



CERTIFICATE



This is to certify that the company

Ormed GmbH

Boetzingen Strasse 90
79111 Freiburg
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 powered exercise equipment for passive and active mobilization of joints, in the field of orthopedic therapy.

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.	020812 MDSAP16
Certificate unique ID	170780342
Date of original certification	2022-09-20
Effective date	2022-09-20
Expiry date	2025-09-19
Frankfurt am Main	2022-09-20



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.: 020812 MDSAP16
Certificate unique ID: 170780342
Effective date: 2022-09-20

Ormed GmbH

Boetzingen Strasse 90
79111 Freiburg
Germany

Audited site

020812
Ormed GmbH
Boetzingen Strasse 90
79111 Freiburg
Germany

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

Design and development, manufacturing, and distribution of powered exercise equipment for passive and active mobilization of joints, in the field of orthopedic therapy.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)
F006244



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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 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