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

Product Service

Supplement to Quality System Certificate

No. SUP 044904 0047 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q5 044904 0046 Rev. 00**

Certificate Holder:

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

Facility(ies):

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

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

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

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

EN ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)" as documented in the audit report no. 72142533 dated 2019-09-18.

Audit Report: 72142533
Dated: 2018-09-18

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: 2020-01-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstrasse 65 · Munich · Germany

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