

# Medical

## High-Performance Materials for Biocompatible Applications

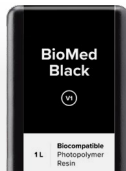
Our library of biocompatible, sterilizable, BioMed Resins are manufactured in an ISO 13485 certified facility to help medical device and point-of-care manufacturers reduce costs, iterate quickly, and print a wide range of end-use tools, instruments, and devices that support the practice of medicine.

\* Please note that resins may not be available in all regions.



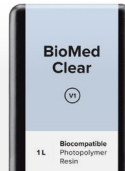
### BioMed White

For white, rigid, biocompatible parts



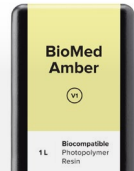
### BioMed Black

For matte black, rigid, biocompatible parts



### BioMed Clear

For long-term bodily contact



### BioMed Amber

For short-term bodily contact

# BioMed White

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

BioMed White Resin is an opaque white material for biocompatible applications requiring long-term skin contact or short-term mucosal contact. Unique in our portfolio, this medical-grade material is also USP <151> Pyrogen and Acute Systemic Toxicity tested and can be used in applications with short-term tissue, bone, dentin contact.

Parts printed with BioMed White Resin are compatible with common solvent disinfection and sterilization methods. BioMed White 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.

**End-use medical devices and device components**

**Patient-specific implant sizing models and molds**

**Cutting and drilling guides**

**Biocompatible molds, jigs, and fixtures**

**Surgical guides and templates**

**Anatomical models that can be used in the OR**



**FLBMWH01**

\* May not be available in all regions

Prepared 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.

Rev. 01 03 . 30 . 2022

# MATERIAL PROPERTIES DATA

# BioMed White Resin

	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
	Post-Cured <sup>2</sup>	Post-Cured <sup>2</sup>	
<b>Tensile Properties</b>			
Ultimate Tensile Strength	45.78 MPa	6640 psi	ASTM D 638-14 (Type IV)
Young's Modulus	2020.16 MPa	293 ksi	ASTM D 638-14 (Type IV)
Elongation	10%	10%	ASTM D 638-14 (Type IV)
<b>Flexural Properties</b>			
Flexural Stress at 5% Strain	74.46 MPa	10800 psi	ASTM D 790-15 (Procedure B)
Flexural Modulus	2020.16 MPa	293 ksi	ASTM D 790-15 (Procedure B)
<b>Hardness Properties</b>			
Hardness Shore D	80 D	-	ASTM D2240-15 (Type D)
<b>Impact Properties</b>			
Notched Izod	15.11 J/m	0.283 ft-lbf/in	ASTM D 256-10 (Method A)
Unnotched Izod	269.03 J/m	5.04 ft-lbf/in	ASTM D 4812-11
<b>Thermal Properties</b>			
Heat Deflection Temp. @ 1.8 MPa	52.4 °C	-	ASTM D 648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	67.0 °C	-	ASTM D 648-18 (Method B)
Coefficient of Thermal Expansion	90.1 µm/m/°C	-	ASTM E 831-13
<b>Other Properties</b>			
Water Absorption	0.40 wt%	-	ASTM D570-98

<b>Sterilization Compatibility</b>	
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

<b>Disinfection Compatibility</b>	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

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

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

<b>ISO Standard</b>	<b>Description <sup>3</sup></b>
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 10993-11: 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:

<b>ISO Standard</b>	<b>Description</b>
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 White Resin settings, washed in a Form Wash for 5 minutes in 99% Isopropyl Alcohol, and post-cured at 60°C, 60 minutes in a Form Cure.

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

## SOLVENT COMPATIBILITY

## BioMed White Resin

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

<b>Solvent</b>	<b>24 hr weight gain, %</b>	<b>Solvent</b>	<b>24 hr weight gain, %</b>
Acetic Acid 5%	0.4	Mineral oil, heavy	< 0.1
Acetone	2.9	Mineral oil, light	< 0.1
Bleach ~5% NaOCl	0.3	Salt Water (3.5% NaCl)	0.4
Butyl Acetate	0.4	Skydrol 5	0.5
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	< 0.1	TPM	0.6
Hydrogen peroxide (3%)	0.3	Water	0.3
Isooctane	< 0.1	Xylene	0.3
Isopropyl Alcohol	0.2		

