



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 04 12974 457

**Manufacturer:****B. Braun Melsungen AG**Carl-Braun-Str. 1  
34212 Melsungen  
GERMANY**Product  
Category(ies):****Sterile non-active medical devices for**

- Infusion, transfusion, nutrition and transfer devices
- Anaesthesia incl. accessories
- Urology, suction and drainage incl. accessories
- Catheterization and ventilation
- Oxygen therapy incl. accessories
- Incontinence
- Examination Gloves
- Wound care

**as well as related configured customized sets  
Irrigation systems for diagnostic**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:**

713128920

**Valid from:**

2018-05-02

**Valid until:**

2023-05-01

**Date,** 2018-04-27

Stefan Preiß

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

Page 1 of 2



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#### Facility(ies):

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Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. BRAUN Vietnam Co., Ltd.  
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VIETNAM

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