



Certificate

No. Q5 012974 0590 Rev. 01

Holder of Certificate: **B. Braun Melsungen AG**
 Carl-Braun-Str. 1
 34212 Melsungen
 GERMANY

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, Distribution, Installation and Servicing of:

Non-active Medical Devices (Sterile and Non-Sterile) for:

- Injection, Infusion, Transfusion and Nutrition
 (Hypodermic Needles, Pen Cannulas for Subcutaneous Injection of Fluid Drug Products, Lancets for Blood Sampling, Intravenous Administration Sets, Tube Connectors, Closing Cones, Vascular Access Devices (Sterile Disposables for Infusion, Transfusion and Vein Puncture), Sterile Disposable Infusion Sets for Volume Control, Measuring of Central Venous Pressure, Filters and Stopcocks for Infusion Therapy, Oral Dispenser (sterile and non-sterile), Withdrawal and Injection Spikes and Needles for Drug Admixture, Syringes, Administration Sets for Enteral Nutrition Therapy)

- Wound care
 (Bandages and Retainers for Compression and Fixation, Sterile Products, Disposables and Sets for Wound Care)

- Anesthesia, Emergency, Intensive and Home Care
 (Central Venous Catheter Sets for Catheterization of the Superior Vena Cava, Needles and Catheters and Sets for Spinal and Epidural Anesthesia, Needles and Catheters and Sets for Plexus Anesthesia, Needles and Catheters and Sets for Combined Spinal and Epidural Anesthesia, Sets for Pleura- and Thorax Drainage, Thoracic Aspiration Set, Wound Drainage System, Sets for Fine Needle Biopsy and Percutaneous Liver Biopsy, Sets for Urology, Nephrology and Incontinence)

- Disinfecting, Cleaning and Rinsing

- Irrigation
 (Administration Accessories, Fixation Accessories for Stoma and Rectal Irrigation)

- Cryotherapy

- Configured Customized Sets

Non-active Medical Devices (Sterile and Non-Sterile):

- Medical Gloves
 (Examination and Surgical Gloves for Surgical and Aseptic Medical

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Applications)

- Sterile Solutions

Active Medical Devices for:

- Fluid Management
(Infusion Pumps, including Management Units, and Software, and
Elastomeric Infusion Pumps)

- Nerve Stimulation
(Nerve Stimulators for Peripheral Regional Anesthesia)

- Wound Drainage System

- Enteral Feeding

- Irrigation
(Irrigation Pump with Power Supply for Stoma and Rectal Irrigation)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 012974 0590 Rev. 01

Report No.: 713218550
Valid from: 2021-10-22
Valid until: 2024-10-21

Date, 2021-10-22



Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016
Facility(ies):	<p>B. Braun Melsungen AG Carl-Braun-Str. 1, 34212 Melsungen, GERMANY</p> <p>Headquarters, of Division Hospital Care Management Quality Management</p> <p>B. Braun Melsungen AG OPM Carl-Braun-Straße 1, 34212 Melsungen, GERMANY</p> <p>Headquarters, of Out Patient Market Management Quality Management</p> <p>B. Braun Melsungen AG Werk A und K Carl-Braun-Str. 1, 34212 Melsungen, GERMANY</p> <p>Design and Development, Manufacture of: Sterile Solutions</p> <p>Manufacture of Non-active Medical Devices for: Anesthesia, Emergency, Intensive and Home Care Injection, Infusion, Transfusion and Nutrition</p> <p>B. Braun Melsungen AG Werk B Dömbach 10, 34286 Spangenberg, GERMANY</p> <p>Design and Development, Manufacture of: Configured Customized Sets</p> <p>B. Braun Melsungen AG Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY</p> <p>Service of Active Medical Devices for: Fluid Management</p> <p>B. Braun Melsungen AG Werk E Schwarzenberger Weg 21-27, 34212 Melsungen, GERMANY</p> <p>Design and Development, Manufacture of Active and Non-active Medical Devices for:</p> <p>Injection, Infusion, Transfusion and Nutrition Anesthesia, Emergency, Intensive and Home Care Nerve Stimulation (Nerve Stimulators for Peripheral Regional Anesthesia) Wound Drainage System Enteral Feeding</p>

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B. Braun Melsungen AG
 PfiEFFwiesen, 34212 Melsungen, GERMANY

Manufacture of Non-active Medical Devices for:
 Injection, Infusion, Transfusion and Nutrition
 Central Laboratories,
 Central Warehouse, Supply Chain Management
 Central Sterilization (Radiation)

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

Headquarters, of Center of Excellence Automated Infusion
 Systems

Management of Active Medical Devices for

Fluid Management
 (Infusion Pumps, including Management Units, and Software)

Irrigation
 (Irrigation Pump with Power Supply for Stoma and Rectal
 Irrigation)

B. Braun Melsungen AG
 Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

Design and Development, Manufacture of:
 Non-active Medical Devices for:
 Emergency, Intensive and Home Care

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

Design and development, Control of production, distribution,
 installation and servicing
 of products for the injection, infusion, transfusion, incontinence
 care, stoma care, wound care, diabetes care, urology, disinfecting,
 cleaning and rinsing, cryotherapy, irrigation (Administration
 Accessories, Fixation Accessories for Stoma and Rectal Irrigation),
 medical gloves for single use, protection clothing, medical waste
 container, home care of patients.
 Individual compounded parenteral nutrition.