ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 061585 0034 Rev. 04

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

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing and Distribution of Sterile and Non-Sterile, Non-Active, Non-Implantable Medical Devices for Wound Bed Preparation, Urinary-Catheter-Irrigation Sterile Solution and various Devices for Channeling Liquid Devices (Wound Irrigation Solution Adapter)**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 061585 0034 Rev. 04
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001182**
Report No.: **713369969**
Effective Date: **2025-06-19**
Expiry Date: **2028-06-18**

Date of Issue: 2025-06-12

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

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: 2025-06-12

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C E R T I F I C A T E

No. QS6 061585 0034 Rev. 04

Facility Scopes:

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

Design and Development, Manufacturing and Distribution of Sterile and Non-Sterile, Non-Active, Non-Implantable Medical Devices for Wound Bed Preparation, Urinary-Catheter-Irrigation Sterile Solution and various Devices for Channeling Liquid Devices (Wound Irrigation Solution Adapter)
REPs Facility ID: F001182

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

Design and Development, Manufacturing, Moist Heat Sterilization and Distribution for Urinary-Catheter-Irrigation Sterile Solution and Medical Devices for Wound Bed Preparation
REPs Facility ID: F002089

Date of Issue: 2025-06-12

(Renee Walker)
Director, US Certification Body, MHS

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