## 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.

Crowns Veneers	Permanent Restorations	Onlays	
Inlays	Crowns	Veneers	
Finilabs Form 3B	Inlays		
(v1) FLPCA201, FLPCA301, FLPCB101, FLPCC201	V1) FLPCA201. FLPC	CA301. FLPCB101. FLPCC201	formlabs %

 Prepared
 10.21.2020

 Rev
 01
 10.21.2020

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	

1	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.