formlabs | healthcare

MEDICAL RESIN

BioMed Clear Resin

Biocompatible Photopolymer Resin for Formlabs SLA Printers

BioMed Clear Resin is a rigid material for biocompatible applications requiring long-term skin or mucosal membrane contact. This USP Class VI certified material is suitable for applications that require wear resistance and low water absorption over time.

Parts printed with BioMed Clear Resin are compatible with common sterilization methods. BioMed Clear Resin is manufactured in our ISO 13485 facility and is supported with an FDA Device Master File.

V1 **FLBMCL01**

In order to achieve biocompatible final parts, you must follow the recommended printing and post-processing outlined in the manufacturing guide. →

Prepared 06/12/2020

Rev. 04 28/04/2025

Material Properties	METRIC [1]	IMPERIAL [1]	METHOD
	Post-Cured [2]	Post-Cured [2]	
Tensile Properties	**METRIC [1]**	**IMPERIAL [1]**	**METHOD**
Ultimate Tensile Strength	52 MPa	7.5 ksi	ASTM D638-10 (Type IV)
Young's Modulus	2080 MPa	302 ksi	ASTM D638-10 (Type IV)
Elongation at Break	12%		ASTM D638-10 (Type IV)
Flexural Properties	**METRIC [1]**	**IMPERIAL [1]**	**METHOD**
Flexural Strength	84 MPa	12.2 ksi	ASTM D790-15 (Method B)
Flexural Modulus	2300 MPa	332 ksi	ASTM D790-15 (Method B)
Hardness Properties	**METRIC [1]**	**IMPERIAL [1]**	**METHOD**
Hardness Shore D	78D		ASTM D2240-15 (Type D)
Impact Properties	**METRIC [1]**	**IMPERIAL [1]**	**METHOD**
Notched Izod	35 J/m	0.658 ft-lb/in	ASTM D256-10 (Method A)
Unnotched Izod	449 J/m	8.41 ft-lb/in	ASTM D4812-11
Thermal Properties	**METRIC [1]**	**IMPERIAL [1]**	**METHOD**
Heat Deflection Temp. @ 1.8 MPa	54 °C	129 °F	ASTM D648-18 (Method B)
Heat Deflection Temp. @ 0.45 MPa	67 °C	152 °F	ASTM D648-18 (Method B)
Coefficient of Thermal Expansion	82 µm/m/°C	45 µin/in/°F	ASTM E831-14
Other Properties	**METRIC [1]**	**IMPERIAL [1]**	**METHOD**
Water Absorption	0.54%		ASTM D570-98 (2018)

Sterilization Compatibility	
E-beam	35 kGy E-beam radiation
Ethylene Oxide	100% Ethylene oxide at 55 °C for 180 minutes
Gamma	29.4 - 31.2 kGy gamma radiation
Steam Sterilization	Autoclave at 134 °C for 20 minutes Autoclave at 121 °C for 30 minutes

For more details on sterilization compatibilities, visit formlabs.com/medical

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Samples printed with BioMed Clear Resin have been evaluated in accordance with ISO 10993-1:2018, ISO 7405:2018, ISO 18562-1:2017 and have passed the requirements associated with the following biocompatibility endpoints:

ISO Standard	Description [3]	ISO Standard	Description [3]
ISO 10993-5:2009	Not cytotoxic	ISO 10993-3:2014	Not mutagenic
ISO 10993-10:2010/(R)2014	Not an irritant	ISO 18562-2:2017	Does not emit particulates
ISO 10993-10:2010/(R)2014	Not a sensitizer	ISO 18562-3:2017	Does not emit VOCs
ISO 10993-17:2002, ISO 10993-18:2005	Not toxic (subacute / subchronic)	ISO 18562-4:2017	Does not emit hazardous water-soluble substances
ISO 10993-11: 2017	No evidence of acute systemic toxicity	ISO 10993-11: 2017/USP, General Chapter <151>, Pyrogen Test	Non-pyrogenic

The product was developed and is in compliance with the following ISO Standards:

ISO Standard	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

[1] Material properties may vary based on part geometry, print orientation, print settings, temperature, and disinfection or sterilization methods used.

[2] Data were measured on post-cured samples printed on a Form 3B printer with 100 µm BioMed Clear Resin settings, washed in a Form Wash for 20 minutes in 99% isopropyl alcohol, and post-cured at 60 °C for 60 minutes in a Form Cure.

[3] BioMed Clear Resin was tested at NAMSA World Headquarters, OH, USA.

