

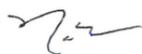
BIOCOMPATIBILITY CERTIFICATION

Date: 22 February 2024

Formlabs, Inc. hereby certifies that parts printed with Silicone 40A resin, and post-processed according to the accompanying instructions, meet the applicable requirements of ISO 10993-1:2020 and are biologically safe for permanent (>30 days) skin contact and limited (\leq 24 hours) mucosal membrane contacting devices. The products were tested for the following endpoints at NAMSA in Northwood, Ohio USA:

To assure biocompatibility, Silicone 40A parts should be printed on a Form 3 3D printer. All parts must be washed with a Form Wash in a mixture of 80% IPA and 20% n-Butyl Acetate. Post-cure Silicone 40A Resin in water in a glass beaker placed inside the Form Cure for 45 minutes at 60°C.

Test Title	Evaluation Endpoint	Test Result
Cytotoxicity Study Using the ISO Elution Method	Cytotoxicity (10993-5:2009)	Non-cytotoxic
UPS and ISO Intracutaneous Study in Rabbits	Irritation (ISO 10993-23:2021)	Non-irritant
ISO Guinea Pig Maximization Sensitization Study	Sensitization (ISO 10993-10:2021)	Non-sensitizer



Nathan Alt
Director, Regulatory Affairs and Quality Assurance