

## Supplement to Quality System Certificate

No. SUP 044904 0055 Rev. 00

**This supplement is only valid in conjunction with the main certificate:** **Q5 044904 0046 Rev. 01**

**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 health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

**Audit Report:** 72180846  
**Dated:** 2022-07-15

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:** 2022-10-26



Christoph Dicks  
Head of Certification/Notified Body