

BioMed Flex 80A

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

* May not be available in all regions

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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 DATA

BioMed Flex 80A

| | METRIC ¹ | IMPERIAL ¹ | METHOD |
|--|-------------------------|-------------------------|-------------------|
| | Post-Cured ² | Post-Cured ² | |
| Mechanical Properties | | | |
| Ultimate Tensile Strength ³ | 7.2 MPa | 1040 psi | ASTM D 412-06 (A) |
| Stress at 50% Elongation | 2.6 MPa | 377 psi | ASTM D 412-06 (A) |
| Stress at 100% Elongation | 4.5 MPa | 653 psi | ASTM D 412-06 (A) |
| Elongation at Break | 135 % | 135 % | ASTM D 412-06 (A) |
| Tear Strength ⁴ | 22 kN/m | 125 lbf/in | ASTM D 624-00 |
| Shore Hardness | 77 - 80A | 77 - 80A | ASTM 2240 |
| Compression Set 23 °C for 22 hours | 24.7 % | 24.7 % | ASTM D 395-03 (B) |
| Compression Set 70 °C for 22 hours | 5.3 % | 5.3 % | ASTM D 395-03 (B) |
| Bayshore Resilience | 29 % | 29 % | ASTM D2632 |

Thermal Properties

| | | | |
|-----------------------------------|-------|-------|-----|
| Glass transition temperature (Tg) | 37 °C | 99 °F | DMA |
|-----------------------------------|-------|-------|-----|

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

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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 | | |