

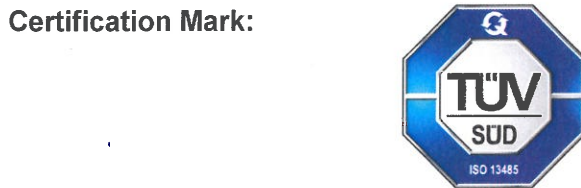


America

CERTIFICATE

No. QS6 061585 0033 Rev. 01

Certificate Holder: B. Braun Medical AG
Seesatz 17
6204 Sempach
SWITZERLAND



Scope of Certificate: Design and Development, Production and Distribution of Sterile Disposables (Syringes, Cannula, Diagnostic Disposables and Accessories), Irrigation Solutions, Organ Preservation Solutions, Sterile Priming Solutions

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Brazil ANVISA, USA FDA, MHLW / PMDA. 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 <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No: 48-276-4180

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Page 1 of 3
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(Dawn M. Tibodeau)
Manager, Certification Body MHS

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