

Declaration of Conformity (No. E2020018)

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 026583 0028

Our authorized representative in the 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)	Standards Applied	
Super-Bond	Dental Adhesive Resin Cement	Ila (Annex IX, Rule 8)	EN ISO 15223-1:2016 EN 1041:2008 EN 1641:2009 EN ISO 7405:2008+A1:2013	EN ISO 10993-1:2009 EN ISO 10993-18:2009 EN ISO 14971:2012 EN 62366:2008

We are exclusively responsible for this statement.



October 23, 2020

Motofumi Kitagawa

Management Representative for Quality Management System

Sun Medical Co., Ltd.

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Schedule A (Part 2)

Product codes	UDI-DIs	Lot number from	Product names
K058E	4560227800754	FV0737	Super-Bond Universal Kit Components: <ul style="list-style-type: none"> - Super-Bond Catalyst V - Super-Bond Quick Monomer - Super-Bond Universal Polymer (Clear) - Super-Bond Universal Polymer (Radiopaque) - Teeth Primer - M&C PRIMER A - M&C PRIMER B - Dispensing Stand - Dispensing Cups - Measuring Spoon (Standard) - Brush Handle (Bent) - Brush Tips (Brush-dip L) - Brush Tips (Brush-dip LL) - Spatula (Grey)
K058TR	4560227800761		
K057E	4560227800730	FV0725	Super-Bond Universal Starter Kit Components: <ul style="list-style-type: none"> - Super-Bond Catalyst V - Super-Bond Quick Monomer - Super-Bond Universal Polymer (Clear) - Teeth Primer - M&C PRIMER A - M&C PRIMER B - Dispensing Stand - Dispensing Cups - Measuring Spoon (Standard) - Brush Handle (Bent) - Brush Tips (Brush-dip LL) - Spatula (Grey)
K057TR	4560227800747		

Schedule A (Part 2)

Product codes	UDI-DIs	Lot number from	Product names
K029E	4560227801386	FV0727 FV0728	Super-Bond Brush-dip Starter Kit Components: <ul style="list-style-type: none"> - Super-Bond Brush-dip Initiator - Super-Bond Brush-dip Monomer - Super-Bond Polymer (Brush-dip Clear) - Enamel Etchant Gel - Dispensing Stand - Dispensing Cups - Brush Handle (Bent) - Brush Tips (Brush-dip L) - 23G Needle Tip
K029T	4560227801393		
T128E	4560227799881	FV0726	Super-Bond Catalyst V
T128TR	4560227800082		
T127M	4560227800570	TBD	Super-Bond Brush-dip Initiator
T127TR	4560227801423		
T037E	4560227800518	FV0732	Super-Bond Quick Monomer
T037T	4560227796712		
T036E	4560227799874	FV0731	Super-Bond Monomer
T036TR	4560227801003		
T035M	4560227800501	TBD	Super-Bond Brush-dip Monomer
T035TR	4560227801430		
T058E	4560227800778	TBD	Super-Bond Universal Polymer (Clear)
T058TR	4560227800785		
T059E	4560227800792	TBD	Super-Bond Universal Polymer (Esthetic)
T059TR	4560227800808		
T060E	4560227800815	TBD	Super-Bond Universal Polymer (Radiopaque)
T060TR	4560227800822		
T049E	4560227800549	FV0733	Super-Bond Polymer (Brush-dip Clear)
T049T	4560227796729		

Schedule A (Part 2)

Product codes	UDI-DIs	Lot number from	Product names
T070E	4560227797252	TBD	Teeth Primer
T070TR	4560227800013		
K770E	4560227800846	TBD	M&C PRIMER
K770TR	4560227800839		
T055E	4560227801768	TBD	Enamel Etchant Gel
T055TR	4560227801775		
T056E	4560227801782	TBD	Dentin Etchant Gel
T056TR	4560227801799		
T030E	4560227801720	FV0729	Super-Bond C&B Red Activator
T030T	4560227801737		
T032E	4560227801744	FV0730	Super-Bond C&B Green Activator
T032T	4560227801751		