

**EU Konformitätserklärung / Déclaration EU de conformité  
EU Declaration of Conformity / Dichiarazione EU de conformità / Declaración de  
conformidad EU**

according to the Regulation (EU) 2017/745 on Medical Devices (MDR), Annex IV

Wir / Nous / We / Noi / Nosotros

**PX Dental SA**

**Boulevard des Eplatures 42, c/o PX Group SA**

**CH-2300 La Chaux-de-Fonds / Suisse**

**CH-MF-000033889 (CHRN-MF-20000347)**

**PX France Sàrl**

**Imp. De la Prairie 70**

**FR-74330 Sillingy**

**France**

**FR-AR-000013884**



Erklären in alleiniger Verantwortung, dass die Medizinprodukten, Klasse IIa Regel 8 (§1):

Déclarons sous notre propre responsabilité que les dispositifs médicaux, Classe IIa Regel 8 (§1):

Declare under our sole responsibility that the medical device, Class IIa, rule Regel 8 (§1):

Dichiariamo sotto propria responsabilità che i dispositivi medici, Classe IIa, regole Regel 8 (§1):

Declaramos bajo nuestra exclusiva responsabilidad que los dispositivos médicos, Clase IIa reglas Regel 8 (§1):

**Dental Precious Alloys**

**Alloys / Basic UDI-DI: ++ D999ALLOYS9V**

entsprechen der Regulation (EU) 2017/745.

sont conformes au Règlement (UE) 2017/745.

comply with Regulation (EU) 2017/745.

sono conformi al Regolamento (UE) 2017/745.

cumplen el Reglamento (UE) 2017/745.

**EMDN Q010601 Dental Alloys**

Entspricht der Norm / Conforme à la norme / Corresponds to the standard / Conformità alla norma / Conforme a la norma

**EN ISO 22674:2022**

Dentistry – Metallic materials for fixed and removable restorations and appliances

Benannte Stelle: / Organisme notifié:

Notified body: Organo notificato:

Organismo notificado

**DQS Medizinprodukte GmbH**  0297

**PX Dental SA**

Ist ein Unternehmen, welches ISO 13485:2016 zertifiziert ist

est une entreprise certifiée ISO 13485:2016.

Is a company that is ISO 13485:2016 certified.

E una ditta certificata ISO 13485:2016.

Es una empresa certificada ISO 13485:2016.

Ort und Datum der Ausstellung:

Lieu et date de l'établissement:

Place and date of issue :

Luogo e data di emissione:

Lugar y fecha de emisión

**Marin, 25.09.2024**

Gültig bis :

La durée de validité du présent certificat est jusqu'au :

This certificate is valid up to and including:

Data di scadenza :

Este certificado es válido hasta:

**31.12.2028**



Marc-Henri Zürcher  
Managing Director  
PX Dental SA

Alain Ramseyer  
RA & QA Manager  
PX Dental SA

## Annex : EU Declaration of Conformity « Alloys »

List of products from the « **Precious Dental Alloys** »  
**EMDN Q010601**      **Dental Alloys**

