

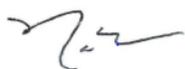
BIOCOMPATIBILITY CERTIFICATION

Date: 17 January 2025

Formlabs, Inc. hereby certifies that parts printed with Nylon 12 Tough Powder meet the applicable requirements of ISO 10993-1:2020 and are biologically safe for limited duration (≤ 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 Tough powder. All parts were 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)	24T_58616-02	Non-cytotoxic
ISO Guinea Pig Maximization Sensitization Study	Sensitization (ISO 10993-10:2021)	24T_58616_08 24T-58616_09	Non-sensitizer
ISO Intracutaneous Reactivity Study	Irritation (ISO 10993-23:2021)	24T_58616_03 24T-58616_04	Non-irritant
USP Rabbit Pyrogen Study, Material Mediated	Material Mediated Pyrogenicity (ISO 10993-11:2017)	24T_58616_07	Non-pyrogenic
ISO Systemic Toxicity Study	Acute Systemic Toxicity (ISO 10993-11: 2017)	24T_58616_05 24T-58616_06	Showed no evidence of systemic toxicity



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