

BIOCOMPATIBILITY CERTIFICATION

Date: 23 April 2021

Formlabs, Inc. hereby certifies that parts printed with Tough 1500 Resin, and post-processed according to the accompanying instructions, were evaluated as skin contacting devices in accordance with ISO 10993-1:2018, and passed the requirements for the following biocompatibility endpoints tested at NAMSA in Northwood, Ohio USA.

ISO 10993 standard testing samples were printed on a Form 3 with 100um Tough 1500 Resin settings, washed in a Form Wash for 20 minutes in $\geq 99\%$ Isopropyl Alcohol, dried for at least 30 minutes and post-cured at 70°C for 60 minutes in a Form Cure.

Test Title	Biocompatibility Endpoint (Standard)	Test Report Number	Test Result
Cytotoxicity Study – ISO Direct Contact Method	Cytotoxicity (10993-5:2009)	20T_72772_01	Non-cytotoxic
ISO Closed Patch Sensitization Study	Sensitization (ISO 10993-10:2010)	21T_26669_02	Non-sensitizer
ISO Skin Irritation Study	Irritation (ISO 10993-10:2010)	21T_26669_01	Non-irritant



Sam Murray
Director, Regulatory Affairs and Quality Assurance