

BioMed Flex 80A Resin

For Flexible, Biocompatible, Transparent Medical Devices and Models

BioMed Flex 80A Resin is a firm, flexible, medical-grade material for applications requiring durability, biocompatibility, and transparency. This ISO 10993 and USP Class VI certified 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 mucosal membrane contact (< 24hrs).

Flexible Biocompatible Medical Devices

Firm Tissue Models to Assist in Surgeries



FLBMFL01

Prepared 20/09/2023

Rev. 01 20/09/2023

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	METRIC ¹	IMPERIAL ¹	METHOD
	Post-Cured ²	Post-Cured ²	
Mechanical Properties	METRIC ¹	IMPERIAL ¹	METHOD
Ultimate Tensile Strength ³	7.2 MPa	1040 psi	ASTM D412-06 (A)
Stress at 50% Elongation	2.6 MPa	377 psi	ASTM D412-06 (A)
Stress at 100% Elongation	4.5 MPa	653 psi	ASTM D412-06 (A)
Elongation at Break	135 %		ASTM D412-06 (A)
Tear Strength ⁴	22 kN/m	125 lb/in	ASTM D624-00
Shore Hardness	77 - 80A		ASTM 2240
Compression Set 23 °C for 22 hours	24.7%		ASTM D395-03 (B)
Compression Set 70 °C for 22 hours	5.3%		ASTM D395-03 (B)
Bayshore Resilience	29%		ASTM D2632
Thermal Properties	METRIC ¹	IMPERIAL ¹	METHOD
Glass transition temperature (Tg)	37 °C	99 °F	DMA

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

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

Disinfection Compatibility

Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes
-----------------------	-------------------------------------

Samples printed with BioMed Flex 80A Resin have been evaluated in accordance with the following biocompatibility endpoints:

ISO Standard	Description ³
ISO 10993-5:2009	Met requirements of test
ISO 10993-23:2021	Met requirements of test
ISO 10993-10:2021	Met requirements of test
USP <88> Biological Reactivity Tests, In-vivo	USP Class VI Certified

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 can vary with part geometry, print orientation, print settings and temperature.

² Data was obtained from parts printed using Form 3B, 100 µm, BioMed Flex 80A Resin settings, and using the BioMed Flex 80A MFG guide.

³ Tensile testing was performed after 3+ hours at 23 °C, using a Die C specimen cut from sheets.

⁴ Tear testing was performed after 3+ hours at 23 °C, using a Die C tear specimen directly printed

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%	1.42	Isooctane (aka gasoline)	9
Acetone	65.3	Mineral oil (light)	0.4
Isopropyl Alcohol	25.9	Mineral oil (Heavy)	0.2
Bleach ~5% NaOCl	0.5	Salt Water (3.5% NaCl)	0.5
Butyl Acetate	97.5	Sodium Hydroxide solution (0.025% PH 10)	0.6
Diesel Fuel	5.1	Water	0.6
Diethyl Glycol Monomethyl Ether	30.9	Xylene	112.5
Hydraulic Oil	2.5	Strong Acid (HCl conc)	37.3
Skydrol 5	28.1	Tripropylene Glycol Methyl Ether (TPM)	31.2
Hydrogen peroxide (3%)	0.7		