

AUDENTAL

Audental Bio-Material Co., Ltd

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www.audental-asia.com

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 Zirconia Ceramics

Model Number: HT, ST, UT, ST-Plus, STML, UTML, 3d-Pro, 3d-Pro Max, 4d-Pro

UMDNS Code: 16187

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 6872-2015, EN ISO11135-1:2007, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-11:2009, EN ISO 14971:2012, ISO 15223:2016, EN 1041:2013

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

Validity of declaration of conformity: May 26, 2024

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(EC) Certificate(s):

Expire Date of the Certificate: May 26, 2024

Start of CE Marking: Jan 21, 2020

Signature:

Position: General Manager

Date: 2021-04-17