





America

# CERTIFICATE

No. QS6 044904 0053 Rev. 00

**Regulatory Requirements: Audit/Certification Criteria**

**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

**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

**Facility Scopes:**

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

Installation, Servicing and Distribution of Renal Products and Design and Development, Production and Distribution of Sterile and Non-Sterile Medical Devices including Subcontract Manufacturing Capabilities, which include Regional Anesthesia Trays, Port Access Devices, Introducers, Y Connectors, CVC Kits, Intravenous Administration Sets, Peritoneal Dialysis Catheters and Sets, Pharmaceutical Admixture and Delivery Devices, Fluid Transfer Sets, Nerve Stimulators, Catheters, Stopcocks, Mixing Containers, Irrigation Sets, Needle Free Access Devices, Caps, Dilators, Syringes, Guide Wires, Inflation Devices, Connectors, Adapters, Check Valves, Needles and Fluid Collection Systems for the areas of General Hospital, Anesthesiology and Cardiovascular Usage  
DUNS No: 00-239-7347

( Dawn M. Tibodeau )  
Manager, Certification Body MHS

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DUNS No: 78-317-9463

**B. Braun Medical, Inc.**

200 Boulder Drive, Breinigsville, PA 18031, USA

Installation, Servicing and Distribution of Renal Products and Design and Development, Production and Distribution of Sterile and Non-Sterile Medical Devices including Subcontract Manufacturing Capabilities, which include Regional Anesthesia Trays, Port Access Devices, Introducers, Y Connectors, CVC Kits, Intravenous Administration Sets, Peritoneal Dialysis Catheters and Sets, Pharmaceutical Admixture and Delivery Devices, Fluid Transfer Sets, Nerve Stimulators, Catheters, Stopcocks, Mixing Containers, Irrigation Sets, Needle Free Access Devices, Caps, Dilators, Syringes, Guide Wires, Inflation Devices, Connectors, Adapters, Check Valves, Needles and Fluid Collection Systems for the areas of General Hospital, Anesthesiology and Cardiovascular Usage  
DUNS No: 61-003-1564

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