



America

CERTIFICATE

No. QS6 016329 0037 Rev. 01

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):

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. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:QS6 016329 0037 Rev. 01

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

REPs Facility ID:

F005712

Report No.:

713221355_CN

Effective Date:

2023-03-06

Expiry Date:

2025-08-23

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Date of Issue: 2023-03-07

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Canada

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

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by
MHLW Ministerial Ordinance No.155 (2020)
- 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

REPs Facility ID: F005713

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(Renee Walker)
Director, US Certification Body, MHS