

Declaration of Conformity for Premium Teeth 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, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Premium Teeth Resin
Manufacturer: (Name on Label)	Formlabs Ohio Inc. 27800 Lemoyne Rd Millbury, OH 43447 USA
Manufacturer's SRN:	US-MF-000002761
Basic UDI-DI:	0850061175FLPTUH
Variants:	HT A2, HT A3, HT B1, HT BL
Intended Purpose:	Premium Teeth Resin is intended to print 3D printed dental appliances, such as denture teeth for complete and partial removable dentures, try-in dentures, and provisional restorations such as temporary crowns and bridges, full-arch implant-supported restorations, inlays, onlays and veneers, to replace or restore missing tooth structures or missing teeth.
MDR Classification:	Class IIa by Annex VIII, Rule 5, 1 st Paragraph, 3 rd Indent
Notified Body:	Intertek Medical Notified Body AB, NB 2862 Box 1103, SE-164 22 Kista Sweden
EC Certificate:	28620124904-01
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Following Article 52(6), conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation as specified in Section 4 of Annex IX.

Name: Nathan Alt

Title: Director, Regulatory Affairs and Quality Assurance

Signature:



Date: 1/16/2026

Who is the natural and legal person with responsibility for the design, manufacture, packaging, and labeling 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.

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+A11:2021	Medical devices — Application of risk management to medical devices
ISO 10993-1:2025	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical products Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2023	Biological evaluation of medical products Part 10: Tests for Sensitization
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2021	Biological evaluation of medical products Part 23: Tests for irritation
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 15223-1:2021 +A1:2025	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 13485:2016+A11:2021	Medical devices — Quality management systems —Requirements for regulatory purposes
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

Product Code	Description/Name	EMDN Code	GTIN
FLPTA201	Premium Teeth Resin HT A2	Q010699	00860002099378
	Premium Teeth Resin HT A2 - Cartridge V2	Q010699	00850061175014
FLPTA301	Premium Teeth Resin HT A3	Q010699	00198168761953
	Premium Teeth Resin HT A3 - Cartridge V2	Q010699	00850061175038
FLPTB101	Premium Teeth Resin HT B1	Q010699	00860002099385
	Premium Teeth Resin HT B1 - Cartridge V2	Q010699	00850061175021
FLPTBL01	Premium Teeth Resin HT BL	Q010699	00860002099392
	Premium Teeth Resin HT BL - Cartridge V2	Q010699	00850061175007

Version History

Version	Author	Approval Date	Description
00	P. Johnson	10 May 2024	First issue
01	P. Johnson	23 July 2024	Updated variant section to include Premium Teeth shade variants
02	P. Johnson	25 Feb 2025	Updated variant section to include Premium Teeth shade variants. Updated the language under “Assessment Route” and the sole responsibility statement per Advena feedback. Appendix II was updated to reflect the current revisions of EN ISO 14971, ISO 10993-10, and EN ISO 13485.
03	P. Johnson	04 Nov 2025	Add statement below the signature section
04	P. Johnson	See Propel	Updated Appendix II to reflect the current revisions of EN ISO 15233-1 and ISO 10993-1