



DECLARATION OF CONFORMITY

Manufacturer:

Name: Andent Dental Co.,Ltd

Address: Huanghua city, Hebei provice, China

E-mail: info@andent.cc

SRN: CN-MF-000008753

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd,
2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the product(s)

Product Name	Dental Wedge	Model	PW01 PW02 PW03 PW04 PW05 PW06 PW07
BASIC UDI-DI	69709838201DENTAWEDGE0778	UMDNS Code	11961
Intend Use	Dental Wedge is used to fix adjacent teeth forming sheet temporarily , short-term, not for wounds.		
Classification	I, (MDR, Annex VIII Rule 1)		

meet(s) the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable Standards:

ISO 13485:2016
ISO 10993-5: 2009
EN 1041:2008

EN ISO 14971:2012
ISO 10993-10:2010
EN 15223-1:2016

ISO 10993-1: 2018
EN 62336-1:2015

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Jingren Wang

Position held in the company: General Manager

Place: Hebei, China

Andent Dental Co.,Ltd

Signature:

Date:

Seal/Stamp:

