

## MEDICAL RESIN

# BioMed Elastic 50A

For Soft, Biocompatible, Transparent Medical Devices and Models

BioMed Elastic 50A Resin is a soft, elastic, medical grade material for applications requiring comfort, 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 contact ( $> 30$  days), and short-term mucosal membrane contact ( $< 24$ hrs).

**Elastic Biocompatible Medical Devices**

**Soft Tissue Models to Assist in Surgeries**



**FLBMEL01**

\* May not be available in all regions

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 DATA

# BioMed Elastic 50A

	METRIC <sup>1</sup>	IMPERIAL <sup>1</sup>	METHOD
	Post-Cured <sup>2</sup>	Post-Cured <sup>2</sup>	
<b>Mechanical Properties</b>			
Ultimate Tensile Strength <sup>3</sup>	2.3	339	ASTM D 412-06 (A)
Stress at 50% Elongation	1	145	ASTM D 412-06 (A)
Stress at 100% Elongation	1.3	189	ASTM D 412-06 (A)
Elongation at Break	150%	150%	ASTM D 412-06 (A)
Tear Strength <sup>4</sup>	11	60.8	ASTM D 624-00
Shore Hardness	50A	50A	ASTM 2240
Compression Set 23 °C for 22 hours	8%	8%	ASTM D 395-03 (B)
Compression Set 70 °C for 22 hours	11%	11%	ASTM D 395-03 (B)
Bayshore Resilience	15%	15%	ASTM D2632
<b>Thermal Properties</b>			
Glass transition temperature (Tg)	-36 °C	-32.8 °F	DMA
<b>Disinfection Compatibility</b>			
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes		

Samples printed with BioMed Elastic 50A Resin have been evaluated in accordance with the following biocompatibility endpoints:

ISO Standard	Description <sup>3</sup>
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

<sup>1</sup> Material properties can vary with part geometry, print orientation, print settings and temperature.

<sup>2</sup> Data was obtained from parts printed using Form 3B, 100 µm, BioMed Elastic 50A settings, and using the BioMed Elastic 50A MFG guide.

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

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

## SOLVENT COMPATIBILITY

## BioMed Elastic 50A

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%	1.5	Isooctane (aka gasoline)	15.6
Acetone	43.4	Mineral oil (light)	0.7
Isopropyl Alcohol	39.2	Mineral oil (Heavy)	0.4
Bleach ~5% NaOCl	0.6	Salt Water (3.5% NaCl)	0.6
Butyl Acetate	133.1	Sodium Hydroxide solution (0.025% PH 10)	0.7
Diesel Fuel	7.9	Water	0.7
Diethyl Glycol Monomethyl Ether	31.4	Xylene	163.9
Hydraulic Oil	3.9	Strong Acid (HCl conc)	45.6
Skydrol 5	41.2	Tripropylene Glycol Methyl Ether (TPM)	43.6
Hydrogen peroxide (3%)	0.9		