MEDICAL RESIN

formlabs | healthcare

# 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**

V1 **FLBMFL01** *** May not be available in all regions**

**Prepared** 20 . 09 . 2023
**Rev. 01** 20 . 09 . 2023

# 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 transistion tempreature (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 **BioMed Flex 80A**

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 | | |