FORMLABS BIOCOMPATIBILITY CERTIFICATION

Formlabs, Inc. hereby certifies that parts printed with BioMed Clear Resin, 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, the results of chemical characterization testing of BioMed Clear, 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 any associated risks are negligible. BioMed Clear 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 and an externally communicating device that has limited ($\leq$ 24 hours) contact with tissue/bone/dentin. The products were tested for the endpoints listed on Page 2 at NAMSA in Northwood, Ohio USA under GLP conditions, 21 CFR part 58 where applicable. Additionally, the material was evaluated as a component in external communicating gas pathway devices such as ventilators by Nelson Labs in Salt Lake City, UT under GMP regulations, 21 CFR parts 210, 211 and 820. This testing is also outlined on page 2 of this document.

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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
Material Mediated Pyrogenicity	Pyrogen Test (USP <151>	21T_66768_02	Absence of Pyrogens
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
Volatile Organic Compounds (VOCs) and Particulates Emitted	ISO 18562-2 ISO18562-3	1306821-S01	All compounds below a Threshold of Toxicological Concern (TTC) of 40 µg/day for permanent contacting devices per ISO 18562, respective permissible daily exposures (PDEs) per USP<467>, or tolerable exposures (TEs) derived per ISO 10993-17. Particulates were below acceptance criteria specified in ISO 18562-2.
Tests for Leachables in Condensate	ISO 18562-4	MU202040-FOR01	Results subjected to toxicological risk assessment and passed. Testing and assessment performed satisfactory for compliance to ISO 18562-4.

BioMed Clear for Use as a Component in Medical Devices: Statement of Biocompatibility

Background

Formlabs has been approached by manufacturers and healthcare providers seeking guidance on the biocompatibility of their 3D printed materials and the appropriateness of use of these materials in a variety of medical device applications including as a component in external communicating gas pathway devices, like ventilators.

This document summarizes what is known about the biocompatibility of Formlabs BioMed Clear and evaluates the appropriateness of its use in medical devices, including those in the gas pathway.

Summary of Biocompatibility Testing Completed on BioMed Clear
A suite of biocompatibility and chemistry tests (data on file with Formlabs) have been conducted on BioMed Clear printed material itself on the range of their suitable listed printers as specified by Formlabs. The material was tested after printing and processing using Formlabs recommended parameters and without sterilization.

Table 1. Biocompatibility Tests Performed on BioMed Clear*

Biological Endpoint	Testing Standard	Result
Cytotoxicity	ISO 10993-5	Pass
Sensitization	ISO 10993-10	Pass
Irritation	ISO 10993-10	Pass
Subacute/Subchronic Toxicity	Pass; evaluated as part of extractables testing and toxicological risk assessment process.	
Genotoxicity	ISO 10993-3	Pass
Modified USP muscle implantation	USP <88>	Pass
Acute Systemic Toxicity	USP <88>	Pass
Intracutaneous Toxicity	USP <88>	Pass
Extractables	ISO 10993-18 ISO 10993-17	Results subjected to toxicological risk assessment and passed. Testing and assessment performed satisfactory for compliance to ISO 18562-4.
Volatile Organic Compounds (VOCs) and Particulates Emitted	ISO 18562-2 ISO 18562-3	All compounds below a Threshold of Toxicological Concern (TTC) of 40 µg/day for permanent contacting devices per ISO 18562, respective permissible daily exposures (PDEs) per USP<467>, or tolerable exposures (TEs) derived per ISO 10993-17. Particulates were below acceptance criteria specified in ISO 18562-2.

**Testing for VOCs and particulates emitted was performed on a 3D printed tube with internal surface area of 68.2 cm^2, biological testing and extractables used a representative device with a surface area of 46 cm^2.*

Gap Assessment, Testing Conducted and Regulatory Expectations for Gas Pathway Applications
Testing was conducted on 3D printed parts made from BioMed Clear material itself (further details on the manufacture of this representative device is on file with Formlabs), assuming applications ranging from permanent contact with intact skin, mucosal membranes, or respiratory pathway. The current regulatory

standard for devices that contact gases which are inhaled by a patient is ISO 18562-1. This standard evaluates risks associated with this mode of contact through direct measurement of VOCs and particulates carried by gases which have passed through the device.

Potential Risk Associated with VOCs: All VOCs emitted from the representative device were below a Threshold of Toxicological Concern (TTC) of 40 µg/day for permanent contacting devices per ISO 18562, respective permissible daily exposures (PDEs) per USP<467>, or tolerable exposures (TEs) derived per ISO 10993-17.

