

### Declaration of Conformity (No. E2020004)

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 VII of the Directive 93/42/EEC as amended on Medical Devices.

Our authorized representative in the EU is EMERGO EUROPE B.V. having its principal office at Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

#### Schedule A (Part 1)

Product	Type of Product	Classification (Applied Rule of Annex)	Standards Applied		Additional Information
Accessories of Super-Bond Family	Accessory for dental adhesive resin cement	I  (In Part 2)	EN ISO 15223-1:2016 EN 1041:2008 EN 1641:2009	EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-18:2009 EN ISO 14971:2012 EN 62366:2008	-

We are exclusively responsible for this statement.



October 14, 2020

Motofumi Kitagawa

Management Representative for Quality Management System

Sun Medical Co., Ltd.

571-2 Furutaka-cho, Moriyama, Shiga, 524-0044, JAPAN

TEL +81-77-582-9981

FAX +81-77-582-9984

**Schedule A (Part 2)**

Product codes	UDI-DIs	Product names	Classification Rules of Annex IX
T021E	4560227801447	Dispensing Stand	Rule 1
T021TR	4560227801454		
T022E	4560227801461	Dispensing Cups	Rule 2
T022TR	4560227801478		
T024E	4560227801508	Brush Tips (Brush-dip S)	Rule 5, Transient use
T024TR	4560227801515		
T025E	4560227801522	Brush Tips (Brush-dip L)	Rule 5, Transient use
T025TR	4560227801539		
T026E	4560227801546	Brush Tips (Brush-dip LL)	Rule 5, Transient use
T026TR	4560227801553		
T027E	4560227801560	Measuring Spoon (Standard)	Rule 1
T027TR	4560227801577		
T057E	4560227801409	23G Needle Tip	Rule 5, Transient use
T057TR	4560227801416		
T280E	4560227801669	Spatula (Grey)	Rule 2
T280TR	4560227801676		
T135E	4560227801584	Brush Handle (Straight)	Rule 1
T135TR	4560227801591		
T136E	4560227801607	Brush Handle (Bent)	Rule 1
T136TR	4560227801614		
T133E	4560227801485	Brush Tips (Blue)	Rule 5, Transient use
T133TR	4560227801492		

**Schedule A (Part 2)**

Product codes	UDI-Dis	Product names	Classification Rules of Annex IX
T140E	4560227801621	Brush Tips White (Small)	Rule 5, Transient use
T140TR	4560227801638		
-	-	Brush Tips (White S)	
T141E	4560227801645	Brush Tips White (Large)	Rule 5, Transient use
T141TR	4560227801652		
-	-	Brush Tips (White L)	
-	-	Dispensing Dish	Rule 2
-	-	Sponge (L,S)	Rule 5, Transient use
-	-	Measuring Spoon (Small)	Rule 1
-	-	Measuring Spoon (Large)	Rule 1