



America

CERTIFICATE

No. QS6 044904 0053 Rev. 03

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, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_044904_0053_Rev.03

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

REPs Facility ID: **F002819**
Report No.: **72196021**
Effective Date: **2024-07-11**
Expiry Date: **2025-08-01**

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Date of Issue: 2024-07-22

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Canada

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

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

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:

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 US Device Manufacturing LLC

901 Marcon Boulevard, Allentown PA 18109-9341, USA

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B. Braun US Device Manufacturing LLC
200 Boulder Drive, Breinigsville PA 18031, USA

Facility Scopes:

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

Corporate Headquarters and Product Registration
REPs Facility ID: F002819

B. Braun US Device Manufacturing LLC
901 Marcon Boulevard, Allentown PA 18109-9341, USA

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