Potential Risk Associated with Particulates: The primary concern with particulates and gas pathway devices is in cases where the device has moving parts that can generate respirable dust; a secondary concern is residual dusts from the manufacturing environment. The technology used to print BioMed Clear relies on photo-polymerization of liquid resins. At no stage in the printing process, postprocessing, and support removal are powdered or particulate substances used. Because there is no source of particulates in the manufacturing, and there is no clear mechanism for generation of particulates from a clean plastic part during use as a component, risks associated with particulates are minimal. PM2.5 and PM10 particulates were measured from the representative device with an average count of zero.

Limits and Recommendations
The risks related to use of 3D printed BioMed Clear in medical devices including those in the gas pathway is considered minimal when fabricated in strict compliance with the manufacturers recommended printing instruction. In situations where the 3D printed component would be in contact with drugs (such as in a nebulizer) additional risks may exist regarding material compatibility that warrant caution. While *in-vitro* and *in-vivo* biocompatibility tests are surface area normalized (and therefore produce results independent of device size), analytical chemistry testing and toxicological risk assessment have results and conclusions which are size dependent; therefore, devices larger than the tested article may produce less favorable results. Any device manufactured from this material should be evaluated in its final, finished, sterilized form.

Conclusion
The minimal biocompatibility risk associated with use of 3D printed BioMed Clear material in medical devices including those in the gas pathway is acceptable. The lowest risk use scenarios are those in which the material is used to print intact skin devices or minority components in a dry or humidified gas pathway.

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2020.09.21 14:24:09
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Important Information: *This document is not equivalent to regulatory approval of BioMed Clear by any regulatory body. It is a third-party expert evaluation of the potential risks of the material when used as described.*

BioMed Clear Sterilization Results

The purpose of this report is to evaluate the compatibility of Formlabs Biomed Clear Resin with various sterilization methods: autoclave, gamma, e-beam, and ethylene oxide sterilization (EtO). Biocompatibility, dimensional accuracy, and mechanical properties were assessed pre- and post- sterilization, results are presented here.

This report is meant to demonstrate that, for these geometries under these conditions, the material can be exposed to these standard methods of sterilization without significant impact to biocompatibility, dimensional accuracy, or mechanical properties. Changes to part geometry or sterilization settings may affect post-sterilization outcomes. It is the device manufacturer's responsibility to determine if the results presented here accurately reflect their use case, or if they need to conduct additional testing on the impact of sterilization on their own printed parts.

Compatibility between BioMed Clear Resin and vaporized hydrogen peroxide sterilization was not assessed by Formlabs, but was evaluated independently by STERIS. The methods and outcomes of that study can be found here: https://pmc.ncbi.nlm.nih.gov/articles/PMC10900786/

Sample Preparation

Printing

All samples were printed on Form 3B SLA printers equipped with clean Build Platforms, Form 3 Resin Tanks and Biomed Clear Resin V1 cartridges. Part orientations and placement were kept constant for all samples.

Post Processing

After printing, testing samples attached to a build platform were washed twice in a Form Wash. The first wash was 10 minutes in ≤95% IPA to remove the majority of uncured resin. The second wash was 10 minutes in >99% IPA to ensure removal of any residual uncured resin. Compressed air was used to dry the parts thoroughly. Parts were removed from supports and cured for 60 minutes at 60°C in a Form Cure. Formlabs Form Wash, Form Cure, and finishing tools were used according to the manufacturing guide to ensure optimal performance and biocompatibility compliance.

Results

Biocompatibility Testing

Printed and post-processed parts were provided to NAMSA for ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity study using the ISO elution method. The results show no evidence of causing cell lysis or cytotoxicity; with 0% lysis detected.

Results and conclusions of the cytotoxicity testing are based on a standard geometry (60mm x 1.5mm disks) and sample set per ISO 10993-5. Biocompatibility and sterilization compatibility results may vary if there are any deviations from the manufacturing guide. Formlabs is not responsible for any biocompatibility results except the one specified in this report. Users are responsible for confirming biocompatibility for their specific application.

Dimensional Testing

Dimensional coupons (the Formtest) were printed and post processed using the process described above. The dimensional coupon includes features measuring 1, 4, 9, 27, and 50 mm. After printing and post processing, the coupons' features were labeled and measured using a calibrated Coordinate Measuring Machine (CMM). These coupons were then sent to vendors for sterilization.

Mechanical Property Testing

Tensile Testing: Tensile bars (ASTM D638 Type I) were prepared as described in the "Sample Presentation" section. The samples were conditioned and tested according to ASTM D638.

