

## DENTAL RESIN

# Permanent Crown

### Photopolymer Resin for Form 3B

Permanent Crown Resin is a tooth-colored, ceramic-filled resin for 3D printing of permanent single crowns, inlays, onlays, and veneers. Permanent Crown Resin produces high strength, long term restorations with accurate and precise fitment. Low water absorption and a smooth finish ensure restorations have a low tendency to age, discolor, or accumulate plaque.

Permanent Crown Resin is only validated for use with the Stainless Steel Build Platform.

Permanent Restorations

Onlays

Crowns

Veneers

Inlays



FLPCA201, FLPCA301, FLPCB101, FLPC201

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To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

## PERMANENT CROWN MATERIALS PROPERTIES DATA

VITA<sup>1</sup> CLASSICAL SHADES: A2, A3, B1, C2

| Mechanical Properties                           | Measured Value              | Method                    |
|---|-----------------------------|---------------------------|
| Density   | 1.4 - 1.5 g/cm <sup>3</sup> | BEGO Standard             |
| Viscosity                                       | 2500 - 6000 MPa*s           | BEGO Standard             |
| Flexural Strength (Post cured) <sup>2,3,4</sup> | 116 MPa                     | EN ISO 10477, EN ISO 4049 |
| Flexural Modulus (Post Cured)                   | 4090 MPa                    | EN ISO 10477, EN ISO 4049 |
| Water Solubility                                | 0.23 µg/mm <sup>3</sup>     | EN ISO 4049               |
| Water Sorption                                  | 3.6 µg/mm <sup>3</sup>      | EN ISO 10477              |

Permanent Crown Resin is a Medical Device as defined in the Medical Device Directive (93/42/EEC) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

Restorations printed with Permanent Crown Resin have been evaluated in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, and ISO 7405:2009/(R)2015, *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*, and passed the requirements for the following biocompatibility risks:

| ISO Standard              | Description <sup>5</sup> |
|---------------------------|--------------------------|
| EN ISO 10993-5:2009       | Not cytotoxic            |
| ISO 10993-10:2010/(R)2014 | Not an irritant          |
| ISO 10993-10:2010/(R)2014 | Not a sensitizer         |
| ISO 10993-3:2014          | Not genotoxic            |
| ISO 10993-1:2009          | Not toxic                |

The product was developed and is in compliance with the following ISO Standards:

| ISO Standard      | Description   |
|-------------------|---|
| EN ISO 13485:2016 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2019 | Medical Devices – Application of Risk Management to Medical Devices                 |

<sup>1</sup> VITA is a registered trademark of a company which is not affiliated with Formlabs Inc.

<sup>2</sup> Material properties may vary based on part geometry, print orientation, print settings, and environmental conditions.

<sup>3</sup> Test samples were printed with a Stainless Steel Build Platform on a Form 3B printer with 50 µm Permanent Crown Resin settings. The printed samples were post-processed as recommended in the Instructions for Use.

<sup>4</sup> Data for post-cured samples were measured on 3 point bending test specimens according to EN ISO 10477 and EN ISO 4049 standards.

<sup>5</sup> Permanent Crown Resin was tested at Eurofins BioPharma Product Testing, Munich GmbH.