

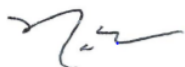
# BIOCOMPATIBILITY CERTIFICATION

Date: 7 March 2023

Formlabs, Inc. hereby certifies that parts printed with Nylon 12 Powder, and post-processed according to the accompanying instructions, meet the applicable requirements of ISO 10993-1:2020 and are biologically safe for limited duration ( $\leq 24$  hours) surface (mucosal membrane), limited duration implant (tissue/bone) or external communicating (Tissue/bone/dentin), and long term ( $>30$  days) surface (intact skin) contacting devices. The products were tested for the following endpoints at NAMSA in Northwood, Ohio USA.

ISO 10993 standard test samples were printed on a Fuse 1 SLS 3D printer with Nylon 12 powder. All parts were cooled in the printer, removed from the cylinder in the Fuse Sift, bead blasted with glass media and then blown with compressed air to remove any loose residue.

Test Title	Evaluation Endpoint	Test Report Number(s)	Test Result
Cytotoxicity Study Using the ISO Elution Method	Cytotoxicity (ISO 10993-5: 2009)	22T_51512_01	Non-cytotoxic
ISO Guinea Pig Maximization Sensitization Study	Sensitization (ISO 10993-10:2021)	22T_51512_02 22T-51512_03	Non-sensitizer
ISO Intracutaneous Reactivity Study	Irritation (ISO 10993-23:2021)	22T_51512_05 22T_51512_04	Non-irritant
USP Rabbit Pyrogen Study, Material Mediated	Material Mediated Pyrogenicity (ISO 10993-11:2017)	23T-22447-03	Non-pyrogenic
ISO Systemic Toxicity Study	Acute Systemic Toxicity (ISO 10993-11: 2017)	23T-22447-01 23T-22447-02	Showed no evidence of systemic toxicity



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