



CERTIFICATE



This is to certify that the company

FMZ GmbH

Charles Darwin Ring 3a
18059 Rostock
Germany

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

Scope of certification:

Design and Development, Manufacturing and Distribution of Dental Implant Systems incl. Implants, Abutments, Surgical Kits, Drills, Screws, Dental Instruments and Accessories.
-CND

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.	204456 MDSAP16
Certificate unique ID	170776290
Effective date	2021-07-12
Expiry date	2024-07-11
Frankfurt am Main	2021-07-12



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

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

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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.

Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



Annex to certificate

Certificate registration No.: 204456 MDSAP16

Certificate unique ID: 170776290

Effective date: 2021-07-12

FMZ GmbH

Charles Darwin Ring 3a
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Audited site

FMZ GmbH

Charles Darwin Ring 3a
18059 Rostock
Germany

DUNS No., site scope and country-specific requirements

Design and Development, Manufacturing and
Distribution of Dental Implant Systems incl.
Implants, Abutments, Surgical Kits, Drills,
Screws, Dental Instruments and Accessories.

-CND

DUNS No.: 313175973



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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. 16/2013 RDC ANVISA n. 23/2012 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