Dental

High-Accuracy Materials for Dental Labs and Practices

Our library of Dental Resins enables dental practices and labs to rapidly manufacture a range of dental products in-house, from biocompatible surgical guides and splints to fixed prosthetic and clear aligner models.

*** Please note that resins may not be available in all regions.**

Model

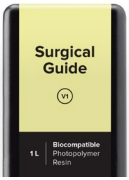
Stone-colored models

Draft

Fast-printing models

Castable Wax

Castable and pressable restorations



Surgical Guide

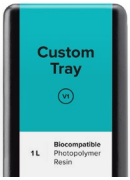
Implant guides

IBT

Indirect bonding trays

Dental LT Clear V2

Occlusal splints



Custom Tray

Custom impression trays

Temporary CB

Temporary crowns, bridges, inlays, onlays, and veneers

VITA CLASSICAL SHADES: A2, A3, B1, C2, BL

Permanent Crown

Permanent crowns, inlays, onlays, and veneers

VITA CLASSICAL SHADES: A2, A3, B1, C2

Denture Base & Teeth

Long term, temporary, and try-in dentures

Soft Tissue (Starter Pack)

Gingiva masks

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Model

A fast-printing material for production of high-accuracy restorative models

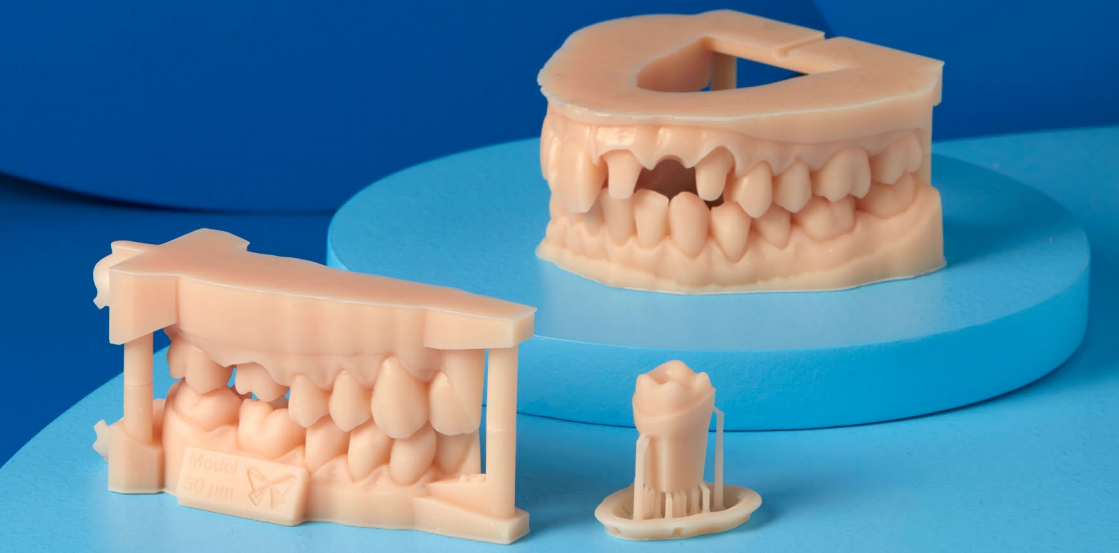
Model Resin was developed to meet the precision, reliability, and throughput requirements of restorative dentistry. Print accurate models and dies with crisp margins and contacts, delivering high-quality results on fast-paced timelines.

Crown and bridge models

Implant analog models

Orthodontic models

Diagnostic models



V3 **FLDMBE03** * May not be available in all regions

Prepared 11 . 09 . 2021

Rev. 01 11 . 09 . 2021

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

MATERIAL PROPERTIES DATA **Model Resin**

	METRIC [1]		IMPERIAL [1]		METHOD
	Green [2]	Post-Cured [3]	Green [2]	Post-Cured [3]	
Mechanical Properties					
Ultimate Tensile Strength	27 MPa	48 MPa	3970 psi	6990 psi	ASTM D 638-14
Tensile Modulus	1.1 GPa	2.3 GPa	160 ksi	331 ksi	ASTM D 638-14
Elongation at Break	14%	4.8%	14%	4.8%	ASTM D 638-14
Flexural Properties					
Flexural Strength	25 MPa	85 MPa	3640 psi	12300 psi	ASTM D 790-15
Flexural Modulus	0.67 GPa	2.2 GPa	97 ksi	320 ksi	ASTM D 790-15
Impact Properties					
Notched Izod	23 J/m	24 J/m	0.43 ft-lbs/in	0.45 ft-lbs/in	ASTM D 256-10
Unnotched Izod	300 J/m	325 J/m	5.6 ft-lbs/in	6.1 ft-lbs/in	ASTM D 4812-19
Thermal Properties					
Heat Deflection Temp. @ 1.8 MPa	41 °C	56 °C	104 °F	133 °F	ASTM D 648-16
Heat Deflection Temp. @ 0.45 MPa	47 °C	75 °C	117 °F	167 °F	ASTM D 648-16
Thermal Expansion	108 µm/m/°C	76 µm/m/°C	60 µin/in/°F	43 µin/in/°F	ASTM E 813-13

[1] Material properties may vary based on part geometry, print orientation, print settings, and temperature.

