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

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 044904 0051 Rev. 00

Manufacturer

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

Product Category(ies):

I.V. Administration Devices and Accessories, Admixture Products, Angioplasty Procedure Devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72147199

Valid from: 2020-01-24
Valid until: 2024-05-26

Date, 2020-01-24

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G2S 044904 0051 Rev. 00

Facility(ies):

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

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

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

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