Declaration of Conformity

for Custom Tray Resin

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices as amended by Regulation (EU) 2020/561

The undersigned declares that the products described in this document meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This EU Declaration is issued under the sole authority of the manufacturer.

General Product Name:	Custom Tray Resin
Manufacturer: (Name on Label)	Formlabs Ohio Inc. 27800 Lemoyne Rd Millbury, OH 43447 USA
Manufacturer's SRN:	US-MF-000002761
Basic UDI-DI:	08600020993FLCTBLRC
Variants:	None
Intended Purpose:	Custom Tray Resin is intended for 3D printing dental appliances such as dental impression trays
MDR Classification:	Class I by Annex VIII, Rule 5, 1st Paragraph, 2nd Indent
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Following Article 52(7), the EU declaration of conformity is issued after drawing up the technical documentation set out in Annexes II and III

Name: Sam Murray **Position:** Senior Director, Regulatory Affairs and Quality Assurance

Signed: **Date:** 26/05/2021

This Declaration of Conformity is issued in Millbury, OH 43447 USA on behalf of Formlabs Ohio Inc.

Appendix I – Applicable Common Specifications

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

Common Specification	Description
N/A	Not Applicable

Appendix II – Applicable Consensus Standards

This present declaration is also in conformity with the following Consensus Standards:

Standard	Description
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15233-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 13485:2016/AC:2018	Medical devices — Quality management systems — Requirements for regulatory purposes

Appendix III – Product Listing/Schedule

Part/Catalog Number	Description/Name	EMDN Code
FLCTBL01	Custom Tray Resin	Q010699

Version History

Version	Complied By	Date	Description
00	S. Murray	26 May 2021	First issue