Formlabs Inc
35 Medford Street,
Somerville MA, 02143 USA

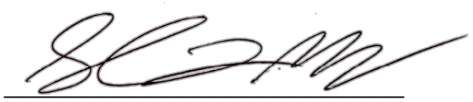
BIOCOMPATIBILITY CERTIFICATION

Date: 13 August 2020

Formlabs, Inc. hereby certifies that parts printed with BioMed Clear and Dental LT Clear V2 resins, and post-processed according to the accompanying instructions, meet the applicable requirements of ISO 10993-1:2018. A biological risk assessment was performed, and to evaluate the biological safety of the device, consideration was given to the following: type of patient contact; potential hazards associated with the materials of construction, the history of clinical use and testing of the materials of construction, the results of biocompatibility testing on BioMed Clear and Dental LT Clear V2, the results of chemical characterization testing of BioMed Clear and Dental LT Clear V2, and other information available in the literature. The results of this risk assessment indicate that exposure to leachables at levels capable of causing an adverse biological response in patients is unlikely under physiological conditions of use of BioMed Clear and Dental LT Clear V2 and any associated risks are negligible. BioMed Clear and Dental LT Clear V2 is considered to meet the requirements of ISO 10993-1:2018, EN ISO 14971:2019, FDA General Guidance on the Use of International Standard ISO 10993-1:2016, and applicable sections of the European Medical Device Regulation 2017/745/EU for a surface device that has long term (>30 days) contact with mucosal membrane. The products were tested for the endpoints listed on Page 2 at NAMSA in Northwood, Ohio USA.

formlabs

Test Title	Biocompatibility Endpoint (Standard)	Test Report Number	Test Result
Cytotoxicity Study – ISO Elution Method	Cytotoxicity (10993-5:2009)	19T_72466_03	Non-cytotoxic
MTT Cytotoxicity Test	Cytotoxicity (10993-5:2009)	19T_80728_05	No cytotoxic potential
ISO Guinea Pig Maximization Sensitization Study	Sensitization (ISO 10993-10:2010)	19T_72466-04 and 19T_72466-05	Non-sensitizer
USP Intracutaneous Study in Rabbits	Irritation (ISO 10993-10:2010)	20T_29676_05 to 08	Non-irritant
ISO Oral Mucosal Irritation Study in Hamsters-14 Day	Irritation (ISO 10993-10:2010)	19T_65771_02	Non-irritant
Acute Systemic Toxicity Study	Acute Systemic Toxicity (USP <88>)	20T_29676_01 to 04	No evidence of systemic toxicity
Chemical Characterization (ISO 10993-18 and ISO 10993-17)	Subacute/Subchronic Toxicity (ISO 10993-11:2017)	19T_65773_03 to 06 and 19T_65773_08 to 10	Non-toxic
Genotoxicity - Bacterial Reverse Mutation Study	Genotoxicity (ISO 10993-3:2003)	19T_80728_03 and 19T_80728_04	Non-mutagenic
Modified USP Muscle Implantation Study in Rabbits - 7 Day	Implantation (USP <88>)	20T_29676_12	Macroscopic reaction was not significant as compared to the negative control article



Sam Murray
Director, Regulatory Affairs and Quality Assurance