SUN MEDICAL

CE mark date: October 30, 2019

Declaration of Conformity（No. E2020001）

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 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**
M&C PRIMER	Dental Prosthesis Priming Agent	IIa (Annex IX, Rule 8)	To be determined	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.

N. Honda　　July, 2, 2020

Narimichi Honda
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Schedule A (Part 2)

Product code	UDI-DI	Product name
K770E	4560227800846	M&C PRIMER
K770TR	4560227800839	