

MEDICAL RESIN

BioMed Clear

Biocompatible Photopolymer Resin for Formlabs SLA Printers

BioMed Clear Resin is a rigid material for biocompatible applications requiring long-term 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.

Consider BioMed Clear Resin for:

Medical devices and device components

Parts containing breathing gas pathways

Respirator and ventilator components

Drug delivery devices

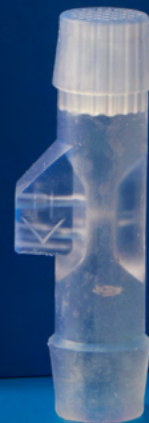
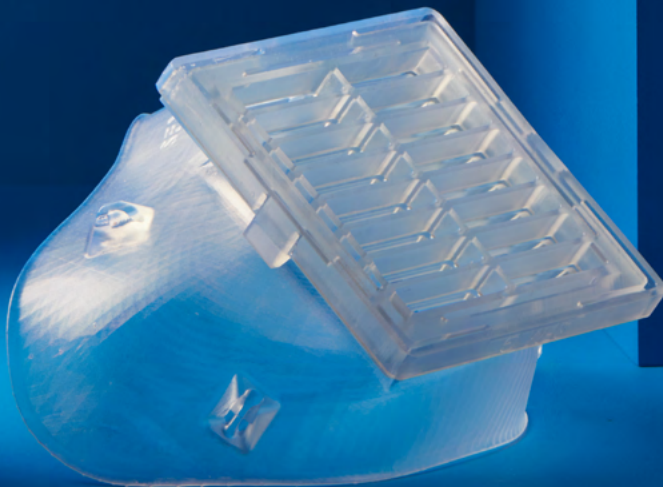
Surgical planning and implant sizing tools

Bioprocessing equipment

Research and development

Jigs and fixtures

Masks



FLBMCL01



BIOMED CLEAR MATERIAL PROPERTIES DATA

	METRIC	IMPERIAL	METHOD
	Post-Cured ^{1,2}	Post-Cured ^{1,2}	
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	78 D	78 D	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

E-beam	35 kGy E-beam radiation
Ethylene Oxide	100% Ethylene oxide at 55°C for 180 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

Disinfection Compatibility

Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes
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For more details on sterilization compatibilities, visit formlabs.com.

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

ISO Standard	Test Description ³
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 mutagenic

ISO Standard	Test Description ³
ISO 10993-17:2002 ISO 10993-18:2005	Not toxic (subacute/subchronic)
ISO 18562-2:2017	Does not emit particulates
ISO 18562-3:2017	Does not emit VOCs
ISO 18562-4:2017	Does not emit hazardous water-soluble substances

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°C for 60 minutes in a Form Cure.

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