

# BIOCOMPATIBILITY CERTIFICATION

Date: 18 May 2020

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 ISO 10993-1:2018 and are biologically safe for limited duration ( $\leq 24$  hours) surface (mucosal membrane) 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



Sam Murray  
Director, Regulatory Affairs and Quality Assurance