

## Declaration of Conformity for Surgical Guide 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.

|                                                    |                                                                                                                                 |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| <b>General Product Name:</b>                       | Surgical Guide Resin                                                                                                            |
| <b>Legal Manufacturer: (Name on Label)</b>         | Formlabs Ohio Inc.<br>27800 Lemoyne Rd<br>Millbury, OH 43447 USA                                                                |
| <b>Manufacturer's SRN</b>                          | US-MF-000002761                                                                                                                 |
| <b>Basic UDI-DI</b>                                | 08600020993FLSGAMSS                                                                                                             |
| <b>Variants:</b>                                   | None                                                                                                                            |
| <b>Intended Use:</b>                               | Formlabs Surgical Guide Resin is intended for 3D printing endosseous dental implant accessories such as dental surgical guides. |
| <b>MDR Classification:</b>                         | Class I by Annex VIII, Rule 5, 1st Paragraph, 2nd Indent                                                                        |
| <b>Notified Body:</b>                              | Not Applicable for Class I                                                                                                      |
| <b>EU Authorized Representative:</b>               | Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.                              |
| <b>EU Authorised Representative SRN:</b>           | MT-AR-000000234                                                                                                                 |
| <b>Medical Device Regulation Assessment Route:</b> | Article 19 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:** 12 September 2024

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                                                                      |
| 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 15233-1:2021        | 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

| Part/Catalogue Number | Description/Name                            | EMDN Code | GTIN           |
|-----------------------|---------------------------------------------|-----------|----------------|
| FLSGAM01              | Surgical Guide Resin                        | Q010699   | 00860002099309 |
|                       | Surgical Guide Resin - Cartridge V2         | Q010699   | 00850061175090 |
|                       | Surgical Guide Resin - Resin Pumping System | Q010699   | 00850061175144 |

## Version History

| Version | Complied By | Date         | Description                                                                                                                                                                                                                                                                                                                                      |
|---------|-------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 00      | S. Murray   | 22 June 2022 | First issue                                                                                                                                                                                                                                                                                                                                      |
| 01      | P. Johnson  | 05 June 2024 | Updated document for MDR, Added standard to Appendix II, Added Cartridge V2 and GTIN                                                                                                                                                                                                                                                             |
| 02      | P. Johnson  | see propel   | <p>Updated the language under “Assessment Route” and the sole responsibility statement per Advena feedback.</p> <p>Updated Appendix II to reflect the current revisions of EN ISO 14971, EN ISO 15233-1, and EN ISO 13485. Replace EN 1041 with ISO 20417:2021</p> <p>Added GTIN for Custom Tray Resin Pumping System under Product Listing.</p> |