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:
- Volumetrie 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
- Configued 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

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®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

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

TÜV SÜD 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

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

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ 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

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

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

A4 / 07.17