

Reference Number: DoC2 Ver. 10



EC Declaration of Conformity

Manufacturer:

Bisco, Inc.
1100 W Irving Park Road
Schaumburg, IL. 60193
USA

Bisco Inc. herewith declares with sole responsibility that the device(s) in the attached device schedule conform to the relevant provisions of EC Council Directive 93/42/EEC of 14 June 1993, Directive 2007/47/EC of 5 September 2007 concerning Medical Devices and is in accordance with the annex listed below as verified by GMED SAS. Bisco Inc. has appointed Bisco France as our EU Authorized Representative. All supporting documentation is retained under the premises of the manufacturer.

EU Authorized Representative: Bisico France, Fred Picavet
208, Allée de la Coudoulette
13680 Lançon de Provence
France

Notified Body: GMED SAS
1, rue Gaston Boissier
75015 Paris
France

Identification Number: 0459

EC Certificate(s): 19096 rev. 18

Place of Declaration Issue: Schaumburg, IL USA

EC Product Class: IIa

Conformity Assessment Route: Annex V section 3

Printed Name: Ryan Hobson

Authorized Signature: *Ryan Hobson*

Title: Regulatory Affairs Manager

Date: 01 April 2021

An ISO 13485 Certified Company

BISCO, Inc.
1100 W. Irving Park Road
Schaumburg, IL 60193 U.S.A.

800-247-3368 or 847-534-6000
Fax: 847-891-5049
www.bisco.com

GMED (0459) reconnait que son certificat CE est valide
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EC Declaration of Conformity
Class: IIa (Page 1 of 9)

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Dental Adhesives	All-Bond 2 TF-ADH1	Kits: B-2510A, B-42500K-EU Refills: B-2511A, B-2511A-JP, B-2512A, B-2512A-JP, B-2502A, B-2506A, B-2506A-JP Primary: B-2511, B-2512, B-2502, B-2501
	All-Bond 3 TF-ADH1	Kits: B-36010P, B-36200K-EU Refills: B-3601P, B-3602P, B-3604P, B-3608P Primary: B-3601, B-3602, B-3604, B-3608
	One-Step TF-ADH1	Refills: U-1101P, U-1101P-JP, U-1103P, U-1102P Primary: U-1101, U-1103, U-1102
	One-Step Plus TF-ADH1	Refills: U-2001P, U-2002S Primary: U-2001, U-2004, U-2021P, U-2002
	All-Bond SE TF-ADH1	Refills: U-3010P, U-3015P Primary: U-3001, U-3002, U-3015
	All-Bond Universal TF-ADH1	Kits: B-7202B0K-EU, B-73050K, B-73100K Refill: B-7202P, B-7204P Primary: B-7202, B-7204, B-7301 Sample Package: B-72060PS, B-7305PS Sample Primary: B-7206S
	Universal Primer TF-ADH1	Refill: B-4110P Primary: B-4101, B-4102

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Class: IIa (Page 2 of 9)

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Dental Acid Etchants	Uni-Etch TF-0020	Kit: E-56610K Refill: E-5502EM, E-5632EM, E-5632EM-JP, E-56611P Primary: E-5622E, E-5637E, E-5661
	Etch-37 TF-0020	Kit: E-56730K Refill: E-5503EM, E-5638E, E-56731P Primary: E-5623E, E-5638E, E-5673
	Liquid Etchant TF-2030	Primary: E-5101E
	Select HV Etch TF-0020	Kit: E-59100K Refill: E-59060P, E-59010P, E-59011P Sample: E-5902PS, E-59011PS Primary: E-5906, E-5901, E-59011S, E-5902S
	Porcelain Etchant (4%) TF-0060	Kit: E-5720E Refill: E-5701E, E-5702EP Primary: E-5702E
	Porcelain Etchant (9.5%) TF-0060	Refill: E-5707P Primary: E-5707
	Barrier Gel TF-0170	Refill: G-96020P Primary: G-9602
Dentin Desensitizer	BisBlock TF-0085	Refill: B-2901P, B-2905P Primary: B-2901, B-2905
Dental Composites	Aelite Kits and Samples TF-COM1	Kit: H-85250K Samples: H-802A2PS, H-804A2PS, H-803A2PS, H-804A2PS, H-722EA2PS

