



# 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)

<b>Product Name</b>	Dental bur holder	<b>Model</b>	BH01 BH02 BH03 BH04 BH05 BH06 BH07 BH08 BH09 BH10 BH11 BH12 BH13 BH14 BH15 BH16 BS06
<b>BASIC UDI-DI</b>	69709838201DBURHOLDER16DL	<b>UMDNS Code</b>	11961
<b>Intend Use</b>	Dental bur holder is used to hold and distribute dental bur and assist bur sterilization		
<b>Classification</b>	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

**Signature:** 

**Position held in the company:** General Manager

**Date:** 2022.7.12

**Place:** Hebei, China

**Seal/Stamp:** 

Andent Dental Co.,Ltd