SUN MEDICAL

CE mark date: February 28, 2019

Declaration of Conformity（No. E2020007）

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 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 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

Product	Type of Product	Classification (Applied Rule of Annex)	Lot Number From:	Standards Applied		Product code (UDI-DI)
Gel Desensitizer	Desensitizer for Hypersensitive Teeth	IIa (Annex IX, Rule 8)	SW11 SX22	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	T931E (4560227799737) T931TR (4560227800648)

We are exclusively responsible for this statement.

N. Honda　　July. 2, 2020

Narimichi Honda
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