



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	Denture Box	Model	DB01 DB02 DB03 DB03S DB04 DB04S DB05 DB06 TB06 DB07 DB08 DB09 DB10 DB10S DB11 DB12 DB13 DB17 DB18 DB19 DB20 DB21 TB01 TB02 TB03 TB03S TB04 TB04S TB05 TB06 TB07 TB08 TB09 TB10 TB11 TB12
BASIC UDI-DI	69709838201DENTURE BOX20L8	UMDNS Code	11961
Intend Use	Denture box is used to keep dentures or dental retainer retaclean cleanly		
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:**