

DECLARACIÓN DE CONFORMIDAD CE

CE DECLARATION OF CONFORMITY

DECLARAÇÃO DE CONFORMIDADE CE



ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A.

Rua Waldir Landgraf, 101 – Jardim Lindóia
 86031-218 – Londrina – PR - **Brazil**

Londrina, October 24, 2013

Declaran bajo su responsabilidad que el producto:
 Declare under their responsibility that the product:
 Declara abaixo sua responsabilidade que o produto:

All the products below cited take care of Standard EN ISO 10477:2004 - DENTISTRY – Polymer-Based Crown and Bridge Materials and the Endodontics products (Codes 820, 821 and 822) take care of to Standard EN ISO 10477:2004 - DENTISTRY – Polymer-Based Crown and Bridge Materials and Standard EN ISO 6876:2001 – Dental Root Canal Sealing Materials.

PRODUCTS				
CODES	PRODUCT	ESPECIFICATIONS	CONTAINING	CLASS/ RULES
300/3001/3002	PROVJET	Universal Temporary Crown	06 for central incisive teeth 06 for side incisive teeth	IIA/7
400/4001/4002	METALPIN	Metallic post for temporary Crown	30 units (10 lrg, 10 sml, 10 med)	IIA/8
460/4601/4602	FIBREX-LAB/ PONTIC SYSTEM	Pre-manufactured pontics in fiberglass and epoxy resin for reinforcement metal-free prosthesis	Kit: 24 units: anterior (04 S, 04 M, 04 L) and posterior (04 S, 04 M, 04 L) + 01 syringe of adhesive C resin-2ml + 01 syringe of adhesive F resin-2ml + 02 Fibrex-Medial boxes with 21 cm of fibers each + 01 Fibrex Bonding Agent 4,0ml.	IIA/8
461/4611/4612	FIBREX-LAB/ PONTIC SYSTEM	Pre-manufactured pontics in fiberglass and epoxy resin for reinforcement metal-free prosthesis	Refill: 24 units: anterior (04 S, 04 M, 04 L) and posterior (04 S, 04 M, 04 L)	IIA/8
470/4701/4702	FIBREX-LAB	Glass fiber reinforced system for prosthesis structures	Complete kit	IIA/8
471/4711/4712	FIBREX MEDIAL	Unidirectional glass fiber replacement	02 units (10,5 cm/un)	IIA/8
472/4721/4722	FIBREX JUNCIONAL	Glass fiber replacement - mesh	02 units (10,5 cm/un)	IIA/8
473/4731/4732	FIBREX CORONAL	Glass fiber replacement - for crown	06 units (2,3 cm/un)	IIA/8
474/4741/4742	FIBREX FITA	Glass fiber tape	06 units (15 cm/un)	IIA/8
475/4751/4752	ADESIVO C	Adhesive C Replacement	01 syringe (2,0 ml)	IIA/8
476/4761/4762	ADESIVO F	Adhesive F Replacement	01 syringe (2,0 ml)	IIA/8
477/4771/4772	AGENTE DE UNIÃO	Bonding Agent Replacement	01 unit (4,0 ml)	IIA/8
479/4791/4792	SILANO	Bonding agent for ceramics and glass fiber posts and structures	01 unit (5,0 ml)	IIA/8
480/4801/4802	MULTIKIT FIBREX-LAB	Structural glass fiber reinforcement for permanent prosthesis	Mini kit	IIA/8
483/4831/4832	INTERLIG	Glass fiber tape impregnated with composed resin.	03 units (8,5 cm/um)	IIA/8
4839	INTERLIG PROMOTIONAL	Glass fiber tape impregnated with composed resin.	04 units (8,5 cm/um)	IIA/8