# 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.

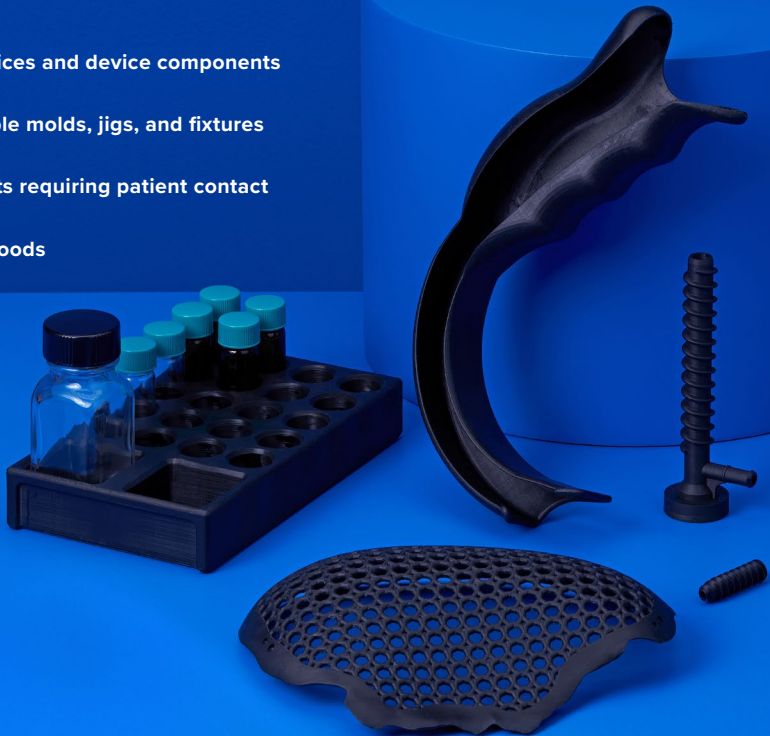
Parts printed with BioMed Black Resin are compatible with common solvent disinfection and sterilization methods. BioMed Black Resin is manufactured in our ISO 13485 facility and is also USP Class VI certified which makes it suitable for pharmaceutical and drug delivery applications.

**Medical devices and device components**

**Biocompatible molds, jigs, and fixtures**

**End-use parts requiring patient contact**

**Consumer goods**



**FLBMBL01**

\* May not be available in all regions

Prepared 03 . 30 . 2022

Rev. 01 03 . 30 . 2022

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# MATERIAL PROPERTIES DATA

# BioMed Black Resin

	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
	Post-Cured <sup>2</sup>	Post-Cured <sup>2</sup>	
<b>Tensile Properties</b>			
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)
<b>Flexural Properties</b>			
Flexural Stress at 5% Strain	5716 MPa	8290 psi	ASTM D 790-15 (Procedure B)
Flexural Modulus	1668.53 MPa	242 ksi	ASTM D 790-15 (Procedure B)
<b>Hardness Properties</b>			
Hardness Shore D	77 D	-	ASTM D2240-15 (Type D)
<b>Impact Properties</b>			
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
<b>Thermal Properties</b>			
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
<b>Other Properties</b>			
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

## Disinfection Compatibility

Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes
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For more details on sterilization compatibilities, visit [formlabs.com/medical](http://formlabs.com/medical)

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.

## 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:

<b>Solvent</b>	<b>24 hr weight gain, %</b>	<b>Solvent</b>	<b>24 hr weight gain, %</b>
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		

# 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.

**Medical devices and device components**

**Ventilator and PPE components**

**Bioprocessing equipment**

**Drug delivery devices**

**Research and Development**



**FLBMCL01**

\* Regional availability may vary.

Prepared 06 . 12 . 2020

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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 DATA

# BioMed Clear Resin

	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
	Post-Cured <sup>2</sup>	Post-Cured <sup>2</sup>	
<b>Tensile Properties</b>			
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)
<b>Flexural Properties</b>			
Flexural Strength	84 MPa	12.2 ksi	ASTM D790-15 (Method B)
Flexural Modulus	2300 MPa	332 ksi	ASTM D790-15 (Method B)
<b>Hardness Properties</b>			
Hardness Shore D	78D	78D	ASTM D2240-15 (Type D)
<b>Impact Properties</b>			
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
<b>Thermal Properties</b>			
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
<b>Other Properties</b>			
Water Absorption	0.54%	0.54%	ASTM D570-98 (2018)
<b>Sterilization Compatibility</b>			
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		
<b>Disinfection Compatibility</b>			
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes		

For more details on sterilization compatibilities, visit [formlabs.com/medical](http://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 <sup>3</sup>	ISO Standard	Description <sup>3</sup>
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

<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 NAMSA World Headquarters, OH, USA.