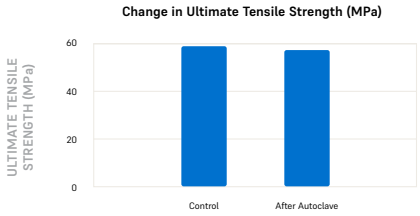
Flexural Testing: Flexural bars were prepared as described in the "Sample Preparation" section. The samples were conditioned and tested according to ASTM D790 - Method B.

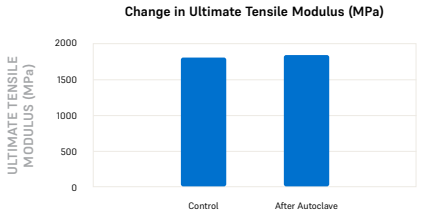
Parts printed and tested under different conditions, such as printer, storage conditions, etc. may produce different results.

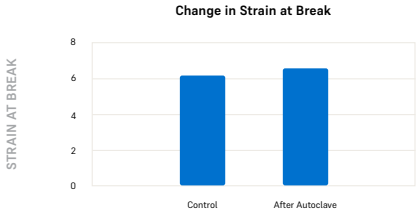
Autoclave (Steam) Sterilization

Tensile and flexural bar samples were provided to STERIS for autoclave processing. The parts underwent 5 cycles of pre-vacuum steam sterilization at 132 °C with a 4-minute sterilization phase and 30 minutes dry phase. Parts were allowed to cool 30 minutes between cycles.

The mechanical property testing below shows the compatibility of Biomed Clear Resin printed parts with autoclave sterilization. No appreciable losses in material properties, deformations, cracking or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.







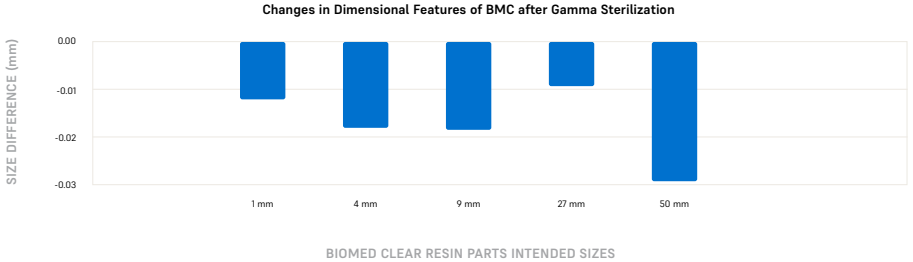
There were no dimensional measurements taken for parts printed with BioMed Clear Resin post-autoclave sterilization, but dimensional accuracy post-autoclave sterilization was evaluated independently by the University Hospital Basel. Their methods and results can be found here: https://pubmed.ncbi.nlm.nih.gov/32429549/

Autoclaved samples were tested by NAMSA for cytotoxicity per ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity evaluation. The results show that post-autoclave sterilization, there is no evidence of causing cell lysis or cytotoxicity.

Gamma Sterilization

Tensile and flexural bar samples were prepared and provided to Sterigenics - Rockaway, NJ for Gamma processing. The samples were exposed to 29.4-31.2 kGy of gamma radiation.

Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Biomed Clear Resin printed parts with gamma sterilization. No appreciable losses in material properties, deformations, or cracking were observed after processing. The material exhibited an increased yellowing after processing. Flexural properties were tested and followed similar trends as tensile testing.



E-beam Sterilization

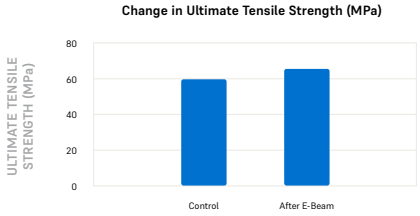
Tensile and flexural bar samples were prepared and provided to Sterigenics - San Diego, CA, for e-beam processing. The samples were exposed to a surface dose of 35 kGy of e-beam radiation.

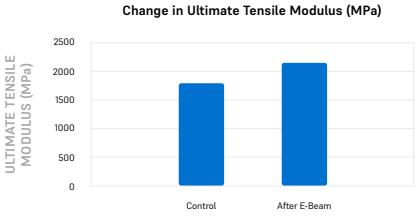
Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Biomed Clear Resin printed parts with e-beam sterilization. No appreciable losses in material properties, deformations, or cracking were observed after processing. The material exhibited an increased yellowing after processing. Flexural properties were tested and followed similar trends as tensile testing.

