



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	Barrier film/sleeves	Model	BF08 BF09 BF10
BASIC UDI-DI	69709838208DBFSLEEVES109V	UMDNS Code	11961
Intend Use	Barrier film/sleeves is used to protect dental equipment temporarily		
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:** 