

# EC Design-Examination Certificate

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

**No.** CE 717746  
Issued To: **Vanguard AG**  
**Landsberger Str. 266**  
**Berlin**  
**12623**  
**Germany**

In respect of:

**Remanufactured Vanguard Ablation Catheters uni LT G BTA, uni LT BTB, uni G BTC, uni LTD**

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: **2021-04-05**

Date: **2021-04-05**

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

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Page 1 of 4

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 717746

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### Remanufactured Vanguard Ablation Catheters uni LT G BTA, uni LT BTB, uni G BTC, uni LTD

Catalog No	Device Name	Model, Type	Intended Use per IFU	Classification
34977	Vanguard Ablation Catheter uni LT G BTA	FC Red 7F 110cm 4p 2-5-2 TC	The Vanguard Ablation Catheter uni BT are intended for the treatment of supraventricular and ventricular tachycardia or atrioventricular node re-entry tachycardia	Class III
34976	Vanguard Ablation Catheter uni LT G BTA	FC Blue 7F 110cm 4p 2-5-2 TC		
34978	Vanguard Ablation Catheter uni LT G BTA	FC Green 7F 110cm 4p 2-5-2 TC		
34971	Vanguard Ablation Catheter uni LT G BTA	FC Black 7F 110cm 4p 2-5-2 TC		
34979	Vanguard Ablation Catheter uni LT G BTA	FC Cyan 7F 110cm 4p 2-5-2 TC		
34980	Vanguard Ablation Catheter uni LT BTB	FC Blue 7F 110cm 4p 2-5-2 TC		
34972	Vanguard Ablation Catheter uni LT BTB	FC Black 7F 110cm 4p 2-5-2 TC		
34981	Vanguard Ablation Catheter uni G BTC	FC Red 7F 110cm 4p 2-5-2 TC		

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Page 2 of 4

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Catalog No	Device Name	Model, Type	Intended Use per IFU	Classification
34982	Vanguard Ablation Catheter uni G BTC	FC Blue 7F 110cm 4p 2-5-2 TC	The Vanguard Ablation Catheter uni BT are intended for the treatment of supraventricular and ventricular tachycardia or atrioventricular node re-entry tachycardia	Class III
34983	Vanguard Ablation Catheter uni G BTC	FC Green 7F 110cm 4p 2-5-2 TC		
34969	Vanguard Ablation Catheter uni G BTC	FC Black 7F 110cm 4p 2-5-2 TC		
34984	Vanguard Ablation Catheter uni G BTC	FC Cyan 7F 110cm 4p 2-5-2 TC		
34985	Vanguard Ablation Catheter uni BT D	FC Red 7F 110cm 4p 2-5-2 TC		
34986	Vanguard Ablation Catheter uni BT D	FC Blue 7F 110cm 4p 2-5-2 TC		
34987	Vanguard Ablation Catheter uni BT D	FC Green 7F 110cm 4p 2-5-2 TC		
34970	Vanguard Ablation Catheter uni BT D	FC Black 7F 110cm 4p 2-5-2 TC		

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Page 3 of 4

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## Certificate History

Date	Reference Number	Action
Current	9634679	First issue

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