

# BioMed Black Resin

Medical-grade matte black material for 3D printing rigid, biocompatible parts

BioMed Black Resin is a matte, opaque material for biocompatible applications requiring long-term skin contact or short-term mucosal membrane contact. This medical-grade material is suitable for applications that require high contrast for visualization, excellent definition and smooth surface quality.

Parts printed with BioMed Black Resin are compatible with common solvent disinfection and sterilization methods. BioMed Black Resin is manufactured in our ISO 13485 facility and is also USP Class VI certified which makes it suitable for pharmaceutical and drug delivery applications.

**Medical devices and device components**

**Biocompatible molds, jigs, and fixtures**

**End-use parts requiring patient contact**

**Consumer goods**



**FLBMBL01**

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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	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
	Post-Cured <sup>2</sup>	Post-Cured <sup>2</sup>	
<b>Tensile Properties</b>	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
Ultimate Tensile Strength	36 MPa	5180 psi	ASTM D638-14 (Type IV)
Young's Modulus	1500 MPa	221 ksi	ASTM D638-14 (Type IV)
Elongation at Break	14%		ASTM D638-14 (Type IV)
<b>Flexural Properties</b>	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
Flexural Stress at 5% Strain	57 MPa	8290 psi	ASTM D790-15 (Procedure B)
Flexural Modulus	1600 MPa	242 ksi	ASTM D790-15 (Procedure B)
<b>Hardness Properties</b>	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
Hardness Shore D	77 D	-	ASTM D2240-15 (Type D)
<b>Impact Properties</b>	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
Notched Izod	25 J/m	0.464 ft-lb/in	ASTM D256-10 (Method A)
Unnotched Izod	348 J/m	6.52 ft-lb/in	ASTM D4812-11
<b>Thermal Properties</b>	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
Heat Deflection Temp. @ 1.8 MPa	49.4 °C	-	ASTM D648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	67.9 °C	-	ASTM D648-18 (Method B)
Coefficient of Thermal Expansion	106.9 µm/m/°C	-	ASTM E831-13
<b>Other Properties</b>	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
Water Absorption	0.44 wt%	-	ASTM D570-98

#### Sterilization Compatibility

E-beam	35 kGy E-beam radiation
Ethylene Oxide	100% Ethylene oxide at 55 °C for 60 min
Gamma	29.0 -31.1 kGy gamma radiation
Steam Sterilization	Autoclave at 132 °C for 4 minutes, 5 cycles (US) Autoclave at 134 °C for 4 minutes, 5 cycles (EU)

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

#### Disinfection Compatibility

Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes
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Samples printed with BioMed Black Resin have been evaluated in accordance with the following biocompatibility endpoints:

ISO Standard	Description <sup>3</sup>
ISO 10993-5:2009	Not cytotoxic
ISO 10993-10:2010/(R)2014	Not an irritant
ISO 10993-10:2010/(R)2014	Not a sensitizer

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 Form3B with 100µm BioMed Black Resin settings, washed in a Form Wash for 5 minutes in 99% Isopropyl Alcohol, and post-cured at 70°C, 60 minutes in a Form Cure.

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