MEDICAL RESIN

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BioMed Clear

Biocompatible Photopolymer Resin for Formlabs SLA Printers

BioMed Clear Resin is a rigid material for biocompatible applications requiring longterm skin or mucosal membrane contact. This USP Class VI certified material is suitable for applications that require wear resistance and low water absorption over time.

Parts printed with BioMed Clear Resin are compatible with common sterilization methods. BioMed Clear Resin is manufactured in our ISO 13485 facility and is supported with an FDA Device Master File.

Medical devices and device components Ventilator and PPE components Drug delivery devices **Bioprocessing equipment Research and Development** FLBMCL01 * Regional availability may vary.

 Prepared
 06.12.2020

 Rev.
 04
 24.04.2023

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

BioMed Clear Resin

	METRIC ¹	IMPERIAL ¹	METHOD
	Post-Cured ²	Post-Cured ²	
Tensile Properties			
Ultimate Tensile Strength	52 MPa	7.5 ksi	ASTM D638-10 (Type IV)
Young's Modulus	2080 MPa	302 ksi	ASTM D638-10 (Type IV)
Elongation	12%	12%	ASTM D638-10 (Type IV)
Flexural Properties			
Flexural Strength	84 MPa	12.2 ksi	ASTM D790-15 (Method B)
Flexural Modulus	2300 MPa	332 ksi	ASTM D790-15 (Method B)
Hardness Properties			
Hardness Shore D	78D	78D	ASTM D2240-15 (Type D)
Impact Properties			
Notched Izod	35 J/m	0.658 ft-lbf/in	ASTM D256-10 (Method A)
Unnotched Izod	449 J/m	8.41 ft-lbf/in	ASTM D4812-11
Thermal Properties			
Heat Deflection Temp. @ 1.8 MPa	54 °C	129 °F	ASTM D648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	67 °C	152 °F	ASTM D648-18 (Method B)
Coefficient of Thermal Expansion	82 μm/m/°C	45 μin/in/°F	ASTM E831-14
Other Properties			
Water Absorption	0.54%	0.54%	ASTM D570-98 (2018)

Sterilization Compatibility		Disinfection Compatibility	
E-beam	35 kGy E-beam radiation	Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes
Ethylene Oxide	100% Ethylene oxide at 55 °C for 180 minutes		lor 5 minutes
Gamma	29.4 - 31.2 kGy gamma radiation		
Steam Sterilization	Autoclave at 134°C for 20 minutes Autoclave at 121°C for 30 minutes		

For more details on sterilization compatibilities, visit formlabs.com/medical

Samples printed with BioMed Clear Resin have been evaluated in accordance with ISO 10993-1:2018, ISO 7405:2018, ISO 18562-1:2017 and have passed the requirements associated with the following biocompatibility endpoints:

ISO Standard	Description ³	ISO Standard	Description ³
ISO 10993-5:2009	Not cytotoxic	ISO 10993-3:2014	Not mutagenic
ISO 10993-10:2010/(R)2014	Not an irritant	ISO 18562-2:2017	Does not emit particulates
ISO 10993-10:2010/(R)2014	Not a sensitizer	ISO 18562-3:2017	Does not emit VOCs
ISO 10993-17:2002, ISO 10993-18:2005	Not toxic (subacute / subchronic)	ISO 18562-4:2017	Does not emit hazardous water-soluble substances
ISO 10993-11: 2017	No evidence of acute systemic toxicity	ISO 10993-11: 2017/USP, General Chapter <151>, Pyrogen Test	Non-pyrogenic

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 14971:2012 Medical Devices – Application of Risk Management to Medical Devices		

¹ Material properties may vary based on part geometry, print orientation, print settings, temperature, and disinfection or sterilization methods used. 2 Data were measured on post-cured samples printed on a Form 3B printer with 100 μm BioMed Clear Resin settings, washed in a Form Wash for 20 minutes in 99% isopropyl alcohol, and post-cured at 60 $^\circ$ C for 60 minutes in a Form Cure.

³ BioMed Clear Resin was tested at NAMSA World Headquarters, OH, USA.