

Certificate

EC Design Examination

Annex II.4 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that a design examination has been carried out on the device(s) listed in annex I to this certificate following the requirements of annex II.4 of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Vanguard AG

Landsberger Str. 266, 12623 Berlin, Germany

ECM certifies that the design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.4 of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.

Report Number

645-0442CB

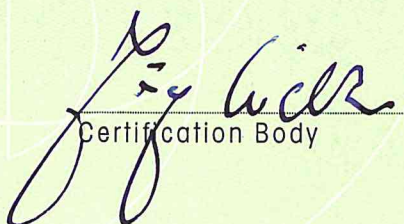
Registered under

Z/19/04603E

Valid until

June 30th, 2021

Valid as of: August 23rd, 2019


Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-240.10.12

Annex I of Certificate Z/19/04603E

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Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
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single use devices	Electrodes, Intracardiac, Conduction Study	17-612
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Steerable Diagnostic catheter SJA

- 34370, Inquiry L 6F 110 10-pole 5 TE1BE1
- 34371, Inquiry M 4F 110 10-pole 2 TE1BE1
- 34372, Inquiry L 5F 110 10-pole 2-5-2 TE1BE1
- 34417, Inquiry M 4F 110 4-pole 2-5-2 TE1BE1
- 34418, Inquiry L 5F 110 4-pole 2-5-2 TE1BE1
- 34419, Inquiry M 5F 110 4-pole 2-5-2 TE1BE1
- 34420, Inquiry L 6F 110 4-pole 2-5-2 TE2BE2
- 34421, Inquiry M 6F 110 4-pole 2-5-2 TE2BE2
- 34422, Inquiry XL 6F 110 4-pole 2-5-2 TE2BE2
- 34423, Inquiry L 6F 110 4-pole 5 TE2BE2
- 34424, Inquiry L 6F 110 8-pole 2 TE1BE1
- 34425, Inquiry M 6F 110 8-pole 2 TE1BE1
- 34426, Inquiry L 4F 110 10-pole 2-5-2 TE1BE1
- 34427, Inquiry M 4F 110 10-pole 2-5-2 TE1BE1
- 34428, Inquiry M 5F 110 10-pole 2-5-2 TE1BE1
- 34429, Inquiry L 6F 110 10-pole 2-5-2 TE1BE1
- 34430, Inquiry M 6F 110 10-pole 2-5-2 TE1BE1
- 34431, Inquiry XL 6F 110 10-pole 2-5-2 TE1BE1
- 34432, Inquiry L 6F 110 10-pole 2 TE1BE1
- 34433, Inquiry XXL 7F 110 20-pole 2-10-2 TE1BE1
- 34434, Inquiry SL 7F 110 20-pole 2-5-2 TE1BE1
- 34435, Inquiry SL 7F 110 20-pole 5 TE1BE1
- 34454, Inquiry M 6F 110 4-pole 5 TE2BE2
- 34455, Inquiry L 6F 110 8-pole 2-5-2 TE1BE1
- 34456, Inquiry M 6F 110 8-pole 2-5-2 TE1BE1

Steerable Diagnostic catheter SJF

- 35091, Inquiry L-Type 5F 110 cm 10p 2-5-2 TE1 RE 1
- 35092, Inquiry M/L-Type 5F 110 cm 10p 2-8-2 TE1 RE 1
- 35093, Inquiry L-Type 5F 110 cm 10p 5 TE1 RE 1
- 35094, Inquiry L-Type 6F 110 cm 10p 2-5-2 TE1 RE 1
- 35095, Inquiry M/L-Type 6F 110 cm 10p 5 TE1 RE 1

¹ UMDNS Code ist optional