SUN MEDICAL

CE mark date: February 15, 2019

Declaration of Conformity（No. E2018020）

We, Sun Medical Co., Ltd., ensure and declare that the product listed in the schedule A below meets the provisions of the Directive 93/42/EEC concerning medical devices. Our product listed in the schedule A below is also in conformity with the safety requirements laid down in Annex I of the Directive 93/42/EEC as amended and the declaration of compliance of our product listed in the schedule A is issued according to Annex VII of the Directive 93/42/EEC as amended on Medical Devices.

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

Schedule A

Product	**Type of Product**	**Classification (Applied Rule of Annex)**	**Lot Number** From:	**Standards Applied**		**Product code / UDI-DI**
Plastic Needle Tip	Accessory for Desensitizer for hypersensitive teeth	I (Annex IX, Rule 5)	-	EN ISO 15223-1:2016 EN 1041:2008 EN 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	T932 / 4560227798853

We declare in our own responsibility,

A. Kanematsu　　Feb. 15, 2019

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