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MEDICAL RESIN

BioMed Flex 50A Resin

For Soft, Biocompatible, Transparent Medical Devices and Models

BioMed Flex 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 (< 24hrs).

Elastic Biocompatible Medical Devices

Soft Tissue Models to Assist in Surgeries

V1 **FLBMEL01**

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Rev. 02 24/06/2024

Material Properties	METRIC [1]	IMPERIAL [1]	METHOD
	Post-Cured [2]	Post-Cured [2]	
Mechanical Properties	METRIC [1]	IMPERIAL [1]	METHOD
Ultimate Tensile Strength [3]	2.3 MPa	339 psi	ASTM D412-06 (A)
Stress at 50% Elongation	1 MPa	145 psi	ASTM D412-06 (A)
Stress at 100% Elongation	1.3 MPa	189 psi	ASTM D412-06 (A)
Elongation at Break	150%		ASTM D412-06 (A)
Tear Strength [4]	11 kN/m	60.8 lb/in	ASTM D624-00
Shore Hardness	50A		ASTM 2240
Compression Set 23 °C for 22 hours	8%		ASTM D395-03 (B)
Compression Set 70 °C for 22 hours	11%		ASTM D395-03 (B)
Bayshore Resilience	15%		ASTM D2632
Thermal Properties	METRIC [1]	IMPERIAL [1]	METHOD
Glass transition temperature (Tg)	-36 °C	-32.8 °F	DMA

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Samples printed with BioMed Flex 50A 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 50A settings, and using the BioMed Flex 50A 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%	1.5	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		