[2] Data for green samples were measured on Type IV tensile bars printed on a Form 3 printer with 100 µm Model Resin settings and washed in a Form Wash for 10 minutes in ≥99% Isopropyl Alcohol.

[3] Data for post-cured samples were measured on Type IV tensile bars printed on a Form 3 printer with 100 µm Model Resin settings, washed in a Form Wash for 10 minutes in ≥99% Isopropyl Alcohol, and post-cured at 60°C for 5 minutes in a Form Cure.

SOLVENT COMPATIBILITY

Percent weight gain over 24 hours for a printed and post-cured 1 x 1 x 1 cm cube immersed in respective solvent:

Solvent	24 hr weight gain, %	Solvent	24 hr weight gain, %
Acetic Acid 5%	0.2	Mineral oil, heavy	0.2
Acetone	0.9	Mineral oil, light	0.2
Bleach ~5% NaOCl	0.1	Salt Water (3.5% NaCl)	0.2
Butyl Acetate	< 0.1	Skydrol 5	0.4
Diesel Fuel	0.1	Sodium hydroxide solution (0.025% pH = 10)	0.2
Diethyl glycol monomethyl ether	< 0.1	Strong Acid (HCl Conc)	< 0.1
Hydraulic Oil	0.1	TPM	0.2
Hydrogen peroxide (3%)	0.1	Water	0.2
Isooctane	< 0.1	Xylene	< 0.1
Isopropyl Alcohol	< 0.1		

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Draft

A cutting-edge material designed to print accurate orthodontic models — fast

Draft Resin is our fastest printing material, capable of printing a dental model in under 20 minutes. This highly accurate resin prints with a smooth surface finish, making Draft Resin the ideal material for aligner and retainer production. Use 200 micron settings for fastest print speeds and same day appliances, or use 100 micron settings for more detailed models.

Rapid model production

Orthodontic models

V2 **FLDRGR02** *** May not be available in all regions**

Prepared 10 . 07 . 2020
Rev. 01 10 . 07 . 2020

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

MATERIAL PROPERTIES DATA

Draft Resin

	METRIC [1]			IMPERIAL [1]			METHOD
	Green [2]	Post-Cured at Room Temperature [3]	Post-Cured at 60 °C [4]	Green [2]	Post-Cured at Room Temperature [3]	Post-Cured at 140 °F [4]	
Tensile Properties							
Ultimate Tensile Strength	24 MPa	36 MPa	52 MPa	3481 psi	5221 psi	7542 psi	ASTM D638-14
Tensile Modulus	0.8 GPa	1.7 GPa	2.3 GPa	122 ksi	247 ksi	334 ksi	ASTM D638-14
Elongation at Break	14%	5%	4%	14%	5%	4%	ASTM D638-14
Flexural Properties							
Flexural Modulus	0.6 GPa	1.8 GPa	2.3 GPa	87 ksi	261 ksi	334 ksi	ASTM D 790-17
Impact Properties							
Notched Izod	26 J/m	29 J/m	26 J/m	0.5 ft-lbf/in	0.5 ft-lbf/in	0.5 ft-lbf/in	ASTM D256-10
Thermal Properties							
Heat Deflection Temp. @ 1.8 MPa	37 °C	44 °C	57 °C	99 °F	111 °F	135 °F	ASTM D 648-16
Heat Deflection Temp. @ 0.45 MPa	43 °C	53 °C	74 °C	109 °F	127 °F	165 °F	ASTM D 648-16

[1] Material properties can vary with part geometry, print orientation, print settings, and temperature.

[2] Data was obtained from green parts, printed using Form 3, 200 µm, Draft Resin settings, washed for 5 minutes in Form Wash and air dried without post cure.

[3] Data was obtained from parts printed using a Form 3, 200 micron, Draft Resin settings, and post-cured with Form Cure at room temperature for 5 minutes.

[4] Data was obtained from parts printed using a Form 3, 200 micron, Draft Resin settings, and post-cured with Form Cure at 60 °C for 5 minutes.