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493/4931/4932	OPAK	Light-curing opaque resin. Color: B 0,5	01 syringe (1,5 ml)	IIA/8
494/4941/4942	OPAK	Light-curing opaque resin. Color: A3	01 syringe (1,5 ml)	IIA/8
491	OPAK LIGHT PINK	Light-curing opaque resin. Color: Light Pink	01 syringe (1,5 ml)	IIA/8
492	OPAK DARK PINK	Light-curing opaque resin. Color: Dark Pink	01 syringe (1,5 ml)	IIA/8
496	PORCELAIN REPAIR KIT	Kit with products for porcelain repair	01 Porcelain Conditioner Angelus with 0.5g, 01 Silano Angelus with 2ml, 01 Opak B0.5 with 0.5g, 01 Opak A3 with 0,5g	IIA/8
630/6301/6302	SISTEMA VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Complete kit: 12 sachets 38 grams each VC alumina powder + 01 bottle 25 grams VC 0 glass powder + 01 bottle 25 grams VC 1 glass powder + 01 bottle 25 grams VC 2 glass powder + 01 bottle 25 grams VC 3 glass powder + 12 bottles 5,0 ml each VC mixing fluid + 01 bottle 2 ml VC additive + 01 bottle 5 ml VC crack detector liquid + 01 container 4 grams VC release agent.	IIA/8
631/6311/6312	VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Refill: 12 sachets 38 grams each VC alumina powder	IIA/8
632/6321/6322	VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Refill: 01 bottle 25 grams VC 0 glass powder	IIA/8
633/6331/6332	VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Refill: 01 bottle 25 grams VC 1 glass powder	IIA/8
634/6341/6342	VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Refill: 01 bottle 25 grams VC 2 glass powder	IIA/8
635/6351/6352	VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Refill: 01 bottle 25 grams VC 3 glass powder	IIA/8
637/6371/6372	LÍQUIDO DE MESCLAR	Mixing fluid	01 bottles 5,0 ml each VC mixing fluid	IIA/8
637/6371/6372	VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Refill: 12 bottles 5,0 ml each VC mixing fluid	IIA/8
638/6381/6382	VITRO-CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	Refill: 01 bottle 2 ml VC additive	IIA/8
646/6462/6462	MINI-KIT VITRO CERAM/ALUMINA	Glass-infiltrated alumina-based all-ceramic system for esthetic copings and frameworks	1 sachet of alumina powder with 38 grams, 1 bottle of mix fluid with 5,0 ml 1 bottle of additive with 2ml	IIA/8
710/7101/7102	REFORPOST CARBON FIBER	Carbon fiber intra-root direct post system	30 units + 03 burses	IIA/8
711/7111/7112	REFORPOST C.F. 1	Carbon fiber direct post (replacement) (1,1 mm)	5 units	IIA/8
712/7121/7122	REFORPOST C.F. 2	Carbon fiber direct post (replacement) (1,3 mm)	5 units	IIA/8
713/7131/7132	REFORPOST C.F. 3	Carbon fiber direct post (replacement) (1,5 mm)	5 units	IIA/8

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714/7141/7142	MINI KIT REF. C.F.	Carbon fiber direct post system	15 units	IIA/8
720/7201/7202	REFORPOST GLASS FIBER	Glass fiber Intra-root direct post system	30 units + 03 burse	IIA/8
721/7211/7222	REFORPOST G.F. 1	Glass fiber direct post (replacement) (1,1 mm)	5 units	IIA/8
722/7221/7222	REFORPOST G.F. 2	Glass fiber direct post (replacement) (1,3 mm)	5 units	IIA/8
723/7231/7232	REFORPOST G.F. 3	Glass fiber direct post (replacement) (1,5 mm)	5 units	IIA/8
724/7241/7242	MINI KIT REF. G.F.	Glass fiber direct post system	15 units	IIA/8
726	REFORPOST G.F. 1	Glass fiber direct post (replacement) (1,1 mm)	10 units	IIA/8
727	REFORPOST G.F. 2	Glass fiber direct post (replacement) (1,3 mm)	10 units	IIA/8
728	REFORPOST G.F. 3	Glass fiber direct post (replacement) (1,5 mm)	10 units	IIA/8
730/7301/7302	REFORPOST MIX KIT	Carbon fiber posts recovered with glass fiber for corono-radicular reinforcement and support of prosthetics crowns	30 posts + 03 Largo Burs + scale for radiographic measuring	IIA/8
731/7311/7312	REFORPOST MIX REPL. I	Replacement for carbon fiber posts recovered with glass fiber (1,1 mm)	5 units	IIA/8
732/7321/7322	REFORPOST MIX REPL. II	Replacement for carbon fiber posts recovered with glass fiber (1,3 mm)	5 units	IIA/8
733/7331/7332	REFORPOST MIX REPL. III	Replacement for carbon fiber posts recovered with glass fiber (1,5 mm)	5 units	IIA/8
749/7491/7492	MINI KIT REFORPOST I	Metallic posts for root reinforcement and prosthetic crowns support	28 units + key and model	IIA/8
750/7501/7502	REFORPOST METALLIC	Intra-root direct post system made of steel	60 units	IIA/8
751/7511/7512	REFORPOST METALLIC	Reforpost I post no. 1 (6,5) (Replacement without head)	5 units	IIA/8
752/7521/7522	REFORPOST METALLIC	Reforpost I post no. 2 (7,5) (Replacement without head)	5 units	IIA/8
753/7531/7532	REFORPOST METALLIC	Reforpost I post no. 3 (9,25) (Replacement without head)	5 units	IIA/8
754/7541/7542	REFORPOST METALLIC	Reforpost I post no. 4 (11) (Replacement without head)	5 units	IIA/8
755/7551/7552	REFORPOST METALLIC	Reforpost II post no 1 (6,5) (Replacement with head)	5 units	IIA/8
756/7561/7562	REFORPOST METALLIC	Reforpost II post no 2 (7,5) (Replacement with head)	5 units	IIA/8
757/7571/7572	REFORPOST METALLIC	Reforpost II post no. 3 (9,25) (Replacement with head)	5 units	IIA/8
758/7581/7582	REFORPOST METALLIC	Reforpost II post no. 4 (11) (Replacement with head)	5 units	IIA/8
797	REFORPIN	Replacement for accessory glass fiber posts to be used in large conducts (Size Universal)	10 units	IIA/8
820	MTA-ANGELUS	Root Canal Repair Cement made of MTA - 1g	01 gram	IIA/8
821/8211/8212	MTA-ANGELUS	Root Canal Repair Cement made of MTA - 2g	02 grams	IIA/8
822	MTA-BRANCO	White root Canal Repair Cement made of MTA - 1g	01 gram	IIA/8

