



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	Dental Bibs Holder	Model	BC01 BC02 BC03 BC04 BC05 BC06 BC07 BC08 BC09 BC10
BASIC UDI-DI	69709838201DENTALBIBH10YT	UMDNS Code	11961
Intend Use	Dental Bibs Holder is used to hold dental bib 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: 2022.7.12

Seal/Stamp: 