



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	Endodontic Instrument	Model	ED01 ED02 ED03 ED06 ED06S ED07 ED07S ED08 ED08A ED09 ED10 ED10S ED11 ED12 ED12S ED13
BASIC UDI-DI	69709838201DENTALENDO135K	UMDNS Code	11961
Intend Use	Endodontic Instrument is used to dental root canal treatment		
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

Signature: 

Position held in the company: General Manager

Date: 2022.7.12

Place: Hebei, China

Seal/Stamp: 

Andent Dental Co.,Ltd