

### Declaration of Conformity

Manufacturer Name & Address	PREVEST DENPRO LIMITED EXPORT PROMOTION INDUSTRIAL PARK (EPIP), BARI BRAHAMANA, JAMMU-181133, INDIA	GMDN CODE
EC Representative	OBELIS s.a. Bd. General Wahis 53, 1030 Brussels, Belgium	
Products	Dental Materials	
Restorative Materials	Magma NT Refill Pack 4g(Reference No. 20001)	35875
	Magma NT Intro Kit 4x4g(Reference No. 20002-1)	35876
	Magma NT Master Kit 7x4g(Reference No. 20002)	35876
	Magma NT Unit Dose Compules 20x0.25g (Reference No. 20003)	35875
	Fusion Universal Composite Refill Pack 4g(Reference No. 20004)	35875
	Fusion Universal Composite Intro Kit 4x4g(Reference No. 20005)	35875
	Fusion Universal Composite Combo Kit 7x4g (Reference No. 20006)	35876
	Fusion Universal Composite Combo Kit 7x4g (Reference No. 20006-1)	35876
	Fusion Universal Composite Unit Dose Compules 20x0.25g (Reference No. 20007)	35875
	Fusion Flo Trial Pack 1x2g (Reference No. 20008-1)	35875
	Fusion Flo Intro Pack 2x2g (Reference No. 20008)	35875
	Fusion Flo 1x1.2ml(Reference No. 20008-2)	35875
	Fusion Flo SE Trial Pack 1x2g (Reference No. 20008-3)	35875
	Fusion Flo SE Intro Pack 2x2g (Reference No. 20008-4)	35875
	Fusion Flo Combo Pack 4x2g (Reference No. 20009)	35875
	Self Comp (Reference No. 20010)	16725
	Fusion Core DC Flo Intro Pack (Reference No. 20011)	38789
	Fusion Core DC Flo Combo Pack (Reference No. 20011-1)	38789
	PF Seal Trial Pack 1x2g (Reference No. 20012-1)	31780
	PF Seal Intro Pack 2x2g (Reference No. 20012)	31780
	PF Seal SE Trial Pack 1x2g (Reference No. 20012-2)	31780
	PF Seal SE Intro Pack 2x2g (Reference No. 20012-3)	31780
	Fusion Ultra DC Intro Pack (Reference No. 30006)	35870
	Fusion Ultra D/C Universal Intro Pack (Reference No. 30007)	35870
	Fusion Self Lute Intro Pack (Reference No.. 30008)	35870
	Fusion Crysta Adhesive Trial Pack 1x4g (Reference No. 10022)	31750
Fusion Crysta Adhesive Intro Pack 2x2g (Reference No. 10023)	31750	
Sealants Liners & Base Materials	Apacal Art Trial Pack 1x2g (Reference No. 30001-1)	38770
	Apacal Art Intro Pack 2x2g (Reference No. 30001)	38770
	Fusion I Seal Trial Pack 1x2g (Reference No. 30002-1)	38770
	Fusion I Seal Intro Pack 2x2g(Reference No. 30002)	38770
	Fusion I Seal Economy Pack 4x2g (Reference No.30003)	38770
	Fusion I Seal 1x3g (Reference No. 30003-1)	38770
	Fusion I Seal 2x3g (Reference No. 30003-2)	38770
	Cal LC Trial Pack 1x2g (Reference No. 30004)	38770
	Cal LC Intro Pack 2x2g (Reference No. 30005)	38770
	Cal LC Economy Pack 4x2g(Reference No. 30005-1)	38770
Adhesives	Fusion Bond 7 Intro Pack 5ml (Reference No. 10001)	34782
	Fusion Self Etch Bond Intro Pack 5ml (Reference No. 10001-1)	34782
	Fusion Bond 7 Economy Pack 2x5ml (Reference No. 10002)	34782
	Fusion Self Etch Bond Economy Pack 2x5ml (Reference No. 10002-1)	34782
	Fusion Bond 5 Intro Pack 5ml(Reference No. 10003)	34782
	Fusion Total Etch Bond Intro Pack 5ml (Reference No. 10003-1)	34782
	Fusion Bond 5 Economy Pack 2x5ml (Reference No. 10004)	34782

