

EC Design-Examination Certificate

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

No. CE 717745
Issued To: Vanguard AG
Landsberger Str. 266
Berlin
12623
Germany

In respect of:

**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.**

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: **2019-10-17**

Date: **2021-04-05**

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

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Page 1 of 5

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 717745

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Remanufactured Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN/Vanguard Variable Loop Diagnostic Catheter NAV eco BWO

Catalogue No Prefix - Suffix	Device Name	Model, Type	Intended Use per IFU	Classification
34437	Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN	D-Type/15 7F/4F 115cm 10p 4.5	Intended for temporary intracardial ECG recording and stimulation (mapping) of the cardiac structures within the scope of electrophysiological examinations.	Class III
34438	Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN	D-Type/15 7F/4F 115cm 20p 4.5	Intended for temporary intracardial ECG recording and stimulation (mapping) of the cardiac structures within the scope of electrophysiological examinations.	Class III
34439	Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN	D-Type/20 7F/4F 115cm 10p 6	Intended for temporary intracardial ECG recording and stimulation (mapping) of the cardiac structures within the scope of electrophysiological examinations.	Class III
34440	Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN	D-Type/20 7F/4F 115cm 20p 6	Intended for temporary intracardial ECG recording and stimulation (mapping) of the cardiac structures within the scope of electrophysiological examinations.	Class III

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Catalogue No Prefix - Suffix	Device Name	Model, Type	Intended Use per IFU	Classification
34846	Vanguard Fixed Loop Diagnostic Catheter NAV eco BWN	D-Type/25 7F/4F 115cm 10p 6	Intended for temporary intracardial ECG recording and stimulation (mapping) of the cardiac structures within the scope of electrophysiological examinations.	Class III
34413	Vanguard Variable Loop Diagnostic Catheter NAV eco BWO	D-Type/15-25 7F/4F 115cm 22p 2-6-2	Intended for temporary intracardial ECG recording and stimulation (mapping) of the cardiac structures within the scope of electrophysiological examinations.	
34436	Vanguard Variable Loop Diagnostic Catheter NAV eco BWO	D-Type/15-25 7F/4F 115cm 12p 8	Intended for temporary intracardial ECG recording and stimulation (mapping) of the cardiac structures within the scope of electrophysiological examinations.	

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Page 3 of 5

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Remanufactured Vanguard Steerable Diagnostic Catheter ID BWAB, bi BWAC, bi ID BWAD

Catalogue No.	Device Name	Model, Type	Intended Use per IFU	Classification
35087	Vanguard Steerable Diagnostic Catheter ID BWAB	D-Type 6F 115cm 10p 2-8-2	The Vanguard Steerable Diagnostic Catheters ID BWAB, bi BWAC, bi ID BWAD are intended for temporary intracardiac electrophysiological recording and stimulation (mapping) during the evaluation of cardiac arrhythmias. The catheter is designed for use in the coronary sinus.	Class III
35050	Vanguard Steerable Diagnostic Catheter ID BWAB	F-Type 6F 115cm 10p 2-8-2		
35051	Vanguard Steerable Diagnostic Catheter bi BWAC	DF-Type 7F 115cm 10p 2-8-2		
35052	Vanguard Steerable Diagnostic Catheter bi ID BWAD	DF-Type 7F 115cm 10p 2-8-2		
35088	Vanguard Steerable Diagnostic Catheter bi ID BWAD	FJ-Type 7F 115cm 10p 2-8-2		

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Page 4 of 5

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Certificate History

Date	Reference Number	Action
17 October 2019	8889610	First Certificate Issue.
Current	9630472	Added Vanguard Remanufactured Steerable Diagnostic Catheters ID BWAB, bi BWAC and bi ID BWAD

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Page 5 of 5

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