

EC Design-Examination Certificate

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

No. **CE 666374**
Issued To: **Vanguard AG**
Landsberger Str. 266
Berlin
12623
Germany

In respect of:

Remanufactured Vanguard Fixed Loop Diagnostic Catheter SJB
Remanufactured Vanguard Fixed Loop Diagnostic Catheter EB SJD
Remanufactured Vanguard Variable Loop Diagnostic Catheter SJC
Remanufactured Vanguard Variable Loop Diagnostic Catheter EB SJE

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: **2018-07-05**

Date: **2019-02-05**

Expiry Date: **2023-07-04**

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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 666374

Issued To:

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Vanguard Fixed Loop Diagnostic Catheter SJB

Vanguard Article No.	Vanguard Product Description
34392	SM/AF20 7F/4F 110cm 10p 5 TE1 RE1
34441	SM/AF20DL 7F/4F 110cm 20p 4 TE2 RE1
34442	SM/AF15 7F/4F 110cm 10p 3.5 TE1 RE1

Vanguard Fixed Loop Diagnostic Catheter EB SJD

Vanguard Article No.	Vanguard Product Description
34443	SM/AF20 7F/4F 110cm 10p 5 TE2 RE1
34444	SM/AF15 7F/4F 110cm 10p 3 TE2 RE1
34445	SM/AF20 7F/4F 110cm 20p 1-2.5-1 TE2 RE1

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Vanguard Variable Loop Diagnostic Catheter SJC

Vanguard Article No.	Vanguard Product Description
34395	SM/OPT25 7F/4F 110cm 10p 7 TE2 RE1
34447	SM/OPT25 7F/5F 110cm 20p 1-4.5-1 TE2 RE1
34449	SM/OPT25 7F/5F 110cm 24p 1-4.5-1 TE2 RE1

Vanguard Variable Loop Diagnostic Catheter EB SJE

Vanguard Article No.	Vanguard Product Description
34446	SM/OPT25 7F/4F 110cm 10p 7 TE2 RE1
34448	SM/OPT25 7F/5F 110cm 20p 1-4.5-1 TE2 RE1

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Certificate History

Date	Reference Number	Action
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Current	8768383	Traceable to NB 0086.

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