



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

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

TÜV®

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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  
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