

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
645-1335FF

Registered under
Z/16/03984E

Valid until
December 22nd, 2021

Aachen, December 23rd, 2016


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/16/03984E
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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
single use devices	Electrodes, Intracardiac, Conduction Study as newly prepared Bard DYNAMIC XT: <ul style="list-style-type: none">- VAN 33263: Large 4.0, 6F, 110 cm, 10-polig 2-5-2- VAN 33382: Large 4.0, 6F, 110 cm, 10-polig 2-6-2- VAN 33383: Large 4.0, 6F, 110 cm, 4-polig 2-5-2- VAN 33384: Large 4.0, 6F, 110 cm, 4-polig 5- VAN 33385: Large 4.0, 6F, 110 cm, 8-polig 2-5-2- VAN 33386: Large 4.0, 6F, 110 cm, 8-polig 2- VAN 33387: Large 4.0, 6F, 110 cm, 8-polig 5- VAN 33388: Large 4.0, 6F, 110 cm, 8-polig 2-10-2- VAN 33389: Large 4.0, 6F, 110 cm, 4-polig 1- VAN 33390: Large 4.0, 6F, 110 cm, 4-polig 2- VAN 33391: Large 4.0, 6F, 110 cm, 6-polig 5	17-612

Special terms of validity:

None.

¹ UMDNS Code ist optional