formlabs | healthcare

MEDICAL RESIN

BioMed White Resin

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.

Surgical guides and templates

Biocompatible molds, jigs, and fixtures

V1 **FLBMWH01**

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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 [1]	IMPERIAL [1]	METHOD
	Post-Cured [2]	**Post-Cured [2]**	
Tensile Properties	METRIC [1]	IMPERIAL [1]	METHOD
Ultimate Tensile Strength	46 MPa	6640 psi	ASTM D638-14 (Type IV)
Young's Modulus	2000 MPa	293 ksi	ASTM D638-14 (Type IV)
Elongation ta Break	10%		ASTM D638-14 (Type IV)
Flexural Properties	METRIC [1]	IMPERIAL [1]	METHOD
Flexural Stress at 5% Strain	74 MPa	10800 psi	ASTM D790-15 (Procedure B)
Flexural Modulus	2020.16 MPa	293 ksi	ASTM D790-15 (Procedure B)
Hardness Properties	METRIC [1]	IMPERIAL [1]	METHOD
Hardness Shore D	80 D	-	ASTM D2240-15 (Type D)
Impact Properties	METRIC [1]	IMPERIAL [1]	METHOD
Notched Izod	15 J/m	0.283 ft-lb/in	ASTM D256-10 (Method A)
Unnotched Izod	269 J/mm	5.04 ft-lb/in	ASTM D4812-11
Thermal Properties	METRIC [1]	IMPERIAL [1]	METHOD
Heat Deflection Temp. @ 1.8 MPa	52.4 °C	-	ASTM D648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	67.0 °C	-	ASTM D648-18 (Method B)
Coefficient of Thermal Expansion	90.1 µm/m/°C	-	ASTM E831-13
Other Properties	METRIC [1]	IMPERIAL [1]	METHOD
Water Absorption	0.40 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 White 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
ISO 10993-11: 2017	No evidence of acute systemic toxicity
ISO 10993-11: 2017/ USP, General Chapter <151>, Pyrogen Test	Non-pyrogenic

[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 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.

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

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

SOLVENT COMPATIBILITY

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%	0.4	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		