



# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

**No. G1 019742 0092 Rev. 01**

**Manufacturer:**

**VascoMed GmbH**

Hertzallee 1  
79589 Binzen  
GERMANY

**Product Category(ies): Ablation Catheters,  
Temporary Catheters and Electrodes for  
Stimulation and Electrophysiology Diagnostics,  
Accessories for Catheters and Electrodes**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10197420092Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G10197420092Rev.01)

**Report No.:** 713203432

**Valid from:** 2021-03-01

**Valid until:** 2024-05-26

**Date,** 2021-03-01

Christoph Dicks  
Head of Certification/Notified Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

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**Design Facility(ies):**

VascoMed GmbH

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