Keystone Industries
Declaration of Conformity Certificate
Class I Medical Devices

Manufacturer: Keystone Industries

Place of Issue: 52 West King Street

Myerstown, PA 17067, USA

SRN: To be determined

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

Product Brand Name(s) and item Number(s):KeyGuide Surgical Guide, item # 4200001 (0.5 KG) and item # 4220001 (1 KG)

Product Risk Classification and Rule according to Annex VIII: Class I, Rule 5 Invasive in a body orifice (not surgically), transient use within the oral cavity, not intended for connection to an active device

Basic UDI-DI: ++H6683DGUIDE0018H

covered by this declaration, is/are in conformity with and/or meets the requirements of:

ISO 13485:2016 (certificate #US04/62506)
European Medical Device Regulation 2017/745
ISO 14971 (Risk Mgmt)
MEDDEV 2.7.1 (Clinical Guidance)

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

to act as our European Authorized Representative as stipulated in Article 11 of the Medical Device Regulation.

Authorized to sign on behalf of Keystone Industries:

Signed: Gloria Zuclich

Printed Name: Gloria Zuclich

Title: Director of Regulatory Affairs

Date of Validity/Issue: 13 October 2021