MEDICAL RESIN

formlabs | medical

BioMed Black

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.

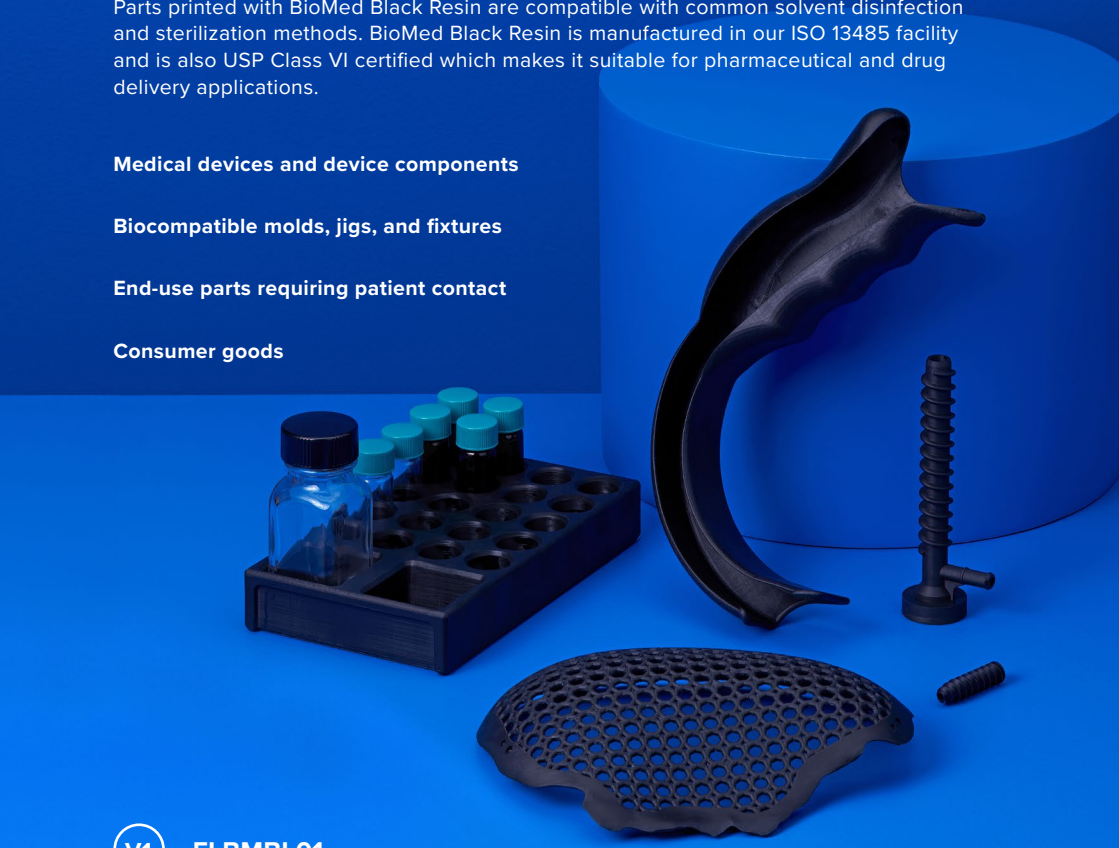
Parts printed with BioMed Black Resin are compatible with common solvent disinfection and sterilization methods. BioMed Black Resin is manufactured in our ISO 13485 facility and is also USP Class VI certified which makes it suitable for pharmaceutical and drug delivery applications.

Medical devices and device components

Biocompatible molds, jigs, and fixtures

End-use parts requiring patient contact

Consumer goods



V1 **FLBMBL01** *** May not be available in all regions**

Prepared 03 . 30 . 2022

Rev. 01 03 . 30 . 2022

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 Black Resin

	METRIC [1]	IMPERIAL [1]	METHOD
	Post-Cured [2]	Post-Cured [2]	
Tensile Properties			
Ultimate Tensile Strength	35.71 MPa	5180 psi	ASTM D 638-14 (Type IV)
Young's Modulus	1523.74 MPa	221 ksi	ASTM D 638-14 (Type IV)
Elongation	14%	14%	ASTM D 638-14 (Type IV)
Flexural Properties			
Flexural Stress at 5% Strain	57.16 MPa	8290 psi	ASTM D 790-15 (Procedure B)
Flexural Modulus	1668.53 MPa	242 ksi	ASTM D 790-15 (Procedure B)
Hardness Properties			
Hardness Shore D	77 D	-	ASTM D2240-15 (Type D)
Impact Properties			
Notched IZOD	24.77 J/m	0.464 ft-lbf/in	ASTM D 256-10 (Method A)
Unnotched IZOD	348.03 J/m	6.52 ft-lbf/in	ASTM D 4812-11
Thermal Properties			
Heat Deflection Temp. @ 1.8 MPa	49.4 °C	-	ASTM D 648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	67.9 °C	-	ASTM D 648-18 (Method B)
Coefficient of Thermal Expansion	106.9 µm/m/°C	-	ASTM E 831-13
Other Properties			
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 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

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

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Samples printed with BioMed Black Resin have been evaluated in accordance with the following biocompatibility endpoints:

ISO Standard	Description [3]
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

[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 Form3B with 100um 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.

[3] BioMed Black Resin was tested at NAMSA World Headquarters, OH, USA.

SOLVENT COMPATIBILITY

BioMed Black Resin

Percent weight gain over 24 hours for a printed and post-cured 1 x 1 x 1 cm cube immersed in respective solvent:

Solvent	24 hr weight gain, %	Solvent	24 hr weight gain, %
Acetic Acid 5%	0.3	Mineral oil, heavy	0.2
Acetone	3.1	Mineral oil, light	0.2
Bleach ~5% NaOCl	0.2	Salt Water (3.5% NaCl)	0.3
Butyl Acetate	0.4	Skydrol 5	0.6
Diesel Fuel	0.1	Sodium hydroxide solution (0.025% pH = 10)	0.3
Diethyl glycol monomethyl ether	1.0	Strong Acid (HCl Conc)	0.2
Hydraulic Oil	0.2	TPM	0.6
Hydrogen peroxide (3%)	0.3	Water	0.3
Isooctane	< 0.1	Xylene	0.3
Isopropyl Alcohol	0.2		