



Revised: May 7, 2018  
Issued: March 6, 2013

To whom it may concern.

### Declaration of Conformity (No. E2018006)

We, Sun Medical Co., Ltd., ensure and declare that the products listed in the schedule A below meet the provisions of the Directive 93/42/EEC concerning medical devices. Our products listed in the schedule A below are also in conformity with the safety requirements laid down in Annex I of the Directive 93/42/EEC as amended and the declarations of compliance of our products listed in the schedule A are issued according to Annex II excl. section 4 of the Directive 93/42/EEC as amended on Medical Devices.

EC Certificate No.: G1 17 04 26583 026

Our authorized representative in EU is: EMERGO EUROPE B.V. having its principal office at Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.  
The notified body is: TÜV SÜD Product Service GmbH (ID No. 0123) at Ridlerstrasse 65. 80339 Munich, Germany

#### Schedule A (Part 1)

Product	Type of Product	Classification (Applied Rule of Annex)	Lot Number From:	Standards Applied	Additional Information
Super-Bond	Dental adhesive resin cement	Ila (Annex IX, Rule 8)	-	EN ISO 15223-1:2016 EN ISO 1041:2008 EN ISO 1641:2009 EN ISO 7405:2008+A1:2013	EN ISO 10993-1:2009/AC:2010 EN ISO 10993-18:2009 EN ISO 14971:2012 EN 62366:2008

We declare in our own responsibility,

Akihito Kanematsu

Quality Management Representative

571-2 Furutaka-cho, Moriyama, Shiga, 524-0044, Japan TEL +81-77-582-9981, FAX +81-77-582-9984

**Schedule A (Part 2)**

Products	From:	Lot Number
Super-Bond C&B Brush-dip Kit		
Kit	EK1	
Quick Monomer	EG1	
Catalyst V	EG12	
Polymer (Brush-dip Clear)	EG3	
Enamel Etchant Gel	EG21	
Super-Bond C&B Bulk-mix Kit		
Kit	EF1	
Quick Monomer	EE4	
Catalyst V	VX22	
Polymer (Bulk-mix Esthetic)	EE5	
Polymer (Bulk-mix Radiopaque)	EE1	
Dentin Etchant Gel	VX2	
Super-Bond C&B Brush-dip Starter Kit		
Kit	VX1	
Quick Monomer	VX1	
Catalyst V	VX21	
Polymer (Brush-dip Clear)	VX1	
Enamel Etchant Gel	VW13	
Super-Bond Brush-dip Starter Kit		
Kit	FT1	
Brush-dip Monomer	FS1	
Brush-dip Initiator	FS12	
Enamel Etchant Gel	FS22	
Polymer Powder (Brush-dip Clear)	FF1F	
Polymer (Opaque Pink)	FF1F	
Enamel Etchant Gel	VW14	
Dentin Etchant Gel	VX1	