

AUDENTAL

Audental Bio-Material Co., Ltd

2-2 88, Jingche Road, Songjiang District, 201661 Shanghai, P.R. China.

Tel: +86-21-37721922

Fax: +86-21-37721922

zhouyang@audental-asia.com

EC Declaration of Conformity

Manufacturer: **Audental Bio-Material Co., Ltd**

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European Authorized Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel: +31645171879

Product Name: Dental Alloys

Model: Audental Cobalt 、 Audental Ultra 、 Audental TC4 、 Audental Ti

UMDNS Code: 16188

Classification (MDD, Annex IX): Class IIa, Rule 8

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards, All supporting documentations are retained under the premises of the manufacturer.

Directives: Council device 93/42/EEC ON MEDICAL Directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EEC of 5 September 2007.

Standard Applied: EN ISO 22674-2022, EN ISO11135-1:2007, EN ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 14971:2019, ISO 15223:2021, EN 1041:2016

Name of Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrabe 2-90431, Nürnberg

Validity of declaration of conformity: December 31, 2028

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(EC) Certificate(s):

Expire Date of the Certificate: May 26, 2024

Start of CE Marking: Jan 21, 2020

Notified Body Confirmation Letter

Reference.: 190154175

Expire Date of the Certificate: December 31, 2028

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices. This letter confirms that the manufacturer had signed the written agreement under MDR by the date of MDD certificate expiry by March 20, 2023 for the relevant devices.

Signature: *Zhouyang Deng*

Position: General Manager

Date: 2024-09-19