

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

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: **2019-10-17**

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 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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Certificate History

Date	Reference Number	Action
Current	8889610	First Certificate Issue.

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