Declaration of Conformity

for Custom Tray Resin

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Custom Tray Resin
Legal Manufacturer: (Name on Label)	Formlabs Ohio Inc. 27800 Lemoyne Rd Suite J Millbury, OH 43447 USA
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Formlabs Surgical Guide Resin is a light-curable polymer-based material designed for 3D printing biocompatible, dental impression trays.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorized Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Signed, 1 July 2020

Sam Murray
Director, Regulatory Affairs and Quality Assurance

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010/(R)2014	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
ISO 7405:2009/(R)2015	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
FLCTBL01	Custom Tray Resin	16730

Version History

Version	Complied By	Date	Description
00	S. Murray	1 July 2020	First issue