



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: Luxus Lebenswelt GmbH
Address: Kochstr. 1,47877,Willich, Germany.
E-mail: info.m@luxuslw.de
Tel: 0049-17 15605732
SRN: DE-AR-000005110

We, the manufacturer, herewith declare that the product(s)

Product Name	Face Shield	Model	F07、 F02、 F13
BASIC UDI-DI	69709838202FACESHIELD13PK	UMDNS Code	11961
Intend Use	Face Shield is used to protect the face during medical examinations and treatments, to block liquid splashes or splashes to prevent cross-infection.		
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:

<i>ISO 13485:2016</i>	<i>EN ISO 14971:2012</i>	<i>ISO 10993-1: 2018</i>
<i>ISO 10993-5: 2009</i>	<i>ISO 10993-10:2010</i>	<i>EN 62336-1:2015</i>
<i>EN 1041:2008</i>	<i>EN 15223-1:2016</i>	

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: 2022.7.30

Place: Hebei, China

Andent Dental Co.,Ltd

