Keystone Industries
Declaration of Conformity Certificate
Class IIa Medical Devices

Company: Keystone Industries

Address: 52 West King Street

Myerstown, PA 17067, USA

Declare under sole responsibility that our products(s): KeyPrint 3-D Resin Material

Product Brand Name(s): KeySplint Soft Tinted Item #4200005 (0.5 Kg), 4220005(1Kg), 4220105(1Kg), 4220115 (1 Kg); and 4250205 (5Kg)

Product Classification: Class IIa, Rule 5, invasive in oral cavity, (not surgically), long term use

Notified Body: SGS Belgium NV NB#:1639
Noorderlaan 87, BE-2030 Antwerpen, Belgium

meet (where applicable) the requirements of:

ISO 13485:2016 (certificate #US04/62506)
Council Directive 93/42/EEC as amended by Directive 2007/47/EC (Annex I & II) of the MDD (EC Certificate #US19/819943613)

As well as current versions of the following (where applicable)

EN ISO 14971 (Risk Mgmt)
EN ISO 10993 (Biological Evaluation)
MEDDEV 2.7.1 (Clinical Guidance)
EN ISO 15223-1 (Symbols to be used with Medical Devices)

We hereby appoint: **Keystone Europe LLC**
Batavenweg 7
5349BC Oss Netherlands

to act as our European Authorized Representative as stipulated in Article 14.2 of the Medical Device Directive 2007/47/EC.

Signed: Gloria Zuclich

Printed Name: Gloria Zuclich

Title: Director of Regulatory Affairs

Date of Validity: May 4, 2020 (Correction on 7/8/2021)*/(amended 09/09/2021)**

*Correction to add item 4220105 and 4220115 which were inadvertently missing.
**Change Approval SGS # WWMC210290_LPMD107