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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Dental Composites (continued)	Aelite Aesthetic Enamel TF-COM1	<p>Syringe Refill: H-852A1P, H-852A2P, H-852A3P, H-852A35P, H-852A4P, H-852B1P, H-852B2P, H-852B3P, H-852B4P, H-852C1P, H-852C2P, H-852C3P, H-852C4P, H-852D2P, H-852D3P, H-852D4P, H-852CLP, H-852FRP, H-852LGP, H-852W2P, H-852A2S</p> <p>Syringe Primary: H-852A1, H-852A2, H-852A2S, H-852A3, H-852A35, H-852A4, H-852B1, H-852B2, H-852B3, H-852B4, H-852C1, H-852C2, H-852C3, H-852C4, H-852D2, H-852D3, H-852D4, H-852CL, H-852FR, H-852LG, H-852W2</p> <p>Unitdose Refill: H-854A1P, H-854A2P, H-854A3P, H-854A35P, H-854A4P, H-854B1P, H-854B2P, H-854B3P, H-854B4P, H-854C1P, H-854C2P, H-854C3P, H-854C4P, H-854D2P, H-854D3P, H-854D4P, H-854CLP, H-854FRP, H-854LGP, H-854W2P, H-771A2S</p> <p>Unitdose Primary: H-854A1, H-854A2, H-854TA2, H-771A2S, H-854A3, H-854A35, H-854A4, H-854B1, H-854B2, H-854B3, H-854B4, H-854C1, H-854C2, H-854C3, H-854C4, H-854D2, H-854D3, H-854D4, H-854CL, H-854FR, H-854LG, H-854W2</p>
	BisFil 2B TF-COM1	<p>Syringe Refill: A-1254P, A-1264K Syringe Primary: A-1251, A-1261, A-1253 Dual-Syringe Refill: A-12710P, A-12810P Dual-syringe Primary: A-12711, A-12811</p>
	BisFil II TF-2000	<p>Syringe Refill: A-1240P Syringe Primary: A-1202P, A-1201P Jar Refill: A-1260PB Jar Primary: A-1232P, A-1214P, A-1234P, A-1213P, A-1231P, A-1233P</p>

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Class: IIa (Page 4 of 9)

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Dental Composites (continued)	Aelite All Purpose Body TF-COM1	Syringe Refill: H-812A1P, H-812A2P, H-812A3P, H-812A35P, H-812B1P, H-812C2P, H-812D3P, H-812A1OP, H-812A35OP
		Syringe Primary: H-812A1, H-812A2, H-812A2S, H-812A3, H-812A35, H-812B1, H-812C2, H-812D3, H-812A1O, H-812A35O
		Unitdose Refill: H-814A1P, H-814A2P, H-814A3P, H-814A35P, H-814B1P, H-814C2P, H-814D3P, H-814A1OP, H-814A35OP
		Unitdose Primary: H-814A1, H-814A2, H-814TA2, H-814A2S, H-814A3, H-814A35, H-814B1, H-814C2, H-814D3, H-814A1O, H-814A35O
	Aelite LS Posterior TF-COM1	Syringe Refill: H-721A1P, H-721A2P, H-721A3P, H-721A35P, H-721B1P, H-721C2P, H-721C4P, H-721D3P
		Syringe Primary: H-721A1, H-721A2, H-721A2S, H-721A3, H-721A35, H-721B1, H-721C2, H-721C4, H-721D3
		Unitdose Refill: H-722A1P, H-722A2P, H-722A3P, H-722A35P, H-722A35P-SP, H-722B1P, H-722B1P-SP, H-722C2P, H-722C2P-SP, H-722C4P, H-722D3P
		Unitdose Sample: H-722PS1-SP Unitdose Primary: H-722A1, H-722A1F, H-722A2, H-722A2F, H-722A2S, H-722A3, H-722A3F, H-722A35, H-722A35F, H-722B1, H-722B1F, H-722C2, H-722C2F, H-722C4, H-722D3
	Reveal TF-COM1	Kits: C-461A12P, C-462BL2P, C-461A22P, C-461A32P, C-462TR2P Primary: C-461A1, C-462BL, C-461A2, C-461A3, C-462TR
	Modeling Resin TF-COM1	Refill: G-9316P Primary: G-9316

