



**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 concerning Medical Devices and is in accordance with the annex listed below. 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:      Bisco 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):                      Not Applicable / Self-certification

Place of Declaration Issue:         Schaumburg, IL USA

EC Product Class:                     I

Conformity Assessment Route:      Annex VII

Printed Name:                        Ryan Hobson

Authorized Signature: \_\_\_\_\_

Title:                                    Global Regulatory Affairs Manager

Date:                                     \_\_\_\_\_



**EC Declaration of Conformity**  
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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
EQUIPMENT	QUICK DIE	Refill: L-11090P Primary: L-11092
INSTRUMENTS	COMPOSITE INSTRUMENTS	Refill: N-5121P, N-5123P, N-5125P, N-5124P, N-5122P
IMPRESSION MATERIAL	REVEAL CLEAR MATRIX	Kit: L-31010K Primary: L-3101
ACCESSORIES	APPLICATORS	Refill: X-80247R, X-80243R, X-80246R, X-80248P, X-80250P, X-80251P, X-80261P, X-80630R
	DISPOSABLE SYRINGE TIPS	Refill: X-81252P, X-81257P, X-81267P, X-81268P, X-81269P, X-81270P, X-81271P, X-81272P, X-80629N, X-80615N, X-80616N, X-80608N, X-80611N, X-80618N, X-80602N, X-80614N, X-80610N, X-80621N, X-80622N, X-80604N Primary: X-80605, X-81254, X-81255, X-81256, X-80619, X-81258S, X-81266
	EMPTY SYRINGES	Refill: X-80580P, X-80582P, X-80583P
	DISPENSERS	Refill: L-22020P, U-30220P
	MIXING PADS & SPATULAS	Mixing Pad Refill: X-80485B, X-80484B Mixing Pad Primary: MXPD-001R1, MXPD-002R1 Mixing Spatula Refill: X-80486B Mixing Spatula Primary: MXSP-001
	MIXING WELLS	Refill: X-80498B, X-80496B, X-80494BP, X-80497P Primary: MXWL-002, MXWL-007, MXWL-008, X-80494B

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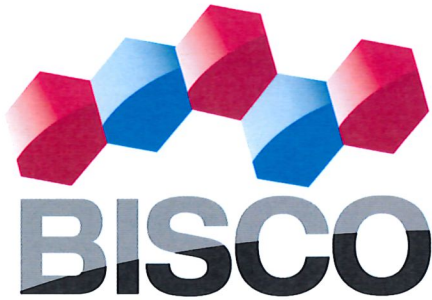


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<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>
ACCESSORIES (continued)	UNIDOSE TUBES & PLUGS	Refill: X-80808P, X-80806P
	UNIT DOSE DISPENSING SYRINGE	Refill: X-80801P
	MOCK UP TRAY	Refill: X-80424P
FINISHING PRODUCTS	FINISHING DISKS	Refill: N-71000P Primary: N-71000P
RESTORATION CLEANER	ZIRCLEAN	Refill: B-7351P Primary: B-7351

**END OF CLASS I DECLARATION OF CONFORMITY**

Reference Number: RA-DoC1 Ver. 9



Note:

From this page forward, these pages are not a part of the Declaration of Conformity.

The following pages are to make it easier to update and to summarize the changes that have occurred since the last signed document.

The schedule of obsolescence and list of additions may be supplied to a distributor to inform them of any changes/scheduled changes to the declaration of conformity since their last registration.



## HISTORY OF ADDITIONS AND REMOVALS

### Added since 05/01/2014

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date Added</u>
ACCESSORIES	EMPTY SYRINGES	Refill: X-80580P, X-80582P, X-80583P	<u>6/18/2014</u>
	DISPOSABLE SYRINGE TIPS	Primary: X-81266	<u>3/17/2015</u>

### Removed since 05/01/2014

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date Removed</u>
	Disposable syringe tips	Refill: X-80580P	Removed and put under empty syringes on 6/18/2014
INSTRUMENTS	COMPOSITE INSTRUMENTS	Refill: N-5114P	For: 11/2014 On 3/18/2015
INSTRUMENTS	COMPOSITE INSTRUMENTS	Refill: N-5115P	For 11/2014 On 3/18/2015
ACCESSORIES	APPLICATORS	Refill: X-80242R	March 2015 On 3/18/2015
ACCESSORIES	COREFORM	Refill: X-81817P	March 2015 On 3/18/2015

### Removed since 06/02/2015

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date Removed</u>
EQUIPMENT	VIP	Refill: V-20110K	August 2015
EQUIPMENT	VIP	Refill: V-20120K-EU	August 2015
EQUIPMENT	VIP	Refill: V-20201A	August 2015
EQUIPMENT	VIP	Refill: V-20221A	August 2015
EQUIPMENT	VIP	Refill: V-10102A	August 2015
EQUIPMENT	VIP	Refill: V-10105A	
EQUIPMENT	TESCERA ATL & ATL PARTS	Kit: T-33010K-NC	November 2015 OR-9070