SOLVENT COMPATIBILITY

Percent weight gain over 24 hours for a printed and post-cured 1 x 1 x 1 cm cube immersed in respective solvent:

Solvent	24 hr weight gain, %	Solvent	24 hr weight gain, %
Acetic Acid 5%	0.2	Mineral oil (Light)	< 1.0
Acetone	4.2	Mineral oil (Heavy)	< 1.0
Bleach ~5% NaOCl	0.1	Salt Water (3.5% NaCl)	0.3
Butyl Acetate	0.1	Skydrol 5	0.3
Diesel Fuel	0.1	Sodium Hydroxide solution (0.025% PH 10)	0.3
Diethyl glycol Monomethyl Ether	0.8	Strong Acid (HCl conc)	< 1.0
Hydraulic Oil	< 0.1	Tripropylene glycol monomethyl ether	0.3
Hydrogen peroxide (3%)	0.2	Water	< 1.0
Isooctane (aka gasoline)	< 1.0	Xylene	< 1.0
Isopropyl Alcohol	< 1.0		

Castable Wax

A highly accurate material for casting and pressing crowns, bridges, and RPD frameworks

Tested at length by dental technicians, Castable Wax Resin provides accurate, sealed margins and contains 20% wax for reliable casting with clean burnout. Printed patterns are strong enough to handle with no post-cure required, allowing for a faster, simpler workflow.

Patterns for casting and pressing

Crowns

Removable partial denture frameworks

Bridges

V1 **FLCWPU01** *** May not be available in all regions**

Prepared 10 . 02 . 2017
Rev. 01 10 . 02 . 2017

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

	METRIC [1]	IMPERIAL [1]	METHOD
	Green [2]	**Green [2]**	
Tensile Properties			
Ultimate Tensile Strength	12 MPa	1680 psi	ASTM D 638-10
Tensile Modulus	220 MPa	32 ksi	ASTM D 638-10
Elongation at Break	13%	13%	ASTM D 638-10
Burnout Properties			
Temp @ 5% Mass Loss	249 °C	480 °C	
Ash Content (TGA)	0.0 - 0.1%	0.0 - 0.1%	

[1] Material properties can vary with part geometry, print orientation, print settings, and temperature.

[2] Data was obtained from parts printed using Form 2, Castable 50 µm Fine Detail settings and washed without post-cure.

Surgical Guide

A premium-quality material for printing surgical implant guides

Surgical Guide Resin is designed to print at 100 micron and 50 micron layer line resolutions on Formlabs SLA printers to produce dimensionally accurate dental implant guides and templates.

Surgical guides

Pilot drill guides

Device sizing templates

Drilling templates

V1 **FLSGAM01** *** Regional availability may vary.**

Prepared 11 . 04 . 2019

Rev. **02** 21 . 07 . 2021

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

	Post-Cured [1, 2]	Method
Elongation	12%	ASTM D638
Flexural Strength	> 102 MPa	ASTM D790
Flexural Modulus	> 2400 MPa	ASTM D790

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

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Surgical Guide Resin is a Class I Medical Device as defined in Article 2 of the Medical Device Regulation 2017/74 (MDR) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

Surgical Guide Resin has been evaluated in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description [3]
EN ISO 10993-5	Not cytotoxic
EN ISO 10993-10	Not an irritant
EN ISO 10993-10	Not a sensitizer

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

ISO Standard	Description
EN ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971	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 for post-cured samples were measured on Type IV tensile bars printed on a Form 2 printer with 100 µm Surgical Guide Resin settings, washed in a Form Wash for 20 minutes in ≥99% Isopropyl Alcohol, and post-cured at 60°C for 30 minutes in a Form Cure.

[3] Surgical Guide Resin was tested at NAMSA World Headquarters, OH, USA.

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IBT Resin

A flexible material that enables efficient, accurate orthodontic bracket placement

Use IBT Resin to 3D print indirect bonding trays for a cost-effective, rapid dental bracket placement process for high quality orthodontics. IBT Resin prints full arch and quadrant bracket transfer trays quickly using 100 micron layer heights, reducing labor time and enabling higher throughput.

Indirect Bonding Trays

V1 **FLIBCL01**

*** Regional availability may vary.**

Prepared 14 . 01 . 2021
Rev. **02** 21 . 07 . 2021

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

	Post-Cured [1,2]	Method
Ultimate Tensile Strength	≥ 5 MPa	ASTM D638
Young's Modulus	> 16 MPa	ASTM D638
Elongation	> 25%	ASTM D638
Hardness Shore A	< 90A	ASTM D2240

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

IBT Resin is a Class I Medical Device as defined in Article 2 of the Medical Device Regulation 2017/74 (MDR) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

IBT Resin has been evaluated in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description [3]
EN ISO 10993-5	Not cytotoxic
EN ISO 10993-10	Not an irritant
EN ISO 10993-10	Not a sensitizer

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

ISO Standard	Description
EN ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971	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 with 100um IBT 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] IBT Resin was tested at NAMSA World Headquarters, OH, USA.

formlabs | dental

Dental LT Clear V2

A durable, color-corrected material for printing hard occlusal splints

Directly print affordable, high-quality occlusal splints in-house with Dental LT Clear Resin (V2). Highly durable and resistant to fracture, this color-corrected material prints clear, polishes to high optical transparency, and resists discoloration over time for a finished appliance you'll be proud to deliver.

