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MEDICAL RESIN

BioMed Durable Resin

For Strong and Impact Resistant Medical Devices and Instruments

BioMed Durable Resin is a clear material for biocompatible applications requiring impact, shatter, and abrasion resistance. This USP Class VI material is made in an FDA-registered, ISO 13485 facility and can be used in applications for long-term skin (>30 days), and short-term tissue, bone, and dentin contact (<24hrs)

Other biocompatibility endpoints have not been evaluated and may be added over time.

End-Use Devices and Components Requiring Biocompatibility and Impact Resistance

Patient-Specific Instruments

Single-Use Instruments



V1 **FLBMDU01**

V1.1 **FLDUCL21**

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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	29.1 MPa	4230 psi	ASTM D638-14 (Type IV)
Young's Modulus	994 MPa	144 ksi	ASTM D638-14 (Type IV)
Elongation at Break	33%		ASTM D638-14 (Type IV)
Flexural Properties	METRIC [1]	IMPERIAL [1]	METHOD
Flexural Stress at 5% Strain	21 MPa	92 ksi	ASTM D790-15 (Procedure B)
Flexural Modulus	643 MPa	3070 psi	ASTM D790-15 (Procedure B)
Hardness Properties	METRIC [1]	IMPERIAL [1]	METHOD
Hardness Shore D	75D		ASTM D2240-15 (Type D)
Impact Properties	METRIC [1]	IMPERIAL [1]	METHOD
Notched Izod	98 J/m	1.84 ft-lb/in	ASTM D256-10 (Method A)
Unnotched Izod	1340 J/m	25.1 ft-lb/in	ASTM D4812-11
Thermal Properties	METRIC [1]	IMPERIAL [1]	METHOD
Heat Deflection Temp. @ 1.8 MPa	40 °C	104 °F	ASTM D648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	46 °C	115 °F	ASTM D648-18 (Method B)
Coefficient of Thermal Expansion	102.9 um/m/C		ASTM E831-13

Sterilization Compatibility	
E-beam	35 kGy E-beam radiation
Ethylene Oxide	100% Ethylene oxide at 55 °C for 180 min
Gamma	29.4 -31.2 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

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

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

ISO Standard	Description [3]	ISO Standard	Description [3]
EN 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	USP <88> Biological Reactivity Tests, In-vivo	USP Class VI Certified

[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 Form 3B with 100um BioMed Durable Resin settings, washed in a Form Wash for 10 minutes in 99% Isopropyl Alcohol, and post-cured at 60°C, 20 minutes in a Form Cure.

[3] BioMed Durable 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%	0.7	Mineral oil, heavy	0.1
Acetone	12.4	Mineral oil, light	0.1
Bleach ~5% NaOCl	0.5	Salt Water (3.5% NaCl)	0.5
Butyl Acetate	5.0	Skydrol 5	0.6
Diesel Fuel	0.1	Sodium hydroxide solution (0.025% pH = 10)	0.5
Diethyl glycol monomethyl ether	3.0	Strong Acid (HCl Conc)	0.7
Hydraulic Oil	0.2	TPM	1.1
Hydrogen peroxide (3%)	0.6	Water	0.5
Isooctane	0.02	Xylene	4.8
Isopropyl Alcohol	2.0		