

# 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; KeySplint Hard Material

Product Brand Name(s): KeySplint Hard, Item #4220004 (1 Kg) & 4200004 (0.5 Kg)

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: *Diamond Bynum*

Printed Name: Diamond Bynum

Title: Regulatory Affairs Associate

Date of Validity: November 16, 2020