DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q1N 044904 0049 Rev. 00

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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development, Production, Installation, Servicing and Distribution of Medical Disposables and Subcontract Manufacturing Capabilities for Sterile and Non-Sterile Devices

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72101380

Valid from: 2018-10-25
Valid until: 2021-09-16

Date, 2018-10-25

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

US-Letter / 07.17

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TÜV SÜD
Product Service

Certificate

No. Q1N 044904 0049 Rev. 00

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

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

Parameters:

Issued by TÜV SÜD Product Service GmbH
(Listed by facilities with finished product responsibility)

B. Braun Medical Inc.
901 Marcon Blvd.
Allentown, PA 18109 USA

- Disposable I.V. Administration Sets
- Pain Control Administration System
- Vascular Access Devices, Introducers and Components
- Pharmaceutical Dispensing Devices and Accessories
- Cardiac Balloon Catheters

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

- Distribution of Hemodialysis Accessories
- Distribution, Installation and Servicing of Hemodialysis Equipment

Munich, CRT2, 2018-08-08

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Product Service

Supplement to Quality System Certificate

No. SUP 044904 0050 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q1N 044904 0049 Rev. 00**

Certificate Holder:

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

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

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of:

EN ISO 11135:2014 Sterilization of Healthcare products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices (ISO 11135:2014)

Audit Report: 72101380
Dated: 2017-08-08

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

Valid from: 2018-10-25

Stefan Preiß

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