



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 012974 0607 Rev. 01

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

- Active medical devices for fluid management:
- Volumetric infusion pumps
 - Infusion syringe pumps
 - Elastomeric Pumps
 - Control & organisation units and systems made out of it
 - Irrigation Pump and Accessories
 - Enteral feeding pumps
 - Devices for nerve Stimulation
 - Pump for negative pressure wound therapy
- Non-active medical devices (sterile and non-sterile) for:
- Injection, Infusion, transfusion and nutrition
 - Anaesthesia, emergency, intensive and home care
 - Disinfecting, cleaning, rinsing
 - Irrigation
 - Cryotherapy
 - Configured customized sets
 - Medical devices for wound care
 - Medical Gloves
 - Sterile Solutions (Irrigation Solutions)
- Sterile products for urology and gastroenterology:
catheters, catheter kits, drainage and irrigation kits, urological
stents, nephrostomy kits, cystometry kits, accessories

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.: 713161992

Valid from: 2019-09-27

Valid until: 2024-05-26

Date, 2019-09-27

Stefan Preiß
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 Melsungen AG
 Werk PfiEFFewiesen, 34212 Melsungen, GERMANY

- B. Braun Melsungen AG
 Am Buschberg 1, 34212 Melsungen, GERMANY

- B. Braun Medical, S.A.
 Crta. de Terrassa, 121, 08191 Rubí (Barcelona), SPAIN

- B. Braun Medical AG
 Route de Sorge 9, 1023 Crissier, SWITZERLAND

- B. Braun Melsungen AG Sparte Pharma
 Mistelweg 2, 12357 Berlin, GERMANY

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

- B. Braun Melsungen AG
 Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

- B. Braun Aesculap Japan Co., Ltd. Tochigi Factory - Hospital Care
 285 Ogaki, Tsuga-machi, Tochigi-shi, Tochigi, 328-0101 JAPAN

- B. Braun Medical AG
 Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

- B. BRAUN Vietnam Co., Ltd.
 Thanh Oai Industrial Complex, Bich Hoa Commune, Thanh Oai
 District, 156800 Hanoi, VIETNAM

- B. Braun Melsungen AG OPM
 Carl-Braun-Straße 1, 34212 Melsungen, GERMANY

- B. Braun Melsungen AG OPM
 Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