Art. No	Alloy No	Brand name	Designation	Form	Class	Rule
1011030	7000	Bioceram 2	Plot Dentaire 7000 QLD/BIOCERAM 2	Ingots for casting	Ila	8
1040573	7000	Bioceram 2	BIOCERAM 2, Laser 0.30 mm	round wire	Ila	8
1011005	7030	PX Premium S	Plot Dentaire PX Premium S	Ingots for casting	Ila	8
1011033	7030	Qualiceram 3	Plot Dentaire 7030 QLD/Q-CERAM 3	Ingots for casting	Ila	8
1040222	7030	PX Premium S	PX Premium S, Laser 0.30 mm	round wire	Ila	8
1011000	7040	PX Premium C	Plot Dentaire PX Premium C	Ingots for casting	Ila	8
1011034	7040	Qualiceram 4	Plot Dentaire 7040 QLD/Q-CERAM 4	Ingots for casting	Ila	8
1040496	7040	PX Premium C	PX Premium C, Laser 0.30 mm	round wire	Ila	8
1040569	7040	Qualiceram 4	QUALICERAM 4, laser 0.30 mm	round wire	Ila	8
1011021	7070	PX Premium PF	Plot Dentaire PX Premium PF	Ingots for casting	Ila	8
1160639	7070	Biolmplant 1	Plot Dentaire 7070 QLD/BIOIMPLANT 1	Ingots for casting	Ila	8
1092415	7071	Qualiceram Bio 4	Plot Dentaire	Ingots for casting	Ila	8
1010999	7101	PX Premium Bio	Plot Dentaire PX Premium Bio	Ingots for casting	Ila	8
1040266	7101	PX Premium Bio	PX Premium Bio, Laser 0.30 mm	round wire	Ila	8
1011004	7102	PX Premium Ideal	Plot Dentaire PX Premium Ideal	Ingots for casting	Ila	8
1040267	7102	PX Premium Ideal	PX Premium Ideal Laser 0.30 mm	round wire	Ila	8
1011070	7104	SNF K1	Plot Dentaire 7104 SNF/K-1	Ingots for casting	Ila	8
1011018	7105	PX Premium Yellow	Plot Dentaire PX Premium Yellow	Ingots for casting	Ila	8
1040208	7105	PX Premium Yellow	PX Premium Yellow Laser 0.30mm	round wire	Ila	8
1040046	7108	PX Premium E	Plot Dentaire PX Premium E	Ingots for casting	Ila	8
1011002	7120	PX Bond SF	Plot Dentaire PX Bond SF	Ingots for casting	Ila	8
1011043	7120	Qualibond 2	Plot Dentaire 7120 QLD/Q-BOND 2	Ingots for casting	Ila	8
1040227	7120	PX Bond SF	PX Bond SF, Laser Ø 0.30mm	round wire	Ila	8
1040265	7120	Qualibond 2	QUALIBOND 2, Laser 0.30 mm	round wire	Ila	8
1011001	7132	PX Bond	Plot Dentaire PX Bond	Ingots for casting	Ila	8
1010998	7133	PX Bondaloy	Plot Dentaire PX Bondaloy	Ingots for casting	Ila	8
1011003	7134	PX Bond Special	Plot Dentaire PX Bond Special	Ingots for casting	Ila	8
1011069	7134	Qualibond 3	Plot Dentaire 7134 QLD/Q-BOND 3	Ingots for casting	Ila	8
1011035	7140	Qualibond 4	Plot Dentaire 7140 QLD/Q-BOND 4	Ingots for casting	Ila	8
1040214	7151	PX Extrapall 2	PX Extrapall 2, Laser 0.30 mm	round wire	Ila	8
1086605	7151	PX Extrapall 2	Plot Dentaire PX Extrapall 2	Ingots for casting	Ila	8
1086817	7151	Qualipall 1	Plot Dentaire 7151 QLD/Q-PALL 1	Ingots for casting	Ila	8
1011066	7152	Qualipall 6NF	Plot Dentaire 7152 QLD/Q-PALL 6 NF	Ingots for casting	Ila	8
1040226	7152	PX Extrapall 6	PX Extrapall 6, Laser 0.30 mm	round wire	Ila	8
1086606	7152	PX Extrapall 6	Plot Dentaire PX Extrapall 6	Ingots for casting	Ila	8
1086401	7154	SNF K-2+	Plot Dentaire 7154 SNF K-2+	Ingots for casting	Ila	8
1011028	7160	PX Bond Budget	Plot Dentaire PX Bond Budget	Ingots for casting	Ila	8
1011036	7160	Qualibond 6	Plot Dentaire 7160 QLD/Q-BOND 6	Ingots for casting	Ila	8
1032717	7160	Qualibond 6	Plot Dentaire 7160 SNF/K-15	Ingots for casting	Ila	8
1085545	7161	Qualibond 36	Plot Dentaire Qualibond 36	Ingots for casting	Ila	8
1011009	7171	PX Ecopal	Plot Dentaire PX Ecopal	Ingots for casting	Ila	8
1011012	7201	PX Inlaygold PF	Plot Dentaire PX Inlaygold PF	Ingots for casting	Ila	8
1011067	7201	Qualigold 2	Plot Dentaire 7201 QLD/Q-GOLD 2	Ingots for casting	Ila	8
1040215	7201	PX Inlaygold PF	PX Inlaygold LF, Laser 0.30 mm	round wire	Ila	8

## Annex : EU Declaration of Conformity « Alloys »

Art. No	Alloy No	Brand name	Designation	Form	Class	Rule
1011014	7202	PX Gold 68	Plot Dentaire PX Gold 68	Ingots for casting	IIa	8
1040219	7202	PX Gold 68	PX Gold 68, Laser 0.30 mm	round wire	IIa	8
1011044	7220	Qualipall 2	Plot Dentaire 7220 QLD/Q-PALL 2	Ingots for casting	IIa	8
1047115	7220	PX PalFit	Plot Dentaire PX PalFit	Ingots for casting	IIa	8
1011008	7231	PX Gold 63	Plot Dentaire PX Gold 63	Ingots for casting	IIa	8
1011051	7231	Qualiplus 1	Plot Dentaire 7231 QLD/Q-PLUS 1	Ingots for casting	IIa	8
1040498	7231	PX Gold 63	PX Gold 63, Laser 0.30 mm	round wire	IIa	8
1040571	7231	Qualiplus 1	QUALIPLUS, laser 0.30 mm	round wire	IIa	8
1011006	7232	PX Gold 51	Plot Dentaire PX Gold 51	Ingots for casting	IIa	8
1040217	7232	PX Gold 51	PX Gold 51, Laser 0.30 mm	round wire	IIa	8
1011071	7233	SNF O-1	Plot Dentaire 7233 SNF/O-1	Ingots for casting	IIa	8
1085547	7238	Qualigold 12	Plot Dentaire Qualigold 12	Ingots for casting	IIa	8
1011052	7240	Qualipall 4	Plot Dentaire 7240 QLD/Q-PALL 4	Ingots for casting	IIa	8
1011024	7252	PX Ecocast G3	Plot Dentaire PX Ecocast G3	Ingots for casting	IIa	8
1011011	7301	PX Bio Gold LF	Plot Dentaire PX Bio Gold LF	Ingots for casting	IIa	8
1040212	7301	PX Bio Gold LF	PX Bio Gold LF, Laser 0.30 mm	round wire	IIa	8
1011022	7302	PX Gold Supra	Plot Dentaire PX Gold Supra	Ingots for casting	IIa	8
1011023	7303	PX Gold Plus	Plot Dentaire PX Gold Plus	Ingots for casting	IIa	8
1011027	7305	PX Gold LF Activ	Plot Dentaire PX Gold LF Activ	Ingots for casting	IIa	8
1070733	7308	PX Gold LF Star +	Plot Dentaire PX Gold LF Star +	Ingots for casting	IIa	8
1011007	7330	PX Gold 72 PF	Plot Dentaire PX Gold 72 PF	Ingots for casting	IIa	8
1011037	7330	Qualigold 3	Plot Dentaire 7330 QLD/Q-GOLD 3	Ingots for casting	IIa	8
1040497	7330	PX Gold 72 PF	PX Gold 72 PF, Laser 0.30 mm	round wire	IIa	8
1040570	7330	Qualigold 3	QUALIGOLD 3, laser 0.30 mm	round wire	IIa	8
1011017	7331	PX Gold LF Eco	Plot Dentaire PX Gold LF Eco	Ingots for casting	IIa	8
1011065	7331	Qualistar 6	Plot Dentaire 7331 QLD/Q-STAR 6	Ingots for casting	IIa	8
1062359	7332	Qualiplus 8	Plot Dentaire 7332 Qualiplus 8	Ingots for casting	IIa	8
1011048	7340	Qualigold 4	Plot Dentaire 7340 QLD/Q-GOLD 4	Ingots for casting	IIa	8
1011010	7350	PX Gold LF	Plot Dentaire PX Gold LF	Ingots for casting	IIa	8
1011038	7350	Qualigold 5	Plot Dentaire 7350 QLD/Q-GOLD 5	Ingots for casting	IIa	8
1040210	7350	PX Gold LF	PX Gold LF, Laser 0.30 mm	round wire	IIa	8
1085567	7381	Qualistar 15	Plot Dentaire Qualistar 15	Ingots for casting	IIa	8
1011040	7420	Qualiplus 2	Plot Dentaire 7420 QLD/Q-PLUS 2	Ingots for casting	IIa	8
1011049	7430	Qualiplus 3	Plot Dentaire 7430 QLD/Q-PLUS 3	Ingots for casting	IIa	8
1011061	7470	Qualiplus 7	Plot Dentaire 7470 QLD/Q-PLUS 7	Ingots for casting	IIa	8
1085346	7470	Qualiplus 7	Laser 0.30 mm	round wire	IIa	8
1085549	7471	Qualistar 16	Plot Dentaire Qualistar 16	Ingots for casting	IIa	8
1040235	7501	PX Presold 1040	PX Presold 1040 (bobine)	rectangular strip	IIa	8
1040268	7501	PX Presold 1040	Fil Rond 0.80 PX Presold 1040	round wire	IIa	8
1040206	7502	PX Presold1110	PX Presold 1110 (fils)	round wire	IIa	8
1040241	7502	PX Presold1110	PX Presold 1110 (bobine)	rectangular strip	IIa	8
1011047	7510	Qualistar 1	Plot Dentaire 7510 QLD/Q-STAR 1	Ingots for casting	IIa	8
1011015	7520	PX Ecocast 2	Plot Dentaire PX Ecocast 2	Ingots for casting	IIa	8
1011041	7520	Qualistar 2	Plot Dentaire 7520 QLD/Q-STAR 2	Ingots for casting	IIa	8
1040203	7521	PX Postsold 800	PX Extrasold 800	round wire	IIa	8
1040237	7521	PX Postsold 800	PX Postsold 800 (fils)	round wire	IIa	8
1040261	7521	PX Postsold 800	PX Postsold 800 (paillons)	pins	IIa	8

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Art. No	Alloy No	Brand name	Designation	Form	Class	Rule
1040204	7561	PX Sold 890 NP	PX Sold 890 NP	round wire	IIa	8
1040218	7561	PX Sold 890 NP	PX Sold 890 NP (fils)	round wire	IIa	8
1040230	7561	PX Sold 890 NP	PX Sold 890 NP (bobine)	rectangular strip	IIa	8
1040495	7562	PX Sold 940	PX Sold 940	round wire	IIa	8
1040202	7590	PX Unifil	PX Unifil 1/2 jonc 1.50 mm	half-ring	IIa	8
1040205	7590	PX Unifil	PX Unifil Ø 1.80 mm	round wire	IIa	8
1040254	7590	PX Unifil	PX Unifil Ø 0.80 mm	round wire	IIa	8
1040256	7590	PX Unifil	PX Unifil Ø 0.90 mm	round wire	IIa	8
1040257	7590	PX Unifil	PX Unifil Ø 1.00 mm	round wire	IIa	8
1040258	7590	PX Unifil	PX Unifil Ø 1.10 mm	round wire	IIa	8
1040259	7590	PX Unifil	PX Unifil Ø 1.20 mm	round wire	IIa	8
1040260	7590	PX Unifil	PX Unifil Ø 1.80 mm	round wire	IIa	8
1098554	7590	PX Unifil	PX Unifil Ø 2.50 mm	round wire	IIa	8
1099662	7590	PX Unifil	PX Unifil Ø 2.80 mm	round wire	IIa	8
1100920	7590	PX Unifil	PX Unifil Ø 2.30 mm	round wire	IIa	8
1005812	7630	PX Supracast	Fil Rond Ø 2.00 MM PX 3866 BR3000	round wire	IIa	8
1005843	7630	PX Supracast	Tube Rond PX 3895 3.25x1.450 BRFAB	tube	IIa	8
1006032	7630	PX Supracast	Fil Rond Ø 5.00 MM PX 4114 BR1000	round wire	IIa	8
1006033	7630	PX Supracast	Fil Rond Ø 5.50 MM PX 4115 BR1000	round wire	IIa	8
1011638	7630	PX Supracast	Fil Rond 2.000 BRFAB	round wire	IIa	8
1040494	7630	PX Supracast	PX Supracast Ø 1.00 mm	round wire	IIa	8
1047754	7630	PX Supracast	Fil Rond 4.500 BR2000	round wire	IIa	8
1068128	7630	PX Supracast	Fil Rond 3.40 BR2000	round wire	IIa	8
1040213	7720	PX Presold 1100	PX Presold 1100 (fils)	round wire	IIa	8
1040242	7720	PX Presold 1100	PX Presold 1100 (bobine)	rectangular strip	IIa	8
1040238	7760	PX Sold LF 950	Bande QUALISOLD P6	round wire	IIa	8
1040244	7760	PX Sold LF 950	PX Sold LF 950	round wire	IIa	8
1011573	7770	PX Sold LF 880	Brasure PX Sold LF 880 (fil)	round wire	IIa	8
1040211	7770	PX Sold LF 880	PX Sold LF 880	round wire	IIa	8
1005817	7810	PX Novostar	Tube Rond PX 3869 4.20x1.45 BRFAB	tube	IIa	8
1005819	7810	PX Novostar	Tube Rond PX 3870 4.50x1.50 BRFAB	tube	IIa	8
1006034	7810	PX Novostar	Fil Rond 5.50 MM PX 4115 BRFAB	round wire	IIa	8
1047121	7810	PX Novostar	Fil Rond 3.80 BR2000	round wire	IIa	8
1047352	7810	PX Novostar	Fil Rond 5.30 BR1500 Maxi	round wire	IIa	8
1066962	7810	PX Novostar	Fil Rond 6.600 BR1200	round wire	IIa	8
1029984	7811	Au-Pt Leg.	Fil Rond 2.00 BR2000	round wire	IIa	8
1032813	7811	Au-Pt Leg.	Fil Rond 3.00 BR2000	round wire	IIa	8
1032814	7811	Au-Pt Leg.	Fil Rond 4.00 BR2000	round wire	IIa	8
1040209	7920	PX Sold 830	PX Sold 830 (fils)	round wire	IIa	8
1040228	7920	PX Sold 830	PX Sold 830 (bobine)	rectangular strip	IIa	8
1040223	7930	PX Sold 780	PX Sold 780 (fils)	round wire	IIa	8
1040232	7930	PX Sold 780	PX Sold 780 (bobine))	rectangular strip	IIa	8
1040216	7940	PX Sold 740	PX Sold 740 (fils)	round wire	IIa	8
1040500	7940	PX Sold 740	PX Sold 740 (bobine)	rectangular strip	IIa	8