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EC Declaration of Conformity

Manufacturer: Huliang(Shanghai)Bio-tech Co., Ltd

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European Authorized Representative:

Share Info Consultant Service LLC Repräsentanzbüro

Heerdter Lohweg 83,40549 Dusseldorf,Germany.

Tel: +49 1767 0057022

Product Name: PMMA Block

Model Number: Monolayer, Multilayer

UMDNS Code: 11282

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 DIRECTIV 2007/47/EEC of 5 September 2007.

Standard Applied: EN ISO 6872-2015, EN ISO11135-1:2007, EN ISO 10993-1:2018, EN ISO10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 14971:2012, ISO15223:2016,EN 1041:2013

Name of Notified Body: SGS House Noorderlaan 87 2030 Antwerp Belgium

Validity of declaration of conformity: December 31, 2028

(EC) Certificate(s):

Expire Date of the Certificate: December 31, 2028

Start of CE Marking: Jan 13, 2021



Signature:

Position: CEO

Date: 2024-05-23