F 92cm 4p 2-5-2 TC
33545	Vanguard Ablation Catheter uni BWA	B-Type 6F 92cm 4p 2-5-2 TR
33477	Vanguard Ablation Catheter uni BWA	D-Type 6F 92cm 4p 2-5-2 TC
33547	Vanguard Ablation Catheter uni BWA	D-Type 6F 92cm 4p 2-5-2 TR
33548	Vanguard Ablation Catheter uni BWA	E-Type 6F 92cm 4p 2-5-2 TC
33549	Vanguard Ablation Catheter uni BWA	A-Type 7F 115cm 4p 2-5-2 TR

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Catalog Number	Device Name	Model, Type
33551	Vanguard Ablation Catheter uni BWA	B-Type 7F 115cm 4p 2-5-2 TC
33550	Vanguard Ablation Catheter uni BWA	B-Type 7F 115cm 4p 2-5-2 TR
33552	Vanguard Ablation Catheter uni BWA	C-Type 7F 115cm 4p 2-5-2 TC
33553	Vanguard Ablation Catheter uni BWA	C-Type 7F 115cm 4p 2-5-2 TR
33260	Vanguard Ablation Catheter uni BWA	D-Type 7F 115cm 4p 2-5-2 TC
33497	Vanguard Ablation Catheter uni BWA	D-Type 7F 115cm 4p 2-5-2 TR
33554	Vanguard Ablation Catheter uni BWA	E-Type 7F 115cm 4p 2-5-2 TC
33555	Vanguard Ablation Catheter uni BWA	E-Type 7F 115cm 4p 2-5-2 TR
33556	Vanguard Ablation Catheter uni BWA	F-Type 7F 115cm 4p 2-5-2 TC
33557	Vanguard Ablation Catheter uni BWA	F-Type 7F 115cm 4p 2-5-2 TR
33392	Vanguard Ablation Catheter uni DS BWP	B-Type 7F 115cm 4p 1-6-2 TC
33395	Vanguard Ablation Catheter uni DS BWP	D-Type 7F 115cm 4p 1-6-2 TC
33265	Vanguard Ablation Catheter uni DS BWP	F-Type 7F 115cm 4p 1-6-2 TC

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Vanguard Ablation Catheter bi BWB/DS BWQ		
<p><b>Indications for Use per IFU</b></p> <p>The Vanguard Ablation Catheter bi BWB/DS BWQ is designed for temporary intercardiac ECG conductance and stimulation (mapping) of the heart within the scope of electrophysiological examinations, in conjunction with compatible connection cables from the Biosense Webster, Inc. Company and suitable devices for electrophysiological mapping. All Vanguard Ablation Catheter bi BWB/DS BWQ are intended for use with compatible RF generators and 8F introducer sheaths. For dispersive electrodes read and follow the manufacturer instruction for use. It is recommended that dispersive electrodes meet or exceed the requirements according EN 60601-2-2.</p>		
<p><b>Classification</b></p> <p>Class III Non-Implantable</p>		
Catalog Number	Device Name	Model, Type
34776	Vanguard Ablation Catheter bi BWB	DD-Type 7F 115cm 4p 1-7-4 TC
34777	Vanguard Ablation Catheter bi BWB	DF-Type 7F 115cm 4p 1-7-4 TC
34778	Vanguard Ablation Catheter bi BWB	FJ-Type 7F 115cm 4p 1-7-4 TC
34772	Vanguard Ablation Catheter bi DS BWQ	DD-Type 7F 115cm 4p 1-7-4 TC
34773	Vanguard Ablation Catheter bi DS BWQ	DF-Type 7F 115cm 4p 1-7-4 TC
34774	Vanguard Ablation Catheter bi DS BWQ	FF-Type 7F 115cm 4p 1-7-4 TC
34775	Vanguard Ablation Catheter bi DS BWQ	FJ-Type 7F 115cm 4p 1-7-4 TC

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Vanguard Irrigated Ablation Catheter BW

### Indications for Use per IFU

The Vanguard Irrigated Ablation Catheter BW is intended for temporary intracardiac electrophysiological mapping (stimulation and recording) in conjunction with compatible connection cables from the Biosense Webster Inc. and suitable devices for electrophysiological mapping and when used with compatible radiofrequency generator, for cardiac ablation. All Vanguard Irrigated Ablation Catheter BW are intended for use with compatible RF generators, cables navigation systems, 8F introducer sheaths and irrigation pumps. It is recommended that dispersive electrodes meet or exceed the requirements according to EN 60601-2-2.

Catheter types with navigation function (see technical data) provide location information when used with a Carto 3 EP Navigation System (version 2.3 or higher).

