HUGE Declaration of Conformity (DoC)

This is a declaration made in accordance with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).	
Legal Manufacturer	Name: Shandong Huge Dental Material Corporation Address: No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong Province, 276800, P.R. China SRN: CN-MF-000013266
EU Authorized Representative (AR)	Name: MedNet EC-REP GmbH Address: Borkstrasse 10, 48163 Muenster, Germany SRN: DE-AR-00000002
Product Information	Product Name: Zirconia Block Product Type: High Translucency (HT), Anterior Translucency (AT), High Strength (HS), Multi-layered High Translucency (MHT), High Translucency Plus (HT PLUS), Gradient Multilayer (GM), MaxMultilayer-4D (MM-4D)
Intended Use	The product is cast by cold isostatic pressing and pre-sintering process with ZrO_2 as the main composition, used for making the crowns, bridges (AT, GM≤3 units), inlays and veneers of the fixed partial denture.
Classification	Class IIa according to Rule 8 in the ANNEX VIII of the regulation (EU) 2017/745
Conformity Assessment Procedure	Chapters I and III of Annex IX of the regulation (EU) 2017/745
EMDN description and code	Q01010199 DENTAL RESTORATION DEVICES - OTHER
MDN code	MDN 1103 Non-active dental implants and dental materials
MDT code	MDT 2003 Devices manufactured using non-metal mineral processing MDT 2011 Devices which require packaging, including labelling
Basic UDI-DI	6909412YHG2A01XN

We herewith declare that we are exclusively responsible for the declaration of conformity that the above mentioned products meet the transposition into national law, the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable REGULATION and MEDDEV(s):

- Regulation (EU) 2017/745
- MEDDEV 2.7.1 rev.4
- MDCG 2023-3
- MEDDEV 2.12/2 rev.2

Standard Applied:

EN ISO 20417:2021	EN ISO 10993-1:2020
EN ISO 10993-3:2014	EN ISO 10993-5:2009
EN ISO 10993-10:2023	EN ISO 10993-11:2018
EN ISO 14971:2019	EN ISO 6872:2015+A1:2018
EN ISO 7405:2018	EN 1641:2009
EN ISO 15223-1:2021	EN 62366-1:2015
ISO 13485:2016/EN ISO 13485:2016	

Notified Body:	Identification No.: 1639 SGS Belgium NV Address: SGS House Noorderlaan 87 2030 Antwerp Belgium
EC Certificate (to be certified):	EC Certificate No.: CN24/00001821 Valid from March 26, 2024 until March 26, 2029

Authorized Signatory: Grace Zhang/Person Responsible for Regulatory Compliance(PRRC)

Rizhao, China/ March 26, 2024
Place and date of issue

Grace Zhang
Signature

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