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824	MTA-BRANCO	White root Canal Repair Cement made of MTA – 0,28g	0,28 grams	IIA/8
830	CEMENT-POST/ RESIN CEMENT	Chemically-cured resin cement	Intro kit: 01 syringe with base paste (2,5 grams) + 01 syringe with catalyst (2,5 grams).	IIA/8
9087	EXACTO - TRANSLUCID KIT 0,5	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	Trial Kit Exacto Translucid – 5 Posts nº 0,5 and 1 bur size 0,5	IIA/8
9097	EXACTO TRANSLUCID - REFILL 05	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	5 posts size 0,5	IIA/8
911/9111/9112	EXACTO/ GLASS FIBER/ CONICAL	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	Trial kit 1 – 5 posts size 01 and 1 bur size 01	IIA/8
912/9121/9122	EXACTO/ GLASS FIBER/ CONICAL	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	Trial kit 2 – 5 posts size 02 and 1 bur size 02	IIA/8
913/9131/9132	EXACTO/ GLASS FIBER/ CONICAL	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	Trial kit 3 – 5 posts size 03 and 1 bur size 03	IIA/8
914/9141/9142	EXACTO/ GLASS FIBER/ CONICAL	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	Intro Kit – 15 posts: 5 post size 02 + 5 posts size 03 + 3 calibrated burs + 1 ruler for radiographic measurement + 15 silicone stops.	IIA/8
915/9151/9152	EXACTO/ GLASS FIBER/ CONICAL	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	5 posts size 01	IIA/8
916/9161/9162	EXACTO/ GLASS FIBER/ CONICAL	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	5 posts size 02	IIA/8
917/9171/9172	EXACTO/ GLASS FIBER/ CONICAL	Glass fiber intraradicular posts for restoration and support of prosthetic crowns	5 posts size 03	IIA/8
9117/9127/9137	EXACTO TRANSLUCENT Trial Kit 1	Glass fiber intraradicular translucent posts for restoration and support of prosthetic crowns	05 Exacto Translucent Posts n.1, 01 Exacto Translucent Drill n.1, 05 Drills Stops White.	IIA/8
9127	EXACTO TRANSLUCENT Trial Kit 2	Glass fiber intraradicular translucent posts for restoration and support of prosthetic crowns	05 Exacto Translucent Posts n.1, 01 Exacto Translucent Drill n.1, 05 Drills Stops White.	IIA/8
9137	EXACTO TRANSLUCENT Trial Kit 3	Glass fiber intraradicular translucent posts for restoration and support of prosthetic crowns	05 Exacto Translucent Posts n.1, 01 Exacto Translucent Drill n.1, 05 Drills Stops White.	IIA/8
9147	EXACTO TRANSLUCENT Mini Kit	Glass fiber intraradicular translucent posts for restoration and support of prosthetic crowns	05 Exacto Translucent Posts n.1, 05 Exacto Translucent Posts n.2, 05 Exacto Translucent Posts n.3, 01 Exacto Translucent Drill n. 1, 01 Exacto Translucent Drill n. 2, 01 Exacto Translucent Drill n. 3, 05 Drills Stops White, 05 Drills Stops Yellow , 05 Drills Stops Blue, 01 Ruler for radiographic measurement.	IIA/8
9157	EXACTO TRANSLUCENT Refill Post 1	Glass fiber intraradicular translucent posts for restoration and support of prosthetic crowns.	05 units Exacto Translucent Post n.1.	IIA/8
9167	EXACTO TRANSLUCENT Refill Post 2	Glass fiber intraradicular translucent posts for restoration and support of prosthetic crowns.	05 units Exacto Translucent Post n.2.	IIA/8

