



DECLARATION OF CONFORMITY

Manufacturer:

Name: Andent Dental Co.,Ltd

Address: Huanghua city, Hebei province, 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	Mixing Tips	Model	TBT200 TBT201 TBT202 TBT203 TBT204 TBT205 TBT206 TBT207 TBT208 TBT209 TBT210 TBT211 TBT2113 TBT2112 TBT214
BASIC UDI-DI	69709838200MIXINGTIP214TG	UMDNS Code	11961
Intend Use	Mixing tips is used to mix two dental impression materials with delivery gun.		
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:

