



America

# CERTIFICATE

No. QS6 016329 0037 Rev. 03

**Certificate Holder:****sfm medical devices GmbH**Brückenstraße 5  
63607 Wächtersbach  
GERMANY**Certification Mark:****Scope of Certificate:****Design and Development, Production and Distribution of Disposable Surgical Instruments, Intravenous Infusion Sets, Transfer Devices, Vial Adapter, Filter Spike, Needles, Vascular Introducers for the areas of Anesthesiology, Electrosurgical Applications, Plastic Surgery, Urology and Biopsy****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\\_016329\\_0037\\_Rev\\_03](http://www.tuvsud.com/ps-cert?q=cert:QS6_016329_0037_Rev_03)

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

**REPs Facility ID:****F005712****Report No.:****713342892****Effective Date:****2025-05-07****Expiry Date:****2028-05-06**

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( 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):

### **sfm medical devices GmbH**

Brückenstraße 5, 63607 Wächtersbach, GERMANY

### **safemed medical devices s.r.o**

Trabantská 292, 19015 Praha 9, CZECH REPUBLIC

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## Facility Scopes:

### **sfm medical devices GmbH**

Brückenstraße 5, 63607 Wächtersbach, GERMANY

Sales, Design and Development, Sourcing, Warehousing, Production, Assembling, Sterile Packaging, (Ethylene Oxide) Sterilization, In-Process Control, Incoming and Outgoing Inspection, Distribution and General Quality Management for both locations of Disposable Surgical Instruments, Intravenous Infusion Sets, Transfer Devices, Vial Adapter, Filter Spike, Needles, Vascular Introducers for the areas of Anesthesiology, Electrosurgical Applications, Plastic Surgery, Urology and Biopsy  
REPs Facility ID: F005712

### **safemed medical devices s.r.o**

Trabantská 292, 19015 Praha 9, CZECH REPUBLIC

Warehousing, Production, Assembling, Sterile Packaging and In-Process Control of Disposable Surgical Instruments, Intravenous Infusion Sets, Transfer Devices, Vial Adapter, Filter Spike, Needles, Vascular Introducers for the areas of Anesthesiology, Electrosurgical Applications, Plastic Surgery, Urology and Biopsy  
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