



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

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

Effective

TÜV®

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Facility(ies):

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

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ALMO-Erzeugnisse Erwin Busch GmbH
Große Allee 84, 34454 Bad Arolsen, GERMANY

B. BRAUN MEDICAL SAS
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B. Braun Medical Kft Production Division
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B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Bich Hoa Commune, Thanh Oai
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