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Product Service

# Supplement to Quality System Certificate
## No. SUP 044904 0055 Rev. 03

**This supplement is only valid in conjunction with the main certificate:** **Q5 044904 0046 Rev. 04**

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

**Facility(ies):**
**B. Braun US Device Manufacturing LLC**
901 Marcon Boulevard, Allentown PA 18109-9341, USA

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

EN ISO 11135:2014 + A1:2019 “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 + A1:2019)”

**Audit Report:** 721011098
**Dated:** 2024-08-19

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:** 2025-10-01

Christoph Dicks
Head of Certification/Notified Body


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