



Certificate

No. Q5 044904 0046 Rev. 03

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

Certification Mark:



Scope of Certificate: **Design and Development, Production, and Distribution of Non-active devices for anesthesia, emergency, intensive care, injection, and infusion. Provision of Manufacturing services for general non-active, non-implantable medical 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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 044904 0046 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_044904_0046_Rev.03)

Report No.: 72198429

Valid from: 2024-09-05

Valid until: 2027-09-04

Date, 2024-09-05



Christoph Dicks

Head of Certification/Notified Body

Certificate

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

Design and Development, Manufacturing, Subcontracting,
Packaging, and Sterilization of non-active devices for anesthesia,
emergency, intensive care, injection, and infusion.

B. Braun US Device Manufacturing LLC
200 Boulder Drive, Breinigsville PA 18031, USA

Warehousing and Distribution

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

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active devices for anesthesia, emergency, intensive care, injection,
and infusion. Provision of Manufacturing services for general non-
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