



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	Suction tips	Model	SA01 SA02 ST02A ST02B ST02C SE01 SE01B SE01G SE01R SE01W ST01A ST01B ST01C ST01AV ST01BV ET04 ET03 ET02 SE02 ET01
BASIC UDI-DI	69709838201SUCTIONTIP049T	UMDNS Code	11961
Intend Use	Suction tips is used to draw blood or saliva during dental examination or treatment		
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:

