



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



Product Service

# 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 015198 0031 Rev. 00**

**Manufacturer:**

**Bionic Medizintechnik GmbH**

Max-Planck-Straße 21

61381 Friedrichsdorf

GERMANY

**Product Category(ies):** **Fistula Needles**  
**Dialysis Catheters**  
**Connection and Disconnection Sets**

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:G10151980031Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G10151980031Rev.00)

**Report No.:** 713166914

**Valid from:** 2020-11-13

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

**Date,** 2020-11-13

Christoph Dicks  
Head of Certification/Notified Body



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## Products:

Fistula needles, fixed wing

Fistula needles, rotating hub

Fistula needles, "Single Needle"

Fistula needles, "Button Hole"

Safety fistula needles

Dialysis Connection and Disconnection Sets

Dialysis catheters, single and multi lumen

Dialysis catheter sets

Dialysis catheter, accessories

DEMERS catheter, implantable