



America

CERTIFICATE

No. QS6 18 02 45700 004

Certificate Holder: B Braun Medical Inc
1601 Wallace Drive, Suite 150
Carrollton, TX 75006
USA

Certification Mark:



Scope of Certificate: Design and Development, Production,
Distribution and Servicing of Infusion
Systems, Pharmacy Compounding Systems

Standard(s): ISO 13485:2003

Regulatory Authority: Health Canada, FDA.
See attached for listing of specific
regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website

<http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder>

TÜV SÜD America Inc. is an MDSAP Authorized Auditing Organization.

DUNS No: 07-843-8977
Effective Date: 2018-02-10
Expiry Date: 2019-02-28

Manuel Bradaric
MHS Certification Manager



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Audit/Certification Criteria

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Effective Date:

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Manuel Bradaric
MHS Certification Manager

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