

EC Design-Examination Certificate

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

No. CE 713013
Issued To: Vanguard AG
Landsberger Str. 266
Berlin
12623
Germany

In respect of:

Remanufactured Vanguard Irrigated Ablation Catheter uni SJG
Remanufactured Vanguard Irrigated Ablation Catheter bi SJH
Remanufactured Vanguard Irrigated Ablation Catheter SE uni SJI
Remanufactured Vanguard Irrigated Ablation Catheter SE bi SJJ

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.

EC Design-Examination Certificate

Supplementary Information to CE 713013

Issued To:

Vanguard AG
Landsberger Str. 266
Berlin
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Catalogue No	Device Name	Model, Type	Intended Use per IFU	Classification
35096	Vanguard Irrigated Ablation Catheter uni SJG	D-Type 8F 115cm 4p 1-4-1 TC TE4	The Vanguard Irrigated Ablation Catheter SJ is intended for the treatment of arrhythmias in combination with compatible accessories: temporary intracardiac ECG mapping and heart stimulation, as well as for the generation of focal lesions during cardiac ablation procedures. The SJI and SJJ navigation catheters (see specifications) provide positioning information when used in conjunction with compatible S.JMTM visualisation and 3D navigation systems. Use should be limited to patients with ventricular tachycardia where epicardial ablation is appropriate.	Class III
35097	Vanguard Irrigated Ablation Catheter uni SJG	F-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35098	Vanguard Irrigated Ablation Catheter uni SJG	J-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35099	Vanguard Irrigated Ablation Catheter bi SJH	DD-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35100	Vanguard Irrigated Ablation Catheter bi SJH	DF-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35101	Vanguard Irrigated Ablation Catheter bi SJH	FF-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35102	Vanguard Irrigated Ablation Catheter bi SJH	FJ-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35103	Vanguard Irrigated Ablation Catheter bi SJH	JJ-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35104	Vanguard Irrigated Ablation Catheter SE uni SJI	D-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35105	Vanguard Irrigated Ablation Catheter SE uni SJI	F-Type 8F 115cm 4p 1-4-1 TC TE4		Class III

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Catalogue No	Device Name	Model, Type	Intended Use per IFU	Classification
35106	Vanguard Irrigated Ablation Catheter SE uni SJI	J-Type 8F 115cm 4p 1-4-1 TC TE4	The Vanguard Irrigated Ablation Catheter SJ is intended for the treatment of arrhythmias in combination with compatible accessories: temporary intracardiac ECG mapping and heart stimulation, as well as for the generation of focal lesions during cardiac ablation procedures. The SJI and SJJ navigation catheters (see specifications) provide positioning information when used in conjunction with compatible S.JMTM visualisation and 3D navigation systems. Use should be limited to patients with ventricular tachycardia where epicardial ablation is appropriate.	Class III
35107	Vanguard Irrigated Ablation Catheter SE bi SJJ	DD-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35108	Vanguard Irrigated Ablation Catheter SE bi SJJ	DF-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35109	Vanguard Irrigated Ablation Catheter SE bi SJJ	FF-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35110	Vanguard Irrigated Ablation Catheter SE bi SJJ	FJ-Type 8F 115cm 4p 1-4-1 TC TE4		Class III
35111	Vanguard Irrigated Ablation Catheter SE bi SJJ	JJ-Type 8F 115cm 4p 1-4-1 TC TE4		Class III

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Certificate History

Date	Reference Number	Action
Date	9788656	First Issue.

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