



EC Declaration of Conformity

Manufacturer: Shandong Huge Dental Material Corporation

ADD: No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong Province, 276800, P.R. China

The Authorized representative in the Europe Community who has been empowered to enter into commitments on our behalf is: Osmunda Medical Technology Service GmbH, having a principal place of business at Georg-Sigismund-von Oppen-Weg 15,14476 Potsdam, Germany.

Product Name: Zirconia Block

Product Type: High Translucency (HT), Anterior Translucency (AT), High Strength (HS), Multi-layered High Translucency (MHT)

Classification: Classified as class IIa according to Annex IX rule 8 of the Directive 93/42/EEC

Conformity Assessment Procedure: Performed according to Annex II (Excluding Section 4) of the Directive 93/42/EEC

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

General applicable directives and MEDDEVs:

- Medical devices DIRECTIVE (MDD 93/42/EEC). as amended by DIRECTIVE 2007/47/EC
- MEDDEV 2.7.1 rev.4
- MEDDEV 2.12/1 rev.8
- MEDDEV 2.12/2 rev.2

Standard Applied:

- EN 1041: 2008+A1:2013
- EN ISO 10993-1: 2009/AC: 2010
- EN ISO 10993-3: 2014
- EN ISO 10993-5: 2009
- EN ISO 10993-10: 2013
- EN ISO 10993-11: 2009
- ISO 13485: 2016/EN ISO 13485:2016
- EN ISO 14971: 2012
- EN ISO 6872: 2015
- EN ISO 7405:2018
- EN 1641: 2009
- EN ISO 15223-1:2016
- EN 62366: 2008

Notified Body: SGS Unitd Kingdom Ltd.

ADD: 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK

EC Certificate No.: CN15/10284.01

Certificate valid from: Jan. 16, 2019

Certificate valid until: Feb. 16, 2023

Place of issue Rizhao

Date of issue: Feb. 11, 2019

Name: Haoyuan Xu

Position: Management Representative

Signature: *Haoyuan Xu*

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HGD/QT-YHG-CE-18	D/1	1/1