



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

Production Quality Assurance System

Directive 93/42/EEC on Medical devices (MDD), Annex V

(Devices in Class I with measuring function and in sterile condition)

No. G2MS 012974 0456 Rev. 01

Manufacturer

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

Sterile non-active medical devices for:

**-Urology, gastroenterology, suction and
drainage**

**as well as related configured customized
sets**

**-Infusion systems for volume control incl.
accessories**

-Measurement of central venous pressure

-Syringes, mixing containers

and dispenser sets for oral application

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements and 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.: 713168172

Valid from: 2019-12-23

Valid until: 2024-05-26

Date, 2019-12-23

Christoph Dicks
Head of Certification/Notified Body

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Facility(ies):

B. Braun Melsungen AG

Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

B. Braun Medical Industries Sdn. Bhd.

Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. Braun Medical AG

Hauptstraße 39, 6182 Escholzmat, SWITZERLAND

ALMO-Erzeugnisse Erwin Busch GmbH

Große Allee 84, 34454 Bad Arolsen, GERMANY

B. BRAUN MEDICAL SAS

13 rue Croix la Comtesse, 28400 Nogent-le-Rotrou, FRANCE

B. Braun Medical Kft Production Division

Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. BRAUN Vietnam Co., Ltd.

Thanh Oai Industrial Complex, Bich Hoa Commune, Thanh Oai
District, 156800 Hanoi, VIETNAM

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