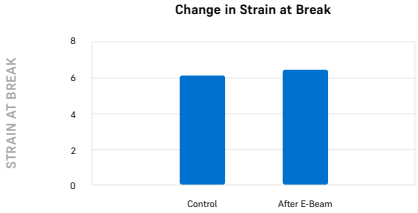
Dimensional coupons were provided back to Formlabs for dimensional measurements using the same CMM as used in the pre sterilization measurements. The data shows a uniform decrease in size across the measured size spectrum. All size differentials were below 100 micron which indicates that e-beam sterilization of BioMed Clear Resin parts is viable for a large number of applications.

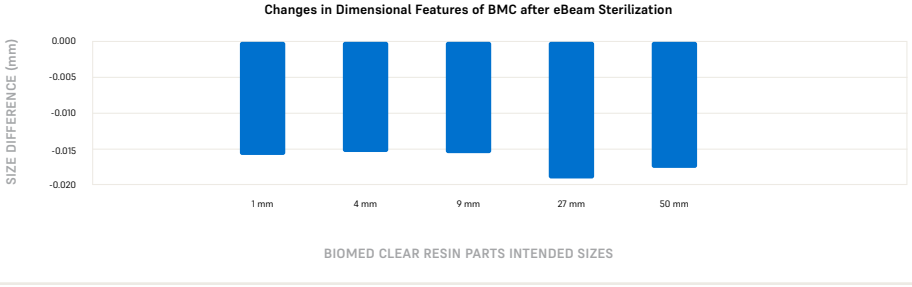
Tensile and flexural bar samples were prepared and provided to Sterigenics - Rockaway, NJ for Gamma processing. The samples were exposed to 29.4-31.2 kGy of gamma radiation.

Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Biomed Clear Resin printed parts with gamma sterilization. No appreciable losses in material properties, deformations, or cracking were observed after processing. The material exhibited an increased yellowing after processing. Flexural properties were tested and followed similar trends as tensile testing.





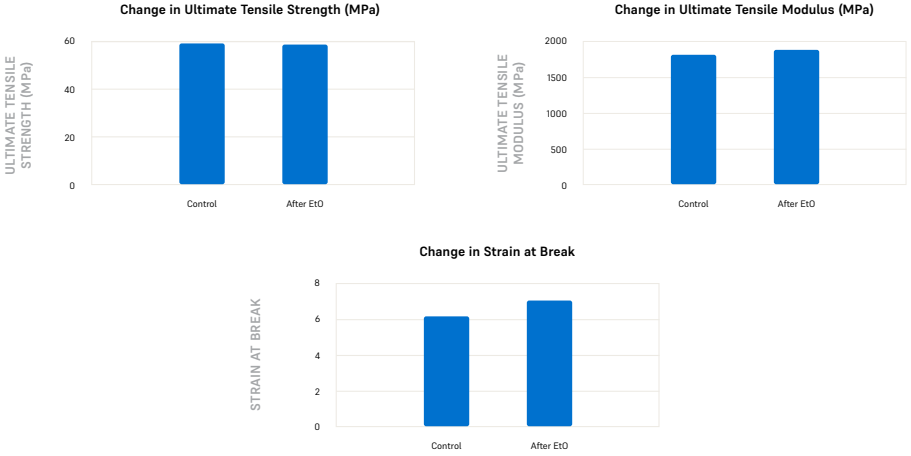




Ethylene Oxide (EtO) Sterilization

Tensile and flexural bar samples were prepared and provided to Blue Line Sterilization Services for EtO processing. The samples were conditioned at 55°C, 50% relative humidity, and 50 mbar for 78 minutes. The samples were then exposed to a single cycle of 100% EtO at 55°C for 180 minutes.

Parts were provided back to Formlabs for mechanical property testing, and off-gassing occurred during transport. For optimal results, appropriate off-gassing time must be built into the sterile processing procedure. Off-gassing of our sample parts occurred over a series of days, but a shorter time frame may be applicable; the appropriate timeframe should be determined by part manufacturer based on part geometry. Mechanical property testing was conducted using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Biomed Clear Resin printed parts with EtO sterilization. No appreciable losses in material properties, deformations, cracking, or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.



Dimensional coupons were provided back to Formlabs for dimensional measurements using the same CMM as used in the pre sterilization measurements. The data shows a uniform decrease in size across the measured size spectrum. All size differentials were below 100 micron which indicates that EtO sterilization of BioMed Clear Resin parts is viable for a large number of applications.