



DECLARATION OF CONFORMITY

Manufacturer:

Name: Andent Dental Co.,Ltd

Address: Huanghua city, Hebei provice, 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	Vacuum Forming Pressure Sheets Film	Model	VHF08 VHF10 VHF15 VHF20 VHF25 VHF30 VFS08 VFS10 VFS15 VFS20 VFS25 VFS30
BASIC UDI-DI	69709838208VFPSFILMHF308U	UMDNS Code	11961
Intend Use	Vacuum Forming Pressure Sheets Film is used to be sheet for thermoforming of dental braces.		
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:

