



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	Cheek Retractor	Model	CR01 CR02 CR03 CR04 CR05 CR06 CR07 CR08 CR09 CR10 CR11 CR12 CR13 CR14 CR15 CR16 CR17 CR18 CR19 CR20 CR21 CR22 CR23 CR24 CR25 MP01 MP02 MP03 MP04
BASIC UDI-DI	69709838201CRETRACTOR23HB	UMDNS Code	11961
Intend Use	Cheek Retractor is used to open mouth 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:

<i>ISO 13485:2016</i>	<i>EN ISO 14971:2012</i>	<i>ISO 10993-1: 2018</i>
<i>ISO 10993-5: 2009</i>	<i>ISO 10993-10:2010</i>	<i>EN 62336-1:2015</i>
<i>EN 1041:2008</i>	<i>EN 15223-1:2016</i>	

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: 2022.7.22

Seal/Stamp: 