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9177	EXACTO TRANSLUCENT Refill Post 3	Glass fiber intraradicular translucent posts for restoration and support of prosthetic crowns.	05 units Exacto Translucent Post n.3.	IIA/8
930/9301/9302	REFORCORE/ PREFABRICATED CORE	Glass fiber core for the support of prosthetic crowns	Complete Kit (30 units): 15 units for anterior tooth (05 L, 05 M, 05 S) + 15 units for premolar (05 L, 05 M, 05 S).	IIA/8
934	REFORCORE/ PREFABRICATED CORE	Glass fiber core for the support of prosthetic crowns	Mini Kit for anterior tooth: 15 units (05 L, 05 M, 05S)	IIA/8
935	REFORCORE/ PREFABRICATED CORE	Glass fiber core for the support of prosthetic crowns	Mini Kit for premolar: 15 units (05 L, 05 M, 05 S).	IIA/8
952	PORCELAIN CONDICIONING	Angelus Porcelain Conditioning is a hydrofluoric acid-based gel base in the concentration of 10%, for acid conditioning of porcelains, aiming at increasing the adhesion of resinous materials.	01 syringe (1,5 ml)	IIA/8
964	MZ PRIMER	Chemical Bonding agent for metal, Zirconia and Alumina	Bottle with 5 ml	IIA/8
826	MTA FILLAPEX	For the final obturation of permanent teeth root canals, in combination with gutta-percha or silver points.	(826) MTA Fillapex (Endodontic Sealer MTA - 1 tube of base paste (12 g) and 1 tube of catalyst paste (18 g) and 1 mixing pad.	IIA/8
827/828	MTA FILLAPEX	For the final obturation of permanent teeth root canals, in combination with gutta-percha or silver points.	(827) MTA Fillapex (Endodontic Sealer MTA-based Cemento 4 g mix syringe) /1 MTA Fillapex double syringe with 2g to base paste and 2 g of catalyst paste and 5 self mixing tips. (828)MTA Fillapex (Endodontic Sealer MTA-based Cemento)/ 3 MTA Fillapex double syringes, 6g of base paste and 6g os catalyst paste, 20 self mixing tips, 5 Multi Use Tips 0,014", 1 mixing pad.	IIA/8
1019/1021	ZIRCON-CAD	Zirconium blocks.	(1019) ZIRCON CAD Blocks 42x20x16mm – Packages with 5/ (1021) ZIRCON CAD Blocks 42x20x16mm - Packages with 3..	IIA/8
871/872	DEFENSE CHROMA	Pit and fissure sealant for permanent and deciduous teeth from patients with high caries activity.	(871) DEFENSE CHROMA MINI KIT: 2 syringes of Defense Chroma 2.5 g, 1 syringe of Phosphoric Acid Gel 3g, and 6 Multi Use Tips. (872) DEFENSE CHROMA/1 syringe with 2,5g + 02units of Multi Use Tips.	IIA/8
602/603/604 and 606	FUSION DURALINK	Fusion Duralink is an adhesive system indicated for direct composite resin restorations and for the adhesive cementation of prefabricated posts (metal and fiber), cast metal posts and indirect restorations (metal, porcelain and composite resin). Its components can also be used for the bonding of orthodontic brackets and amalgam.	(602)FUSION DURALINK/ 2 mL the dental adhesive; (603) FUSION DURALINK/ 4 mL the dental adhesive;(604) FUSION DURALINK Primer/4 mL the Primer; (606) KIT FUSION DURALINK/Dental Adhesive system with phosphoric acid syringe with 3 mL, primer bottle	IIA/8

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			with 4 mL, adhesive bottle with 4 mL and catalyst bottle with 2 mL.	
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Referência/Reference:

De acordo com o Anexo II.3 da Diretiva MDD 93/42/EEC + Emenda 2007/47/EEC.

De acuerdo con Anexo II.3 de la Directiva MDD 93/42/EEC + Enmienda 2007/47/EEC.

Conforms with Annex II.3 of the Directive MDD 93/42/EEC +Amendment 2007/47/EEC.

Fontes/Fuentes/Sources:

Guide to the implementation of directives base to the New Approach and the Global Approach (1999)/EN ISO 10477:2004 - DENTISTRY – Polymer-Based Crown and Bridge Materials /EN ISO 6876:2001 – Dental Root Canal Sealing Materials.

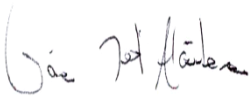


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