



America

CERTIFICATE

No. QS6 061585 0033 Rev. 02

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

Certification Mark:



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 www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001182**

Effective Date: **2022-07-21**

Expiry Date: **2025-06-18**

Page 1 of 3

Date of Issue: 2022-07-27

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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No. QS6 061585 0033 Rev. 02

Regulatory Requirements: Audit/Certification Criteria

Brazil

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

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
Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

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

Page 2 of 3

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Facility Scopes:

B. Braun Medical AG

Seesatz 17, 6204 Sempach, SWITZERLAND

Distribution of Irrigation Solutions

REPs Facility ID: F001182

B. Braun Medical AG

Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

Design and Development, Production and Distribution of Sterile
Disposables (Syringes, Cannula, Diagnostic Disposables and
Accessories)

REPs Facility ID: F002088

B. Braun Medical AG

Route de Sorge 9, 1023 Crissier, SWITZERLAND

Design and Development, Production and Distribution of
Irrigation Solutions, Organ Preservation Solutions, Sterile
Priming Solutions

REPs Facility ID: F002089

Page 3 of 3

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(Renee Walker)
Manager, US Certification Body,
Medical and Health Services