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ZLG-BS-244.10.08

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 012974 0457 Rev. 01

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.: 713168175

Valid from: 2019-12-03
Valid until: 2024-05-26

Date, 2019-12-03

Christoph Dicks
Head of Certification/Notified Body

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

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Facility(ies):

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

ALMO-Erzeugnisse Erwin Busch GmbH
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B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Bich Hoa Commune, Thanh Oai District, 156800 Hanoi, VIETNAM

B. BRAUN MEDICAL SAS
13 rue Croix la Comtesse, 28400 Nogent-le-Rotrou, FRANCE

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

B. Braun Medical AG
Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

B. Braun Medical Inc.
901 Marcon Boulevard, Allentown PA 18109-9341, USA

B. Braun Melsungen AG Werk Spangenberg
Dörnbach 10, 34286 Spangenberg, GERMANY

Parameter:

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