

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

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TÜV®

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Facility(ies):

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