



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 Rubber Dam Frame	Model	DF01 DF02 DF03
BASIC UDI-DI	69709838201RUDAMFRAME03KL	UMDNS Code	11961
Intend Use	Dental Rubber Dam Frame is used to support rubber dam		
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:**