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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM NUMBER)</u>
Dental Composites (continued)	AeliteFlo LV TF-COM1	Refill: H-664A2F, H-664A35F Primary: H-661A2, H-661A35, H-664A2, H-664A35F
	AeliteFlo TF-COM1	Kits: H-6701F Refill: H-671A1F, H-671A2F, H-681A2F, H-671A2OF, H-671A3F, H-671A35F, H-681A35F, H-671A5F, H-672B1F, H-672B3F, H-673C2F, H-673C3F, H-674D3F, H-675TIF, H-675OWF, H-675OWF-JP Primary: H-671A1, H-681A1, H-671A2, H-681A2, H-671A2O, H-671A3, H-671A35, H-681A35, H-671A5, H-672B1, H-672B3, H-673C2, H-683C2, H-673C3, H-674D3, H-684D3, H-675TI, H-675OW
Dental Sealants	Fortify TF-1060	Kit: G-9300F Refill: G-9301F, G-9301F-JP, G-9302F, G-9309F Primary: G-9302, G-9301F, G-9309F
	Fortify Plus TF-1060	Refill: G-9310F Primary: G-9310, G-9310S
Dental Liquid Polish	BisCover LV TF-1062	Refill: G-9334PS, G-93353P, G-93353P-JP, G-9335P Primary: G-9334S, G-9335, G-93353
Dental Cements	BisCem TF-CEM1	Refill: D-45001S, D-45011P, D-45012P Primary: D-45011, D-45012
	TheraCem Ca TF-CEM1	Syringe Primary: D-46501 Syringe Packaged: D-46501P Sample Syringe Primary: D-46502S Sample Syringe Packaged: D-46502PS
	C&B Cement TF-CEM1	Syringe Refill: B-2400N, B-2200Q, Syringe Primary: B-2213Q, B-2212Q, B-2211Q Dual Syringe Refill: B-22210P, B-22110P Dual Syringe Primary: B-22210, B-22110

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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Pulp Protectant Material	TheraCal LC TF-1019	Syringe Refill: H-3301P, H-33014P Syringe Primary: H-3301 Sample Packaged: H-3302PS Sample Unpackaged: H-3302S
	TheraCal PT TF-3115	Primary: H-34010 Refill: H-34110P
	TheraBase Ca TF-3111BCA	Primary: H-3501, H-3502S Refill: H-35010P, H-3502PS
	Dental Core Materials	Bis-Core TF-3050
Core-Flo TF-2003		Jar Kit : A-1750B, A-1750B-FN, A-17610 Jar Primary: A-1752B, A-1772B, A-1752BN, A-1751B
Core-Flo DC TF-COR1		Kits: A-2311K-EU, AB-23410K Refill: A-23011P, A-23013P, A-23012P Primary: A-23011, A-23012
Core-Flo DC Lite TF-COR1		Kits: AB-17410K Refill: A-17801P, A-17803P, A-17801SP Primary: A-17801, A-17803, A-17801S
Light-Core TF-COR1		Syringe Refill: A-17262TS, A-1727P, A-17261BS, A-1728P Syringe Primary: A-17262S, A-1727, A-1728, A-17261BS Unitdose Refill: A-1725P, A-17150B, A-1729P Unitdose Primary: A-1725, A-1729