### Classification

Class III Non-Implantable

Catalog Number	Device Name	Model, Type
34474	Vanguard Irrigated Ablation Catheter bi BWH	DF-Type 8F 115cm 4p 2-5-2 TC TE3.5
34830	Vanguard Irrigated Ablation Catheter bi BWH	FF-Type 8F 115cm 4p 2-5-2 TC TE3.5
34831	Vanguard Irrigated Ablation Catheter bi BWH	FJ-Type 8F 115cm 4p 2-5-2 TC TE3.5
34758	Vanguard Irrigated Ablation Catheter NAV bi BWJ	DF-Type 8F 115cm 4p 2-5-2 TC TE3.5
34808	Vanguard Irrigated Ablation Catheter NAV bi BWJ	FJ-Type 8F 115cm 4p 2-5-2 TC TE3.5
34833	Vanguard Irrigated Ablation Catheter NAV uni BWI	B-Type 8F 115cm 4p 2-5-2 TC TE3.5
34834	Vanguard Irrigated Ablation Catheter NAV uni BWI	C-Type 8F 115cm 4p 2-5-2 TC TE3.5

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Catalog Number	Device Name	Model, Type
34473	Vanguard Irrigated Ablation Catheter NAV uni BWI	D-Type 8F 115cm 4p 2-5-2 TC TE3.5
34835	Vanguard Irrigated Ablation Catheter NAV uni BWI	F-Type 8F 115cm 4p 2-5-2 TC TE3.5
34836	Vanguard Irrigated Ablation Catheter NAV uni BWI	J-Type 8F 115cm 4p 2-5-2 TC TE3.5
34842	Vanguard Irrigated Ablation Catheter SF bi BWS	BD-Type 8F 115cm 6p 2-5-2 TC TE3.5
34832	Vanguard Irrigated Ablation Catheter SF bi BWS	BF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34472	Vanguard Irrigated Ablation Catheter SF bi BWS	DF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34843	Vanguard Irrigated Ablation Catheter SF bi BWS	FJ-Type 8F 115cm 6p 2-5-2 TC TE3.5
34805	Vanguard Irrigated Ablation Catheter SF NAV bi BWU	BD-Type 8F 115cm 6p 2-5-2 TC TE3.5
34806	Vanguard Irrigated Ablation Catheter SF NAV bi BWU	BF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34844	Vanguard Irrigated Ablation Catheter SF NAV bi BWU	DD-Type 8F 115cm 6p 2-5-2 TC TE3.5
34469	Vanguard Irrigated Ablation Catheter SF NAV bi BWU	DF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34807	Vanguard Irrigated Ablation Catheter SF NAV bi BWU	FJ-Type 8F 115cm 6p 2-5-2 TC TE3.5
34471	Vanguard Irrigated Ablation Catheter SF NAV uni BWT	D-Type 8F 115cm 6p 2-5-2 TC TE3.5

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Catalog Number	Device Name	Model, Type
34840	Vanguard Irrigated Ablation Catheter SF NAV uni BWT	F-Type 8F 115cm 6p 2-5-2 TC TE3.5
34841	Vanguard Irrigated Ablation Catheter SF NAV uni BWT	J-Type 8F 115cm 6p 2-5-2 TC TE3.5
34837	Vanguard Irrigated Ablation Catheter SF uni BWR	B-Type 8F 115cm 6p 2-5-2 TC TE3.5
34470	Vanguard Irrigated Ablation Catheter SF uni BWR	D-Type 8F 115cm 6p 2-5-2 TC TE3.5
34838	Vanguard Irrigated Ablation Catheter SF uni BWR	F-Type 8F 115cm 6p 2-5-2 TC TE3.5
34839	Vanguard Irrigated Ablation Catheter SF uni BWR	J-Type 8F 115cm 6p 2-5-2 TC TE3.5
34827	Vanguard Irrigated Ablation Catheter uni BWG	B-Type 7F 115cm 4p 2-5-2 TC TE3.5
34828	Vanguard Irrigated Ablation Catheter uni BWG	D-Type 7F 115cm 4p 2-5-2 TC TE3.5
34475	Vanguard Irrigated Ablation Catheter uni BWG	F-Type 7F 115cm 4p 2-5-2 TC TE3.5
34829	Vanguard Irrigated Ablation Catheter uni BWG	J-Type 7F 115cm 4p 2-5-2 TC TE3.5

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## Certificate History

Date	Reference Number	Action
14 September 2016	10162332	First Issue.
14 November 2016	10165847	Addition of Remanufactured Celsius bi-directional/Celsius DS bi-directional Ablation Catheters.
18 April 2017	10170600	Rebranded remanufactured Celsius product line to Vanguard Ablation Catheter uni BWA, uni DS BWP, bi BWB, and bi DS BWQ.
14 August 2018	8734888	Addition of Remanufactured Celsius Thermocool uni-Directional (SF and non-SF) and bi-directional (SF and non-SF) Irrigation Ablation Catheter Families including Navigation and Non-Navigation variants.
05 February 2019	8768383	Traceable to NB 0086.
18 October 2019	9659451	Addition of remanufacturing cycles (3x remanufacturing) for Vanguard Irrigated Ablation Catheters uni BWG, Nav uni BWI, SF uni BWR, SF NAV uni BWT, bi BWH, NAV bi BWJ, SF bi BWS, SF NAV bi BWU.
Current	3320003	Certificate renewal. Addition of product table.

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