

MEDICAL RESIN

# BioMed Clear

## Biocompatible Photopolymer Resin for Form 2 and Form 3B

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

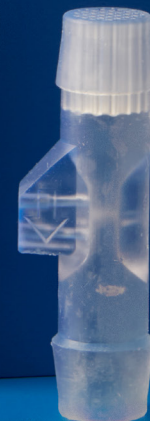
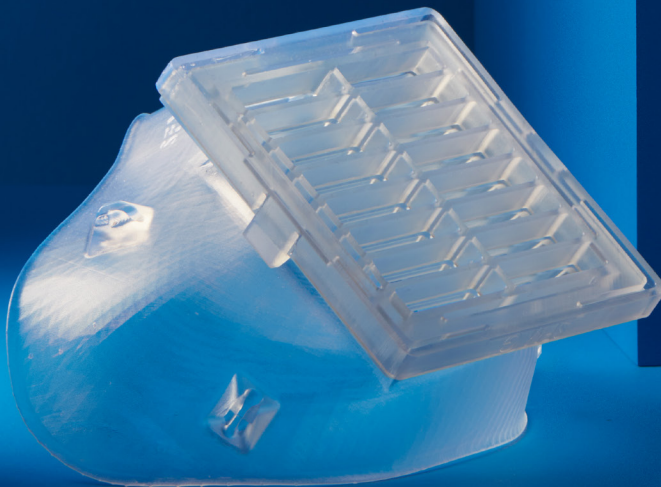
Drug delivery devices

Surgical planning and implant sizing tools

Bioprocessing equipment

Research and development

Jigs and fixtures



FLBMCL01



## BIOMED CLEAR MATERIAL PROPERTIES DATA

	METRIC	IMPERIAL	
Mechanical Properties	Post-Cured <sup>1,2</sup>	Post-Cured <sup>1,2</sup>	Method
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 Strength at 5% Strain	84 MPa	12.2 ksi	ASTM D790-15 (Method B)
Flexural Modulus	2300 MPa	332 ksi	ASTM D790-15 (Method B)
Hardness Shore D	78 D	78 D	ASTM D2240-15 (Type D)
IZOD Unnotched Impact Strength	449 J/m	8.41 ft-lbf/in	ASTM D4812-11 (Unnotched)
Water Absorption	0.54%	0.54%	ASTM D570-98 (2018)

### Sterilization Recommendations

- Pre-vacuum Steam Autoclave
- Ethylene Oxide
- E-Beam
- Gamma

For more details on sterilization compatibilities, visit [formlabs.com](http://formlabs.com).

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

ISO Standard	Test Description <sup>3</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 10993-11:2017	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 14971:2012	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 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.

<sup>3</sup> BioMed Clear Resin was tested at NAMS World Headquarters, OH, USA.