**Registered Office & Factory :**

UNIT-I : 38, Industrial Estate, Digiana, Jammu 180010, India. Phone : +91 191 2430442, 2432548, Fax : 2475287  
 UNIT-II : Export Promotion Industrial Park, Bari Brahmna, Jammu-181133, India. Phone : +91 1923 222774 / 222779, Fax : 222774  
 E-mail : info@prevestdenpro.com, Web : www.prevestdenpro.com

	Fusion Total Etch Bond Economy Pack 2x5ml (Reference No. 10004-1)	34782
	Fusion Bond DC (Reference No. 10005)	34782
	Renew MDP Regular Pack 1x5ml (Reference No. 10016)	34782
	Renew Universal Intro Pack 1x1.2ml (Reference No. 10017)	34782
	Renew Universal Regular Pack 1x5ml(Reference No. 10018)	34782
	Renew Universal 2x5ml (Reference No. 10019)	34782
	Fusion Crysta Adhesive Primer Regular Pack (Reference No. 10021)	31750
	Fusion Crysta Orthodontic Adhesive Kit (Reference No. 10024)	31750
Dental Cements	Micron Silver (Reference No. 30009)	34779
	Micron Bioactive (Reference No. 30009-1)	34779
	Micron Superior (Reference No. 30010)	34783
	Micron Superior Capsules (Reference No. 30010-3)	34783
	Micron Luting (Reference No. 30011)	34779
	Poly Zinc + Intro Pack (Reference No. 30012)	16705
	Poly Zinc + Economy Pack (Reference No. 30013)	16705
	Zinc F+ Intro Pack (Reference No., 30014)	16710
	Zinc F+ Economy Pack (Reference No. 30014-1)	16710
	Temporary Filling Materials	Orafil G 40g (Reference No. 11001)
Orafil Plus 40g (Reference No. 11002)		38778
Oratemp NE Manual Mix Paste (Reference No. 11003)		46939
Oratemp NE Automix Mix Paste (Reference No. 11004)		46939
Orafil LC 1x3g (Reference No. 11002-1)		38778
Oratemp C&B (Reference No. 11005)		31783
Zinc Oxide Powder 110g (Reference No. 40028)		16709
Root Canal Sealing Materials	GuttaFill BA (Reference No. 40001)	36095
	Eposeal (Reference No. 40013)	36095
	Eposeal Manual Mix Cartridge (Reference No. 40013-1)	36095
	Zical Automix Paste (Reference No. 40010)	36095
	Zical Manual Mix Paste (Reference No. 40011)	36095
	Endoseal Plus (Reference No. 40012)	36095
	MTA Plus Trial Pack 1g (Reference No. 40024)	36095
	MTA Plus Aqua (Reference No. 40024-1)	36095
	MTA Plus Intro Pack 2g (Reference No. 40025)	36095
	MTA Plus Economy Pack 6g (Reference No. 40032)	36095
	Cerafill RCS 1x1.2g (Reference No. 40037)	36095
	Cerafill RCS 1x2g (Reference No. 40037-1)	36095
Endodontic Materials	Dolo EDTA Gel Trial Pack 1x2g (Reference No. 40002)	45233
	Dolo EDTA Gel Intro Pack 1x3g (Reference No. 40002-1)	45233
	Dolo EDTA Gel Economy Pack 4x2g (Reference No. 40003)	45233
	EDTA Solution 15ml (Reference No. 40004)	40016
	EDTA Solution 100ml (Reference No. 40004-1)	40016
	Carvene 10ml (Reference No. 40030)	45234
Pulp Capping Materials	Calcigel Trial Pack 1x2g (Reference No. 40007)	38770
	Calcigel Intro Pack 1x3g (Reference No. 40007-1)	38770
	Calcigel Regular Pack 1x2.2g (Reference No. 40007-2)	38770
	Calcigel Economy Pack 4x2g (Reference No. 40008)	38770
	Pulp X 6g (Reference No. 40021)	38770
	Calcium Hydroxide Powder 10g (Reference No. 40029)	38770
Desensitizers & Varnishes	Nano Coat 5ml (Reference No. 20013)	34771
	Copal F 15ml (Reference No. 40027)	35698
	FlouroDip Bioactive 10ml (Reference No. 80001)	42341

