MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 061585 0034 Rev. 01

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

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Disinfection and Hygiene Products, Medical Devices for Wound Bed Preparation, Physically Acting Medical Devices for Multi-Drug-Resistant-Organism Decolonization for Topical and Oral Application, Irrigation Solutions**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, 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**

Effective Date: **2019-06-26**

Expiry Date: **2022-06-25**

Date of Issue: 2019-07-23

(Dawn M. Tibodeau)
Manager, Certification Body MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

B. Braun Medical AG
Seesatz 17, 6204 Sempach, SWITZERLAND

B. Braun Medical AG
Route de Sorge 9, 1023 Crissier, SWITZERLAND

Date of Issue: 2019-07-23

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Facility Scopes:

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DUNS No: 48-619-4868

Date of Issue: 2019-07-23

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