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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Dental Cements (continued)	Choice 2 Cement TF-CEM1	Kit: C-3900K-EU Refill: C-411A1P, C-411A2P, C-411A3P, C-411B1P, C-411B3P, C-411C2P, C-411D2P, C-411TRP, C-411MOP, C-411OPP, C-411MBP Primary: C-411A1, C-411A2, C-411A3, C-411B1, C-411B3, C-411C2, C-411D2, C-411TR, C-411MO, C-411OP, C-411MB
	Duo-Link TF-CEM1	Syringe Refill: A-1920B Syringe Primary: A-1901B, A-1902B Dual-Syringe Refill: A-19010P, A-19070S Dual-Syringe Primary: A-19010, A-19070S
	Duo-Link Universal TF-CEM1	Kit: A-19620K, A-19710K Refill: A-19030P, A-197MWP Syringe Primary: A-19030, A-197MW Sample Package: A-19031PS Sample Primary: A-19031S
	eCement TF-CEM1	Kit: C-52410K-EU Refill (eCEMENT L/C): C-52120P, C-52230P, C-52010P Refill (eCEMENT D/C): C-52340P Primary (eCEMENT L/C): C-5212, C-5223, C-5201 Primary (eCEMENT D/C): C-52340
Try-In Paste	Choice 2 Try-In Paste TF-0112	Refill: C-412A1P, C-412A2P, C-412A3P, C-412B1P, C-412C2P, C-412D2P, C-412TRP, C-412MOP, C-412OPP, C-412MBP Primary: C-412A1, C-412A2, C-412A3, C-412B1, C-412C2, C-412D2, C-412TR, C-412MO, C-412OP, C-412MB
	eCement Try-In Paste TF-0112	Refill (eCEMENT Try-In Paste): C-531A1P, C-531TRP, C-531MBP Primary (eCEMENT Try-In Paste): C-531A1, C-531TR, C-531MB

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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Orthodontic Materials	Ortho Band LC TF-1050	Kit: F-6414P Primary: F-6411, F-6414
	Ortho Bracket LC TF-1040	Kit: F-63020P Primary: F-6302
	Ortho-One TF-2030	Kit: F-61040P Paste Refill: F-6101D Paste Primary: F-6101, F-6104 Primer Refill: F-6102D Primer Primary: F-6102, F-6103
Temporary Dental Restorative Materials	Pro-V TF-0211 TF-1002	Coat Refill: H-4011P Coat Primary: H-4011
Shading Materials	Characterization Tints TF-0132	Refill: T-14018P, T-14019P, T-14017P, T-14012P, T-14014P, T-14016P, T-14021P, T-14022P Primary: T-14018, T-14019, T-14017, T-14012, T-14014, T-14016, T-14021, T-14022
	Opaquer TF-3040	Refill: B-2122Q, B-2112Q Primary: B-2122, B-2112
Wetting Agent	Aqua-Prep F TF-0080	Refill: B-2821S, B-2822P, B-2824P Primary: B-2821, B-2822, B-2822P, B-2821S, B-2824
Dental Prosthesis Primer	Porcelain Primer TF-0050	Secondary Packaging: B-2221P Primary Packaging: B-2221, SB-2223
	Bis-Silane TF-0050	Refill: B-3210P Primary: B-3211, B-3212
	Z-Prime Plus TF-0052	Refill: B-6001P, B-6002P, B-6003PS Primary: B-6001, B-6002, B-6003S

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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
Dental Prosthesis Primer (continued)	Porcelain Bonding Resin TF-1090	Refill: B-3110P Primary: B-3110
	Repair Kit	Intraoral Repair Kit TF-0052 Kit: B-22300K
Posts and Drills	DT LightPost TF-P7030	Kit: G-91300K Refill: X-80751P, X-80752P, X-80753P, X-80746P Primary: X-80751P, X-80752P, X-80753P, X-80746P
	DT LightPost Illusion X-RO TF-P7030	Kit: G-91820K Refill: X-81811P, X-81810P, X-81812P, X-81813P
	Drills TF-P730	Drill Refill: X-80781P, X-80782P, X-80783P, X-80784P, Primary: X-80781P, X-80782P, X-80783P, X-80784P,
	Post Removal Kit TF-P7030	Refill: X-80692P Primary: X-80692P
	Transluma TF-P7030	Kit: G-91620K Refill: X-81622P, X-81522P, X-81623P, X-81523P, X-81620P, X-81621P, X-81521P Primary: X-81622, X-81522, X-81623, X-81523, X-81621, X-81620, X-81521, X-815373, X-815382, X-81610, X-81611, X-81612, X-81613
Dental Burs	RAPTOR TF-P810	Kit: N-81000K Refill: N-81011R, N-81002R, N-81014R, N-81017R, N-81022R, N-81021R Primary: N-81011, N-81002, N-81014, N-81017, N-81022, N-81021

END OF CLASS IIa DECLARATION OF CONFORMITY

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