



CERTIFICATE



This is to certify that the company

Sutter Medizintechnik GmbH

Alfred-Walz-Straße 22
79312 Emmendingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design and Development, Manufacturing and distribution of electrosurgical medical devices and medical and surgical instruments.

- **AUS (a), BRA, CND, JPN, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

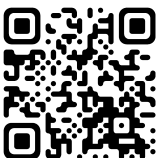
including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	005332 MDSAP16
Certificate unique ID	1000323772
Effective date	2026-07-01
Expiry date	2029-05-17
Frankfurt am Main	2026-07-01



DQS Medizinprodukte GmbH

Sven Hoffmann
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
The validity of the certification can only be verified by the QR-code.



Annex to certificate
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Audited site

005332
Sutter Medizintechnik GmbH
Alfred-Walz-Straße 22
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Germany

REPs FEI No.: site scope and country-specific requirements

Design and Development, Manufacturing and
distribution of electrosurgical medical devices
and medical and surgical instruments.
- AUS (a), BRA, CND, JPN, USA (a,b,c,d)
REPs FEI No.: F008998



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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821