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	FlouroDip Bioactive Monodose 10x0.5ml (Reference No. 80001-2)	42341	
	FlouroDip Bioactive Monodose 10x0.5ml (Reference No. 80001-3)	42341	
	Shield Activ 5ml (Reference No. 80003)	45232	
	BioEnamel Gel 2ml (Reference No. 90012)	45232	
Denture Base Polymers	Hiflex RR (Model No. 15001)	16737	
	Hiflex H (Model No. 15004)	16737	
Etching Materials	Actino Gel Trial Pack 1x2ml (Reference No. 10006-1)	36153	
	Actino Gel 1x3ml (Reference No. 10006-2)	36153	
	Actino Gel Intro Pack 5ml (Reference No. 10006)	36153	
	Actino Gel Economy Pack 4x5ml(Reference No. 10007)	36153	
	Actino Gel Jumbo Pack 50ml (Reference No. 10008)	36153	
	Actino Liquid 10ml (Reference No. 10009)	17737	
	Microgel SF Intro Pack 5ml (10010)	36156	
	Microgel SF Economy Pack 4x5ml (10011)	36156	
	Cera Etch Intro Pack 1x1.2ml (10012)	36153	
	Cera Etch Economy Pack 10ml (10013)	36153	
Auxiliary Dental Materials	Silane X Intro Pack 1x1.2ml (Reference No. 10014)	34782	
	Silane X Economy Pack 10ml (Reference No. 10015)	34782	
	Micron Dentin Conditioner 10ml (Reference No. 30010-1)	34779	
	Ultra Dry Intro Pack 1x1.2ml (Reference No. 40033)	34524	
	Ultra Dry Economy Pack 10ml (Reference No. 40034)	34524	
	EpoSolv 15ml (Reference No. 40035)	35717	
	Platina Hi Gloss 4g (Reference No. 50001)	34814	
	ACE (Reference No. 50002)	35877	
	Spectra Fresh Mint Prophylaxis Paste 200g (Reference No. 50005)	34814	
	Spectra Fresh Mint Prophylaxis Paste 340g (Reference No. 50005-1)	34814	
	Spectra Fresh Mint Prophylaxis Paste 75g (Reference No. 50006)	34814	
	Spectra Fresh Fruit Prophylaxis Paste 75g (Reference No. 50007)	34814	
	Spectra Fresh Strawberry Prophylaxis Paste 75g (Reference No. 50008)	34814	
	Spectra Fresh Orange Prophylaxis Paste 75g (Reference No. 50009)	34814	
	Spectra Fresh Pineapple Prophylaxis Paste 75g (Reference No. 50010)	34814	
	Reveal 5ml (Reference No. 80002)	38783	
	Gingiva Shield VLC Intro Pack 2x1.2ml (Reference No. 90010)	34872	
	Gingiva Shield VLC Economy Pack 4x1.2ml (Reference No. 90011)	34872	
	Zinc Oxide Eugenol Temporary Filling Material	Zinconol (Powder 15g, Liquid 10ml) (Reference No. 30015)	38773
		Zinconol (Powder 75g, Liquid 40ml) (Reference No. 30015-1)	38773
Zitemp (Powder 15g, Liquid 10ml) (Reference No. 30016)		38773	
Brand Name	Not applicable		
Classification of the device	IIa as per annex IX of MDD		
Conformity Assessment Route	Annexure –II.3		
Standards Applied	ISO 9001: 2008, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 14155: 2011, EN 1041: 2008, EN ISO 10993-1: 2018, ISO 15223-1: 2016, EN ISO 10993-5: 2009, EN ISO 10993-10: 2010, EN ISO 10993-11: 2017, MEDDEV 2.12-1 Rev 8: Jan 2013, MEDDEV 2.12/2 Rev 2 Jan 2012, MEDDEV. 2.7.1 Rev.4 : 2016, EN ISO 7405:2018, EN ISO 1641:2009.		
Notified body, Address and Number	TUV SUD Product service Gmbh, Ridlerstrabe 65, D-80339, Munchen,Germany and number is 0123		
EC Certificate No.	G10953770008		
Start of CE Marking	24.04.2020		
Place / Date	Jammu (India)/16.07.2020		

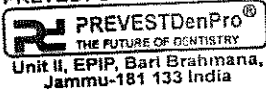


We herewith declare that the above mentioned product meets the provision of council of directive 93/42/EEC for medical device. All documentation shall be retained under premises of manufacturing facility. We herewith declare that as the manufacturer of the above mentioned product "we are exclusively and sole responsible for the declaration of conformity"

(Atul Modi)

Managing Director

PREVEST DENPRO LIMITED



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