



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 044904 0052 Rev. 00**

**Manufacturer:**

**B. Braun Medical Inc.**

824 Twelfth Avenue  
Bethlehem PA 18018  
USA

**Product Category(ies): I.V. Administration Devices and  
Accessories, Port Access Devices,  
Subcutaneous Catheter Infusion Devices,  
Safety Introducer Needles**

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. See also notes overleaf.

**Report No.:**

72147201

**Valid from:**

2020-02-21

**Valid until:**

2024-05-26

**Date,**

2020-02-21

Christoph Dicks  
Head of Certification/Notified Body



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## Facility(ies):

B. Braun Medical Inc.  
901 Marcon Boulevard, Allentown PA 18109-9341, USA

B. Braun of Dominican Republic Inc.  
Z. Franca, Ind'l Las Americas, Las Americas, KM #22, Santo  
Domingo, DOMINICAN REPUBLIC

B. Braun Medical Inc.  
824 Twelfth Avenue, Bethlehem PA 18018, USA

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