9

ш







CERTIFICATE

No. QS6 044904 0053 Rev. 00

Certificate Holder:

B. Braun Medical Inc.

824 Twelfth Avenue Bethlehem PA 18018

USA

Certification Mark:



Scope of Certificate:

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

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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No:

00-239-7347

Effective Date:

2019-08-07

Expiry Date:

2022-08-01

Page 1 of 3

Date of Issue: 2019-08-08

Chion Pitrodean

(Dawn M. Tibodeau) Manager, Certification Body MHS





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

Page 2 of 3

Date of Issue: 2019-08-08

Claim Phodean

(Dawn M. Tibodeau)

Manager, Certification Body MHS



CERTIFICATE

No. QS6 044904 0053 Rev. 00

B. Braun Medical Inc.

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

Page 3 of 3

Date of Issue: 2019-08-08

Caron Pitrodean

(Dawn M. Tibodeau) Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com