



America

CERTIFICATE

No. QS6 044904 0053 Rev. 01

Certificate Holder: **B. Braun Medical Inc.**
824 Twelfth Avenue
Bethlehem PA 18018
USA

Certification Mark:



Scope of Certificate: See Page 2 for Overall Scope Statement.

Standard(s): ISO 13485:2016

Regulatory Authority(ies): 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 www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F002819

Effective Date: 2022-08-02

Expiry Date: 2025-08-01

Page 1 of 3

Date of Issue: 2022-07-21

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: Audit/Certification Criteria

Canada

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

Japan

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

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Overall Scope Statement:

Installation, Servicing, and Distribution of Renal Therapy Products; Design and Development, Production, and Distribution, including Subcontract Manufacturing Capabilities, of Non-Sterile and Sterile Medical Devices, including Infusion Systems, Pharmacy Compounding Systems, Renal Therapy Devices, Regional Anesthesia and Pain Management Devices, Vascular Access Devices, IV Sets and Accessories, Infusion Therapy Devices, Pharmaceutical Preparation and Delivery Devices, Irrigation Devices, Angioplasty Procedure Devices, and Fluid Collection Devices; Distribution of Needles and Syringes, Wound Care Devices, Closed System Transfer Devices, Pharmaceutical Preparation and Delivery Devices, Vascular Access, IV Sets and Accessories, Fluid Collection Devices, Regional Anesthesia and Pain Management for the areas of General Hospital, Anesthesiology and Cardiovascular Usage

Facility(ies):

B. Braun Medical Inc.
 824 Twelfth Avenue, Bethlehem PA 18018, USA

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

B. Braun Medical, Inc.
 200 Boulder Drive, Breinigsville, PA 18031, USA

Page 2 of 3

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Facility Scopes:

B. Braun Medical Inc.

824 Twelfth Avenue, Bethlehem PA 18018, USA

Installation, Servicing, Production, and Distribution
of Renal Therapy Devices
REPs Facility ID: F002819

B. Braun Medical Inc.

901 Marcon Boulevard, Allentown, PA 18109-9341, USA

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including Subcontract Manufacturing Capabilities, of Non-Sterile
and Sterile Medical Devices, including Infusion Systems, Pharmacy
Compounding Systems, Renal Therapy Devices, Regional Anesthesia
and Pain Management Devices, Vascular Access Devices, IV Sets
and Accessories, Infusion Therapy Devices, Pharmaceutical
Preparation and Delivery Devices, Irrigation Devices, Angioplasty
Procedure Devices, and Fluid Collection Devices for the areas
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B. Braun Medical, Inc.

200 Boulder Drive, Breinigsville, PA 18031, USA

Distribution of Non-Sterile and Sterile Medical Devices,
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Renal Therapy Products, Vascular Access Devices, IV Sets
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Page 3 of 3

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