

BIOCOMPATIBILITY CERTIFICATION

Date: 25 October 2021

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

Test Title	Evaluation Endpoint	Test Report Number	Test Result
Cytotoxicity Study Using the ISO Elution Method	Cytotoxicity	18T_64967_02	Non-cytotoxic
ISO Oral Mucosal Irritation Study in Hamsters-Collar Method-7 day	Irritation	19T_32194_02	Non-irritant
ISO Guinea Pig Maximization Sensitization Study	Sensitization	19T_31244_02 and 19T_31244_03	Non-sensitizer
USP Rabbit Pyrogen Study, Material Mediated	Pyrogenicity	21T_62887_02	Non-pyrogenic
ISO Acute Systemic Toxicity Study in Mice	Systemic Toxicity (Acute)	21T_62887_03 and 21T_62887_04	Non-toxic



Sam Murray
Director, Regulatory Affairs and Quality Assurance