HUGE DENTAL MATERIAL CO., LTD.
www.hugedental.com T / 86 633 2277268 F / 86 633 2277298
Middle Shanhai Road, Rizhao City, Shandong Province, 276800, P.R. China

Declaration of conformity

Manufacturer: HUGE DENTAL MATERIAL CO., LTD.

Add.: Middle Shanhai Road, 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: PMMA BLOCK

Product Type: Monolayer, Multilayer

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 15223-1:2016
- 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 10477: 2004
- EN ISO 7491: 2000
- EN ISO 7405:2018
- EN 1641: 2009
- EN 62366:2008

Notified Body: SGS Unitd Kingdom Ltd.

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

EC Certificate: CN15/10284.02

Certificate valid from: Feb. 09, 2018

Certificate valid until: Feb. 09, 2023

Place: Rizhao

Date of Issue: Jan. 21, 2019

Name: Grace Zhang

Position: Management representative

Signature: Grace Zhang