



CERTIFICATE



This is to certify that the company

PX Dental SA

Champs-Montants 16a
2074 Marin
Switzerland

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 Precious Metals Dental Alloys
-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. 354508 MDSAP16

Certificate unique ID 170777480

Effective date 2022-03-15

Expiry date 2025-03-14

Frankfurt am Main 2022-02-18



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.



Annex to certificate

Certificate registration No.: 354508 MDSAP16

Certificate unique ID: 170777480

Effective date: 2022-03-15

PX Dental SA

Champs-Montants 16a
2074 Marin
Switzerland

Audited site

354508

PX Dental SA

Champs-Montants 16a
2074 Marin
Switzerland

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

Design, development, manufacturing and
distribution of Precious Metals Dental Alloys

-CND

REPs FEI No.: F002515



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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. 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