



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
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 ZLG-BS-244.10.08



Product Service

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CERTIFICATE ◆ **CERTIFICADO** ◆ **CERTIFIKAT** ◆ **認證證書** ◆ **CERTIFICATE** ◆ **CERTIFIKAT**

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. 02

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
 - 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.: 713181267

Valid from: 2020-06-09
Valid until: 2024-05-26

Date, 2020-07-17

Christoph Dicks
 Head of Certification/Notified Body

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

Effective

