

CERTIFICATE

No. QS6 094089 0005 Rev. 00

Certificate Holder:

B. Braun Melsungen AG

Carl-Braun Strasse 1

34212 Melsungen

34209 Melsungen

GERMANY

Certification Mark:



Scope of Certificate:

See Page 3 for Overall Scope Statement.

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA.

See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

31-501-6972

Effective Date:

2018-11-14

Expiry Date:

2021-11-13

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Date of Issue: 2019-02-04

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(Arie Henkin)

Manager, Certification Body MHS

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Regulatory Requirements:	Audit/Certification Criteria
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Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

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CERTIFICATE

No. QS6 094089 0005 Rev. 00

Overall Scope Statement:

The Design and Development, Manufacture, Distribution, Installation, and Servicing of Blood Glucose Measuring System for Self-Monitoring of Blood Sugar, Pen Needles for Subcutaneous Injection of Fluid Drug Products, Lancets and Lancing Devices for Blood Sampling, Bandages and Retainers for Compression and Fixation, Sterile Products, Accessories and Sets for Wound Care, Urology, Nephrology and Incontinence, Examination and Surgical Gloves for Surgical and Aseptic Medical Applications and Examination Gloves for Non-Aseptic Medical Applications, Irrigation Pump with Administration Accessories, Fixation Accessories and Power Supply for Stoma and Rectal Irrigation, Administration Sets for Enteral Nutrition Therapy, Withdrawal and Injection Spikes and Needles for Drug Admixture, Syringes for Application of Fluids in the Medical Field, Sets for Pleura- and Thorax Drainage, Thoracic Aspiration Set, Wound Drainage System, Infusion Pumps, including Management Units, Disposables, and Software, Intravenous Administration Sets, Tube Connectors, Closing Cones, Vascular Access Devices, Filters, and Stopcocks for Infusion Therapy, 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 Fine Needle Biopsy and Percutaneous Liver Biopsy, Elastomeric Infusion Pumps and Disposables, Nerve Stimulators for Peripheral Regional Anesthesia

Facility(ies):

B. Braun Melsungen AG
Carl-Braun Strasse 1, 34212 Melsungen, 34209 Melsungen,
GERMANY

B. Braun Melsungen AG
Werk Pfiesswiesen, 34212 Melsungen, GERMANY

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Facility Scopes:

B. Braun Melsungen AG

Carl-Braun Strasse 1, 34212 Melsungen, 34209 Melsungen,
GERMANY

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DUNS No: 31-501-6972

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CERTIFICATE

No. QS6 094089 0005 Rev. 00

B. Braun Melsungen AG

Werk Pfieffewiesen, 34212 Melsungen, GERMANY

The Design and Development of Manufacturing, Distribution, Installation, and Servicing of Blood Glucose Measuring System for Self-Monitoring of Blood Sugar, Pen Needles for Subcutaneous Injection of Fluid Drug Products, Lancets and Lancing Devices for Blood Sampling, Bandages and Retainers for Compression and Fixation, Sterile Products, Accessories and Sets for Wound Care, Urology, Nephrology and Incontinence, Examination and Surgical Gloves for Surgical and Aseptic Medical Applications and Examination Gloves for Non-Aseptic Medical Applications, Irrigation Pump with Administration Accessories, Fixation Accessories and Power Supply for Stoma and Rectal Irrigation, Administration Sets for Enteral Nutrition Therapy, Withdrawal and Injection Spikes and Needles for Drug Admixture, Syringes for Application of Fluids in the Medical Field, Sets for Pleura- and Thorax Drainage, Thoracic Aspiration Set, Wound Drainage System, Infusion Pumps, including Management Units, Disposables, and Software, Intravenous Administration Sets, Tube Connectors, Closing Cones, Vascular Access Devices, Filters, and Stopcocks for Infusion Therapy, 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 Fine Needle Biopsy and Percutaneous Liver Biopsy, Elastomeric Infusion Pumps and Disposables, Nerve Stimulators for Peripheral Regional Anesthesia
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