



# CERTIFICATE



This is to certify that the company

## AF Medical GmbH

Hermann-Winker Str. 7  
78549 Spaichingen  
Germany

with the organizational units/sites as listed in the annex

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

Scope of certification:

Design, development, manufacturing and distribution of orthopedic implants for upper and lower extremities and reusable surgical 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)

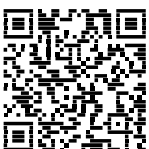
Certificate registration no.	539351 MDSAP16
Certificate unique ID	1000147824
Effective date	2024-02-16
Expiry date	2027-02-15
Frankfurt am Main	2024-02-16



### DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.  
Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.  
The validity of this certificate can only be verified by the QR-code.



**Annex to certificate**  
**Certificate registration No.: 539351 MDSAP16**  
**Certificate unique ID: 1000147824**  
**Effective date: 2024-02-16**

## **AF Medical GmbH**

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### **Audited site**

**539351**  
**AF Medical GmbH**  
Hermann-Winker Str. 7  
78549 Spaichingen  
Germany

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

Design, development, manufacturing and  
distribution of orthopedic implants for upper and  
lower extremities and reusable surgical  
instruments  
**-BRA, USA (a,b,c,d)**  
**REPs FEI No.: F007155**



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

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
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 Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 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