# BioMed Amber

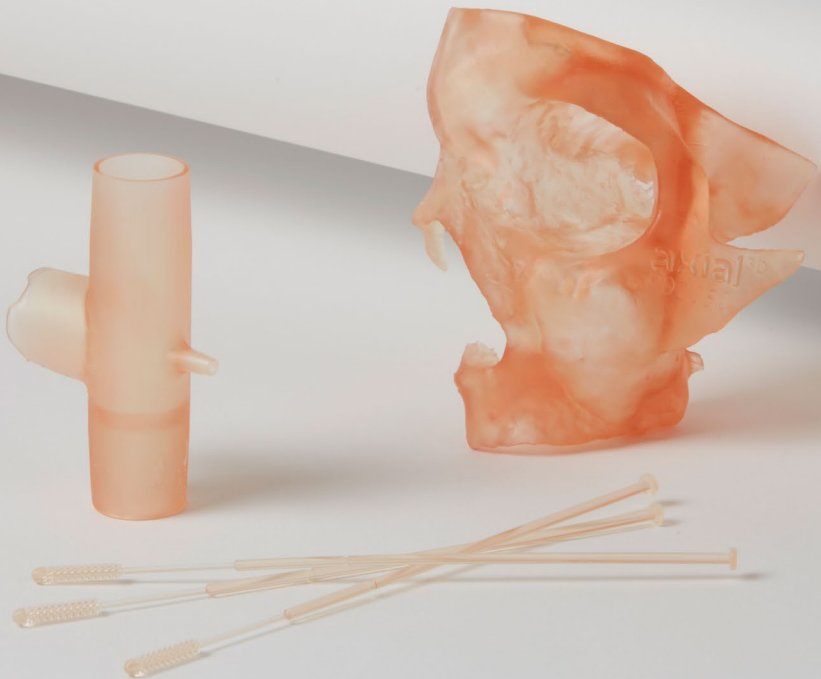
## Biocompatible Photopolymer Resin for Formlabs SLA Printers

BioMed Amber Resin is a rigid material for biocompatible applications requiring short-term contact. Parts printed with BioMed Amber Resin are compatible with common solvent disinfection and sterilization methods. BioMed Amber Resin is manufactured in our ISO 13485 facility.

**Medical devices and device components**

**Research and development**

**Surgical planning and implant sizing tools**



**FLBMAM01**

\* May not be available in all regions

**Prepared** 11 . 04 . 2019

**Rev. 02** 31 . 01 . 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 Amber Resin

	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
	Post-Cured <sup>2</sup>	Post-Cured <sup>2</sup>	
<b>Tensile Properties</b>			
Ultimate Tensile Strength	73 MPa	11 ksi	ASTM D638-10 (Type IV)
Young's Modulus	2900 MPa	420 ksi	ASTM D638-10 (Type IV)
Elongation	12%	12%	ASTM D638-10 (Type IV)
<b>Flexural Properties</b>			
Flexural Strength	103 MPa	15 ksi	ASTM D790-15 (Method B)
Flexural Modulus	2500 MPa	363 ksi	ASTM D790-15 (Method B)
<b>Hardness Properties</b>			
Hardness Shore D	67 D	67 D	ASTM D2240-15 (Type D)
<b>Impact Properties</b>			
Notched Izod	28 J/m	0.53 ft-lbf/in	ASTM D256-10 (Method A)
Unnotched Izod	142 J/m	2.6 ft-lbf/in	ASTM D4812-11
<b>Thermal Properties</b>			
Heat Deflection Temp. @ 1.8 MPa	65 °C	149 °F	ASTM D648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	78 °C	172 °F	ASTM D648-18 (Method B)
Coefficient of Thermal Expansion	66 µm/m/°C	37 µin/in/°F	ASTM E831-14

### 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/medical](http://formlabs.com/medical)

BioMed Amber Resin has been evaluated in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405:2009/(R)2015, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description <sup>3</sup>	ISO Standard	Description <sup>3</sup>
ISO 10993-5:2009	Not cytotoxic	ISO 10993-11: 2017	No evidence of acute systemic toxicity
ISO 10993-10:2010/(R)2014	Not an irritant	ISO 10993-11: 2017/USP, General Chapter <151>, Pyrogen Test	Non-pyrogenic
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 for post-cured samples were measured on Type IV tensile bars printed on a Form 2 and Form 3B (impact and thermal measurements) printers with 100 µm BioMed Amber Resin settings, washed in a Form Wash for 20 minutes in 99% Isopropyl Alcohol, and post-cured at 60 °C for 30 minutes in a Form Cure.

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