

# EC Design-Examination Certificate

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

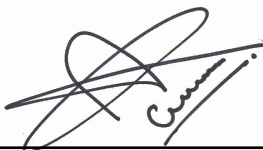
**No.** **CE 652103**  
Issued To: **Vanguard AG**  
**Landsberger Str. 266**  
**Berlin**  
**12623**  
**Germany**

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):



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 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.

A member of BSI Group of Companies.

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

Vanguard Article No.	Vanguard Product Description
33396	A-Typ 6F 92cm 4p 2-5-2 TC
33397	A-Typ 6F 92cm 4p 2-5-2 TR
33398	B-Typ 6F 92cm 4p 2-5-2 TC
33545	B-Typ 6F 92cm 4p 2-5-2 TR
33477	D-Typ 6F 92cm 4p 2-5-2 TC
33547	D-Typ 6F 92cm 4p 2-5-2 TR
33548	E-Typ 6F 92cm 4p 2-5-2 TC
33549	A-Typ 7F 115cm 4p 2-5-2 TR
33551	B-Typ 7F 115cm 4p 2-5-2 TC
33550	B-Typ 7F 115cm 4p 2-5-2 TR
33552	C-Typ 7F 115cm 4p 2-5-2 TC
33553	C-Typ 7F 115cm 4p 2-5-2 TR
33260	D-Typ 7F 115cm 4p 2-5-2 TC
33497	D-Typ 7F 115cm 4p 2-5-2 TR
33554	E-Type 7F 115cm 4p 2-5-2 TC
33555	E-Type 7F 115cm 4p 2-5-2 TR
33556	F-Type 7F 115cm 4p 2-5-2 TC
33557	F-Type 7F 115cm 4p 2-5-2 TR

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### VANGUARD ABLATION CATHETER uni DS BWP

Vanguard Article No.	Vanguard Product Description
33392	B-Typ 7F 115cm 4p 1-6-2 TC
33395	D-Typ 7F 115cm 4p 1-6-2 TC
33265	F-Typ 7F 115cm 4p 1-6-2 TC

### VANGUARD ABLATION CATHETER bi BWB

Vanguard Article No.	Vanguard Product Description
34776	DD-Typ 7F 115cm 4p 1-7-4 TC
34777	DF-Typ 7F 115cm 4p 1-7-4 TC
34778	FJ-Typ 7F 115cm 4p 1-7-4 TC

### VANGUARD ABLATION CATHETER bi DS BWQ

Vanguard Article No.	Vanguard Product Description
34772	DD-Typ 7F 115cm 4p 1-7-4 TC
34773	DF-Typ 7F 115cm 4p 1-7-4 TC
34774	FF-Typ 7F 115cm 4p 1-7-4 TC
34775	FJ-Typ 7F 115cm 4p 1-7-4 TC

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### VANGUARD IRRIGATED ABLATION CATHETER uni BWG

Vanguard Article No.	Vanguard Product Description
34827	B-Type 7.5F 115cm 4p 2-5-2 TC TE3.5
34828	D-Type 7.5F 115cm 4p 2-5-2 TC TE3.5
34475	F-Type 7.5F 115cm 4p 2-5-2 TC TE3.5
34829	J-Type 7.5F 115cm 4p 2-5-2 TC TE3.5

### VANGUARD IRRIGATED ABLATION CATHETER SF uni BWR

34837	B-Type 8F 115cm 6p 2-5-2 TC TE3.5
34470	D-Type 8F 115cm 6p 2-5-2 TC TE3.5
34838	F-Type 8F 115cm 6p 2-5-2 TC TE3.5
34839	J-Type 8F 115cm 6p 2-5-2 TC TE3.5

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### VANGUARD IRRIGATED ABLATION CATHETER bi BWH

Vanguard Article No.	Vanguard Product Description
34474	DF-Type 8F 115cm 4p 2-5-2 TC TE3.5
34830	FF-Type 8F 115cm 4p 2-5-2 TC TE3.5
34831	FJ-Type 8F 115cm 4p 2-5-2 TC TE3.5

### VANGUARD IRRIGATED ABLATION CATHETER SF bi BWS

Vanguard Article No.	Vanguard Product Description
34842	BD-Type 8F 115cm 6p 2-5-2 TC TE3.5
34832	BF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34472	DF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34843	FJ-Type 8F 115cm 6p 2-5-2 TC TE3.5

### VANGUARD IRRIGATED ABLATION CATHETER NAV uni BWI

Vanguard Article No.	Vanguard Product Description
34833	B-Type 8F 115cm 4p 2-5-2 TC TE3.5
34834	C-Type 8F 115cm 4p 2-5-2 TC TE3.5
34473	D-Type 8F 115cm 4p 2-5-2 TC TE3.5
34835	F-Type 8F 115cm 4p 2-5-2 TC TE3.5
34836	J-Type 8F 115cm 4p 2-5-2 TC TE3.5

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### VANGUARD IRRIGATED ABLATION CATHETER SF NAV uni BWT

Vanguard Article No.	Vanguard Product Description
34471	D-Type 8F 115cm 6p 2-5-2 TC TE3.5
34840	F-Type 8F 115cm 6p 2-5-2 TC TE3.5
34841	J-Type 8F 115cm 6p 2-5-2 TC TE3.5

### VANGUARD IRRIGATED ABLATION CATHETER NAV bi BWJ

Vanguard Article No.	Vanguard Product Description
34758	DF-Type 8F 115cm 4p 2-5-2 TC TE3.5
34808	FJ-Type 8F 115cm 4p 2-5-2 TC TE3.5

### VANGUARD IRRIGATED ABLATION CATHETER SF NAV bi BWU

Vanguard Article No.	Vanguard Product Description
34805	BD-Type 8F 115cm 6p 2-5-2 TC TE3.5
34806	BF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34844	DD-Type 8F 115cm 6p 2-5-2 TC TE3.5
34469	DF-Type 8F 115cm 6p 2-5-2 TC TE3.5
34807	FJ-Type 8F 115cm 6p 2-5-2 TC TE3.5

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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.
Current	8768383	Traceable to NB 0086.

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