

Declaration of Conformity

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

Whose single Authorized Representative : KTR Europe GmbH
Mergenthalerallee 77,
65760, Eschborn, 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	Smartcord 0 ⁴	35861	880937041SmartcordNN
		Smartcord 0 ³		
		Smartcord 0 ²		
		Smartcord 0		
		Smartcord 1		
		Smartcord 2		

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



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 10993-5[2009], EN ISO 10993-10[2013], EN ISO 10993-12[2021], EN ISO 10993-18[2020], EN ISO 13485[2016], EN ISO 14971[2019], ISO/TR 24971:2020, EN ISO 15223-1[2016], ISO 20417[2020], EN IEC62366-1[2015], EN IEC TR 62366-2[2016], 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
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March 20, 2024 / Yongin, Korea
Place, date

Hyonsu Kim / CEO
Legally binding signature, Function