



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 18 04 12974 455

### Manufacturer:

**B. Braun Melsungen AG**

Carl-Braun-Str. 1  
34212 Melsungen  
GERMANY



### Product Category(ies):

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

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.:

713128918

### Valid from:

2018-05-11

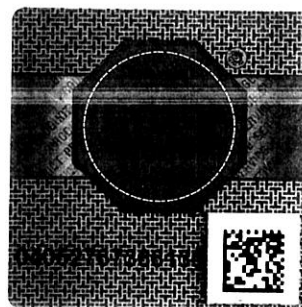
### Valid until:

2023-05-01

Date, 2018-05-11

*S. Preiß*

Stefan Preiß



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

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#### Facility(ies):

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

ALMO-Erzeugnisse Erwin Busch GmbH  
Große Allee 84, 34454 Bad Arolsen, GERMANY

B. Braun Medical SAS  
13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCE

B. BRAUN Vietnam Co., Ltd.  
170 La Thanh Road, Dong Da District, 63000 Hanoi, VIETNAM

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

B. Braun Medical AG  
Hauptstraße 39, 6182 Escholz matt, SWITZERLAND

B. BRAUN Vietnam Co., Ltd.  
Thanh Oai Industrial Complex, 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

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

NOTAR IN MEI

## USA

\* Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA



Maßnahmen, die

23. Mai 2018

Answer:

## Apostille

(Convention de La Haye du 5 octobre 1961)

1. Land: Bundesrepublik Deutschland  
Diese öffentliche Urkunde
2. ist unterschrieben von **Nils Weigand**
3. in seiner Eigenschaft als **Notar**
4. sie ist versehen mit dem Siegel des **Notars Nils Weigand** in **Melsungen**

### Bestätigt

5. in **Kassel**
6. am **10.07.2018**
7. durch **den Präsidenten des Landgerichts Kassel**
8. unter **91Eb1445/18**
9. Siegel/Stempel

10. Unterschrift

Der Präsident des Landgerichts Kassel



  
Simon