## **Custom Tray**

## A production-ready material that enables highly accurate definitive impressions

Use Custom Tray Resin to directly print impression trays for implants, dentures, crowns and bridges, and other comprehensive cases. Digitally manufactured impression trays provide consistent, accurate impressions for high-quality dentistry. Custom Tray Resin prints full impression trays quickly using 200 micron layer heights, reducing labor time and enabling higher throughput.

**Impression Trays** 



FLCTBL01

<sup>®</sup> Regional availability may vary.

 Prepared
 10.07.2020

 Rev.
 02
 21.07.2020

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.

## MATERIAL PROPERTIES DATA

## **Custom Tray Resin**

	Post-Cured <sup>1, 2</sup>	Method
Ultimate Tensile Strength	> 70 MPa	ASTM D638
Young's Modulus	> 2500 MPa	ASTM D638
Elongation	> 3%	ASTM D638
Flexural Strength	≥ 100 MPa	ASTM D790
Flexural Modulus	≥ 2600 MPa	ASTM D790
Hardness Shore A	> 80 D	ASTM D2240

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Custom Tray Resin is a Class I Medical Device as defined in Article 2 of the Medical Device Regulation 2017/74 (MDR) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

Custom Tray Resin has been evaluated in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description <sup>3</sup>
EN ISO 10993-5	Not cytotoxic
EN ISO 10993-10	Not an irritant
EN ISO 10993-10	Not a sensitizer

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

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

<sup>1</sup> Material properties may vary based on part geometry, print orientation, print settings, temperature, and disinfection or sterilization methods used.

- <sup>2</sup> Data for post-cured samples were measured on Type IV tensile bars printed on a Form 2 printer with 200 µm Custom Tray Resin settings, washed in a Form Wash for 10 minutes in ≥99% Isopropyl Alcohol, and post-cured at 60°C for 30 minutes in a Form Cure.
- <sup>3</sup> Custom Tray Resin was tested at NAMSA World Headquarters, OH, USA.