

EC Design-Examination Certificate

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

No. CE 721173
Issued To: Vanguard AG
Landsberger Str. 266
Berlin
12623
Germany

In respect of:

Remanufactured Vanguard Irrigated Ablation Catheter NAV uni ST BWV
Remanufactured Vanguard Irrigated Ablation Catheter NAV bi ST BWV
Remanufactured Vanguard Irrigated Ablation Catheter SF NAV uni ST BWX
Remanufactured Vanguard Irrigated Ablation Catheter SF NAV bi ST BWY

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: **2021-05-04**

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 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.

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Supplementary Information to CE 721173

Issued To:

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Catalogue No	Device Name	Model, Type	Intended Use per IFU	Classification
35117	Vanguard Irrigated Ablation Catheter NAV uni ST BWW	D-Type 8F 115cm 4p 1-6-2 TC TE3.5	<p>The Vanguard Irrigated Ablation Catheter NAV ST BW is indicated in conjunction with compatible accessories for catheter-based electrophysiological mapping (stimulation and recording) and in conjunction with a compatible RF generator for cardiac ablations.</p> <p>In combination with a compatible CARTO 3 navigation system, the Vanguard Irrigated Ablation Catheter NAV ST BW provides real-time information on the contact force between the catheter tip and the heart wall as well as on the position of the catheter tip.</p>	Class III
35118	Vanguard Irrigated Ablation Catheter NAV uni ST BWW	F-Type 8F 115cm 4p 1-6-2 TC TE3.5		Class III
35119	Vanguard Irrigated Ablation Catheter NAV uni ST BWW	J-Type 8F 115cm 4p 1-6-2 TC TE3.5		Class III
35123	Vanguard Irrigated Ablation Catheter NAV bi ST BWW	DD-Type 8F 115cm 4p 1-6-2 TC TE3.5		Class III
35124	Vanguard Irrigated Ablation Catheter NAV bi ST BWW	FF-Type 8F 115cm 4p 1-6-2 TC TE3.5		Class III
35125	Vanguard Irrigated Ablation Catheter NAV bi ST BWW	JJ-Type 8F 115cm 4p 1-6-2 TC TE3.5		Class III
35126	Vanguard Irrigated Ablation Catheter NAV bi ST BWW	FJ-Type 8F 115cm 4p 1-6-2 TC TE3.5		Class III
35127	Vanguard Irrigated Ablation Catheter NAV bi ST BWW	DF-Type 8F 115cm 4p 1-6-2 TC TE3.5		Class III
35120	Vanguard Irrigated Ablation Catheter SF NAV uni ST BWX	D-Type 8F 115cm 6p 1-6-2 TC TE3.5		Class III
35121	Vanguard Irrigated Ablation Catheter SF NAV uni ST BWX	F-Type 8F 115cm 6p 1-6-2 TC TE3.5		Class III

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Catalogue No	Device Name	Model, Type	Intended Use per IFU	Classification
35122	Vanguard Irrigated Ablation Catheter SF NAV uni ST BWX	J-Type 8F 115cm 6p 1-6-2 TC TE3.5	The Vanguard Irrigated Ablation Catheter NAV ST BW is indicated in conjunction with compatible accessories for catheter-based electrophysiological mapping (stimulation and recording) and in conjunction with a compatible RF generator for cardiac ablations.	Class III
35128	Vanguard Irrigated Ablation Catheter SF NAV bi ST BWY	DD-Type 8F 115cm 6p 1-6-2 TC TE3.5		Class III
35129	Vanguard Irrigated Ablation Catheter SF NAV bi ST BWY	FF-Type 8F 115cm 6p 1-6-2 TC TE3.5		Class III
35130	Vanguard Irrigated Ablation Catheter SF NAV bi ST BWY	JJ-Type 8F 115cm 6p 1-6-2 TC TE3.5		Class III
35131	Vanguard Irrigated Ablation Catheter SF NAV bi ST BWY	FJ-Type 8F 115cm 6p 1-6-2 TC TE3.5		Class III
35132	Vanguard Irrigated Ablation Catheter SF NAV bi ST BWY	DF-Type 8F 115cm 6p 1-6-2 TC TE3.5	In combination with a compatible CARTO 3 navigation system, the Vanguard Irrigated Ablation Catheter NAV ST BW provides real-time information on the contact force between the catheter tip and the heart wall as well as on the position of the catheter tip.	Class III

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