



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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. 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