



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

Page 1 of 3
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®

TÜV SÜD
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT

A4 / 07.17

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



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

B. Braun Medical AG
Seesatz 17, 6204 Sempach, SWITZERLAND

B. Braun Melsungen AG Werk Spangenberg
Dörnbach 10, 34286 Spangenberg, GERMANY

B. Braun Melsungen AG Werk E
Schwarzenberger Weg 21-27, 34212 Melsungen, GERMANY

B. BRAUN MEDICAL SAS
Z.I. de Layats, 64500 Saint-Jean-de-Luz, FRANCE

B. Braun Medical B.V.
Euterpehof 10, 5342 CW OSS, THE NETHERLANDS

-