CERTIFICATE

This is to certify that the company

SIS Medical GmbH

Max-Planck-Str. 9/6
78549 Spaichingen
Germany

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

Scope of certification:
Design, developement, manufacturing and distribution of orthopedic implants for upper and lower extremities and reusable durgical instruments.
-**BRA, 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.	539351 MDSAP16
Certificate unique ID	1000271225
Effective date	2025-12-20
Expiry date	2027-02-15
Frankfurt am Main	2025-12-20

MDSAP
Medical Device Single Audit Program

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to certificate
Certificate registration No.: 539351 MDSAP16
Certificate unique ID: 1000271225
Effective date: 2025-12-20

SIS Medical GmbH

Max-Planck-Str. 9/6
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Audited site	**REPs FEI No.: site scope and country-specific requirements**
539351 **SIS Medical GmbH** Max-Planck-Str. 9/6 78549 Spaichingen Germany	Design, developement, manufacturing and distribution of orthopedic implants for upper anc lower extremities and reusable durgical instruments -**BRA, USA (a,b,c,d)** **REPs FEI No.: F007155**

Annex to certificate
Certificate registration No.: 539351 MDSAP16
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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