



Certificate

No. Q5 012974 0590 Rev. 03

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 Sets for Central and Peripheral Regional 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 and Nephrology)

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

- Configured Customized Sets
Non-active Medical Devices (Sterile and Non-Sterile)

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

- Sterile Solutions

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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. 03

Report No.: 713272203

Valid from: 2024-02-01

Valid until: 2024-10-21

Date, 2024-02-01



Christoph Dicks

Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **B. Braun Melsungen AG**
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Headquarters, of Division Hospital Care
Management

B. Braun Melsungen AG Werk A und K
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Design and Development, Manufacture of:
Sterile Solutions
Manufacture of Non-active Medical Devices for:
Anesthesia, Emergency, Intensive and Home Care
Injection, Infusion, Transfusion and Nutrition

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

Design and Development, Manufacture of:
Configured Customized Sets

B. Braun Melsungen AG Werk E
Schwarzenberger Weg 21-27, 34212 Melsungen, GERMANY

Design and Development, Manufacture of Active and Non-active
Medical Devices for:

Injection, Infusion, Transfusion and Nutrition
Anesthesia, Emergency, Intensive and Home Care
Nerve Stimulation (Nerve Stimulators for Peripheral Regional
Anesthesia)
Wound Drainage System
Enteral Feeding
Wound care
Diabetes care (Syringes and Pen Cannulas)
Urology
Irrigation (Administration Accessories, Fixation Accessories for
Stoma and Rectal Irrigation)
Medical gloves for single use
Elastomeric infusion pumps

B. Braun Melsungen AG
Pfieffewiesen, 34212 Melsungen, GERMANY

Manufacture of Non-active Medical Devices for:

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Injection, Infusion, Transfusion and Nutrition
Central Laboratories,
Central Warehouse, Supply Chain Management
Central Sterilization (Radiation)
Quality Management

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)