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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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No. G1 044904 0052 Rev. 00

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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