Declaration of Conformity

Manufacturer : EASTDENT Co., Ltd.
#601-1, 64, Gugal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 16972, Korea

Whose single Authorized Representative : BIOGERI
Am Pfeilshof 12,
22393 Hamburg, Germany

We, the manufacturer, herewith declare that the products

Rule, class	General name	Model name	GMDN Code	Basic UDI-DI
Rule 5, class I	Gingival Retraction cord	Septofil N 0^4	35861	8809370410400
		Septofil N 0^3		8809370410417
		Septofil N 0^2		8809370410424
		Septofil N 0		8809370410431
		Septofil N 1		8809370410448
		Septofil N 2		8809370410455

Meets the provisions of Regulation(EU) 2017/745 which apply to them.
The medical device has been assigned to class I according to Regulation(EU) 2017/745. It bears the mark

CE

The product concerned has been designed and manufactured under a quality management system according to Annex II, excluding section 4 of Regulation(EU) 2017/745.

Applied harmonized standards, references to the specifications in relation to which conformity is declared;

EN 1041[2008+A1:2013], EN 1641[2009], EN ISO 7405[2018], EN ISO 10993-1[2018], EN ISO 10993-10[2010], ISO 10993-12[2021], EN ISO 10993-18[2020], EN ISO13485[2016], EN ISO14971[2019], EN ISO 15223-1[2016], EN 62366-1[2015], Regulation(EU) 2017/745, Meddev 2.7.1 Rev.4, Meddev 2.12.1 Rev.8, Meddev 2.12.2 Rev.2

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company : EASTDENT Co., Ltd
Address : , #601-1, 64, Gugalro, Giheung-gu, Yongin-si, Gyeonggi-do 16972, Korea.

May 12, 2021 / Yongin, Korea
Place, date

Hyonsu Kim / CEO
Legally binding signature, Function