



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 15 04 12974 420

**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

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.:**

713060155

**Valid from:**

2015-05-20

**Valid until:**

2019-10-27

**Date,** 2015-05-21

Hans-Heiner Junker



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

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**Facility(ies):**

B. Braun Melsungen AG  
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B. Braun Melsungen AG  
Pfieffewiesen, 34212 Melsungen, GERMANY

B. Braun Medical Industries Sdn. Bhd.  
Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. Braun Melsungen AG  
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

B. Braun Melsungen AG  
Am Buschberg 1, 34212 Melsungen, GERMANY