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
Legal 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 Use:	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 for Class I
EU Authorized 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: Nathan Alt
Title: Director, Regulatory Affairs and Quality Assurance
Signature:

Date: 20 May 2024

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EU Declaration of Conformity

QD-0064 Version: 01
Date: 20 May 2024

Appendix I – Applicable Standards

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

Standard/Document Name	Description
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
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
ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 15233-1:2016	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

Appendix III – Product Listing/Schedule

Part/Catalogue Number	Description/Name	EMDN Code	GTIN
FLCTBL01	Custom Tray Resin	Q010699	00860002099323
	Custom Tray Resin - Cartridge V2	Q010699	00850061175069

Version History

Version	Complied By	Date	Description
00	S. Murray	See Propel	First issue
01	P. Johnson	See Propel	Updated for MDR, added Cartridge V2 and corresponding GTIN