

SQS as a conformity assessment body identification number 1250 herewith certifies the company

PX Dental SA
Champs-Montants 16a
2074 Marin-Epagnier
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the result of the audit documented in the report dated January 6, 2020.

The scope of validity covers the products

**Dental alloys as wires, profiles,
plates and dental attachments**

The following CE label can be applied to these products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Reg. no. 32204

Validity 16.01.2020–25.05.2024
Issue 16.01.2020

Approved Medical Responsible
16.01.2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



sqs.ch

ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection with the following certificate:

Registration Number 32204

Validity from January 16, 2020 up to and including May 25, 2024

This approval includes the following Medical Device/s:

<i>Alloy Nr.</i>	<i>PX Dental</i>	<i>Other name</i>
High gold ceramic alloys		
7000		Bioceram 2
7030	PX Premium S	Qualiceram 3
7040	PX Premium C	Qualiceram 4
7070	PX Premium PF	Bioimplant 1
7071		Qualiceram Bio 4
7101	PX Premium Bio	
7102	PX Premium Ideal	
7104	SNF K-1	
7105	PX Premium Yellow	
7108	PX Premium E	
Gold reduced ceramic alloys		
7120	PX Bond SF	Qualibond 2
7132	PX Bond	
7133	PX Bondaloy	
7134	PX Bond Special	Qualibond 3
7140		Qualibond 4
7161		Qualibond 36
Palladium based ceramic alloys		
7151	PX Extrapall 2	Qualipall 1
7152	PX Extrapall 6	Qualipall 6NF
7154	SNF K-2+	
7160	PX Bond Budget	Qualibond 6
7171	PX Ecopal	
7220	PX PalFit	Qualipall 2
7240		Qualipall 4
Universal alloys		
7301	PX Bio Gold LF	Bioqual 4
7302	PX Gold Supra	
7303	PX Gold Plus	
7305	PX Gold LF Activ	
7308	PX Gold LF Star +	
7331	PX Gold LF ECO	Qualistar 6
7350	PX Gold LF	Qualigold 5
High gold casting alloys		
7201	PX Inlaygold PF	Qualigold 2
7202	PX Gold 68	
7231	PX Gold 63	
7232	PX Gold 51	
7430		Qualiplus 3
7233	SNF O-1	
7330	PX Gold 72 PF	
7238		Qualigold 12
7471		Qualistar 16
7381		Qualistar 15
7340		Qualigold 4



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This approval includes the following Medical Device/s

<i>Alloy Nr.</i>	<i>PX Dental</i>	<i>Other name</i>
Ag-Pd based casting alloys		
7252	PX Ecocast G3	
7420		Qualiplus 2
7470		Qualiplus 7
7332		Qualiplus 8
7510		Qualistar 1
7520	PX Ecocast 2	Qualistar 2
Precious alloys in wires and tubes		
7590	PX Unifil	Qualifil
7630	PX Supracast	Qualitherm
7810	PX Novostar	
7811		Au-Pt Leg
Gold basis dental solders		
7501	PX Presold 1040	
7502	PX Presold 1110	
7521	PX Postsold 800	
7521	PX Extrasold	
7561	PX Sold 890 NP	
7562	PX Sold 940	
7720	PX Presold 1100	Qualisold P2
7730		Qualisold P3
7760	PX Sold LF 950	Qualisold P6
7770	PX Sold LF 880	Qualisold P7
7920	PX Sold 830	Qualisold 2
7930	PX Sold 780	Qualisold 3
7940	PX Sold 740	Qualisold 4
Non-precious alloys		
PX C60	PX C60	
PX C62	PX C62	
PX N61	PX N61	
Dental attachments		
<ul style="list-style-type: none"> - Sfera system - Ecco system - Tima system - Mooser posts - Cylinco posts - GP-Ball - Mini-NPG system - Micro and Macro bars - Rondo system 		

Appendix issue date: January 16, 2020