### Removed Since 3/10/2016

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date Removed</u>
ACCESSORIES	TESCERA SEPARATOR	Refill: T-1801P Primary: T-1801	3/28/2016 per OR13-019
ACCESSORIES	COMPOSIDISK	Refill: X-81818P	November 2016
ACCESSORIES	COMPOSIDISK	Primary: X-81818P	November 2016
ACCESSORIES	COREFORM	Refill: X-818171P	November 2016
ACCESSORIES	COREFORM	Refill: X-818172P	November 2016
ACCESSORIES	COREFORM	Refill: X-818173P	November 2016
ACCESSORIES	COREFORM	Refill: X-818174P	November 2016
ACCESSORIES	COREFORM	Refill: X-818175P	November 2016

### Added Since 3/10/2016

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date added</u>
ACCESSORIES	DISPOSABLE SYRINGE TIPS	Refill: X-81268P	12/1/16
ACCESSORIES	DISPOSABLE SYRINGE TIPS	Refill: X-80269N Changed to X-80629N	12/19/16 12/27/16

### Removed Since 5/2017

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date Removed</u>
ACCESSORIES	APPLICATORS	X-80245R	8/8/2017
GUIDES	REFLEXIONS SHADE GUIDE	Refill: H-9001P	8/8/2017
ACCESSORIES	APPLICATORS	Refill: X-80241R	8/8/2017 OR-10012



**Added Since 5/2017**

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date added</u>
ACCESSORIES	DISPOSABLE SYRINGE TIPS	Primary: X-81255	9/20/2017

**Added Since 5/2018**

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date added</u>
RESTORATION CLEANER	ZIRCLEAN	Refill: B-7351P Primary: B-7351	11/19/2018

**Removed**

**2018 (removed 11-19-18)**

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date to be Removed/ Reference Number</u>
INSTRUMENTS	TESCERA UBEAM GUAGE	Refill: N-5120P	1/15/2018
	COMPOSITE INSTRUMENTS	Refill: N-5119P, N-5118P	1/15/ 2018
	REVERSE ACTION PLIERS	Refill: N-5117P	3/25/2018 OR13-004
INSTRUMENTS	COMPOSITE INSTRUMENTS	N-5107P,	3/25/18 OR13-011
EQUIPMENT	TESCERA ATL & ATL PARTS	Kit: T-91000, T-90000	10 April 2018 OR13-020

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EQUIPMENT	TESCERA ATL & ATL PARTS	Refills: , T-33020P-ROK, T-33020-ROK, Note T-33020P also on obsolescence but not on DoFC	16 April 2018 OR13-022
EQUIPMENT	TESCERA ATL & ATL PARTS	Refill: N-6100P , N-6200P	4/25/2018 per order sent on 4/22/13 3/28/13 per OR 13-019
		Kit: T-33010K-NC, T-91000, T-90000	
		Refills: T-1811P, T-1816P, T-33020P-ROK, T-33020-ROK, T-33010-ROK, T-1805P, T-1814P, T-1821P, T-1852P-ROK, T-1821P-IS, T-1821P-SA, T-1821P-SL, T-1821P-PRC, T-1821P-DM, T-1821P-GB, T-1821P-IT, T-1821P-JP, T-1821P-OA, T-1821P-US, T-1812P, T-1813P, T-1815P, T-1823P, T-1825P, T-33011P, T-33012P	
	TESCERA POLISHING PASTE	Refill: T-1803P Primary: T-1803	3/28/13 per OR 13-019
	RUBBER SEPARATOR	Refill: T-18310P Primary: T-1831B	3/28/13 per OR 13-019
	DISPOSABLE SYRINGE TIPS	Refill: L-21030P	OR14-013
	BRUSH HANDLES & TIPS	Refill: X-80210R , X-80211R, X-80214R, X-80213R, X-80212R, X-80216R, X-80223R, X-80222R	OR14-030
	BRUSH HANDLES & TIPS		OR-14-013 OR14-040

**Corrected 2018**

	MIXING WELLS	Refill: changed X-80498BP, to X-80498B
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**Corrected 2019**

	MIXING PADS & SPATULAS	Mixing Pad Primary: changed MXPDP-001 to MXPDP-001R1 Mixing Pad Primary: changed MXPDP-002 to MXPDP-002R1
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**To be removed**

**2019**

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date to be Removed/ Reference Number</u>
ACCESSORIES	DISPENSERS	L-21010P	OR14-003 Removed 9/9/19

**Added 2019**

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date / Reference Number</u>
ACCESSORIES	APPLICATORS	Refill: X-80248P	Added 9/ 2019, but had been in TFs for a long time in kits

**Added 2020**

<u>CATEGORY</u>	<u>FAMILY</u>	<u>PRODUCT REF (ITEM) NUMBER</u>	<u>Date / Reference Number</u>
ACCESSORIES	APPLICATORS	Refill: X-80630R	Added 3/10/2020, Replaces X- 80248P – same brush, labeled.
ACCESSORIES	DISPOSABLE SYRINGE TIPS	Refill: X-81269P, X-81270P, X-81271P, X- 81272P	Added September 2020; December 2020

**2020**