Occlusal guards **Splints**

V1 **FLDLCL02**

*** May not be available in all regions**

Prepared 09 . 16 . 2020
Rev. 01 09 . 16 . 2020

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

	METRIC [1]	METHOD
	Post-Cured [2]	
Tensile Properties		
Ultimate Tensile Strength	52 MPa	ASTM D638-10 (Type IV)
Young's Modulus	2080 MPa	ASTM D638-10 (Type IV)
Elongation	12%	ASTM D638-10 (Type IV)
Flexural Properties		
Flexural Strength	84 MPa	ASTM D790-15 (Method B)
Flexural Modulus	2300 MPa	ASTM D790-15 (Method B)
Hardness Properties		
Hardness Shore D	78D	ASTM D2240-15 (Type D)
Impact Properties		
IZOD Impact Strength	449 J/m	ASTM D4812-11 (Unnotched)
Other Properties		
Water Absorption	0.54%	ASTM D570-98 (2018)

Dental LT Clear Resin (V2) has been evaluated in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405:2018, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	**Description [3]**
ISO 10993-5:2009	Not cytotoxic
ISO 10993-10:2010/(R)2014	Not an irritant
ISO 10993-10:2010/(R)2014	Not a sensitizer
ISO 10993-3:2014	Not mutagenic
ISO 10993-17:2002, ISO 10993-18:2005	Not toxic (subacute / subchronic)

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 Dental LT Clear Resin (V2) 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] Dental LT Clear Resin (V2) was tested at NAMSA World Headquarters, OH, USA.

Custom Tray

A production-ready material that enables highly accurate definitive impressions

Use Custom Tray Resin to directly print impression trays for implants, dentures, crowns and bridges, and other comprehensive cases. Digitally manufactured impression trays provide consistent, accurate impressions for high-quality dentistry. Custom Tray Resin prints full impression trays quickly using 200 micron layer heights, reducing labor time and enabling higher throughput.

Impression Trays

V1 **FLCTBL01** * Regional availability may vary.

Prepared 10 . 07 . 2020
Rev. **02** 21 . 07 . 2020

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

	Post-Cured [1, 2]	Method
Ultimate Tensile Strength	> 70 MPa	ASTM D638
Young's Modulus	> 2500 MPa	ASTM D638
Elongation	> 3%	ASTM D638
Flexural Strength	≥ 100 MPa	ASTM D790
Flexural Modulus	≥ 2600 MPa	ASTM D790
Hardness Shore A	> 80 D	ASTM D2240

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Custom Tray Resin is a Class I Medical Device as defined in Article 2 of the Medical Device Regulation 2017/74 (MDR) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

Custom Tray Resin has been evaluated in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description [3]
EN ISO 10993-5	Not cytotoxic
EN ISO 10993-10	Not an irritant
EN ISO 10993-10	Not a sensitizer

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

ISO Standard	Description
EN ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971	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 for post-cured samples were measured on Type IV tensile bars printed on a Form 2 printer with 200 µm Custom Tray Resin settings, washed in a Form Wash for 10 minutes in ≥99% Isopropyl Alcohol, and post-cured at 60°C for 30 minutes in a Form Cure.

[3] Custom Tray Resin was tested at NAMSA World Headquarters, OH, USA.

Temporary CB

A validated material for comfortable, aesthetic temporary restorations

Temporary CB Resin is a Class IIa material designed to 3D print biocompatible dental prosthetics with the Form 3B and Form 2 printers. This tooth-colored resin can print at 50 micron layer line resolutions to produce precisely fitting temporaries with a smooth surface finish, high resolution, and dimensional stability. Restorations made from Temporary CB Resin may remain in the mouth for up to 12 months.

Temporary CB Resin is only validated for use with the Stainless Steel Build Platform.

Temporary Restorations:

Bridges (up to 7 units)

Crowns

Veneers

Onlays

Inlays

V1

FLTCA201
FLTCA301

FLTCB101
FLTCC201

FLTCBL01

*** May not be available in all regions**

Prepared 06 . 09 . 2020
Rev. 02 25 . 01 . 2022

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MATERIAL PROPERTIES DATA

Temporary CB Resin

VITA[1] CLASSICAL SHADES: A2, A3, B1, C2, BL

	MEASURED VALUES	METHOD
Mechanical Properties		
Density	1.4 - 1.5 g/cm^3	BEGO Standard
Viscosity	2500 - 6000 MPa*s	BEGO Standard
Flexural Strength (post cured) [2, 3, 4]	≥ 100 MPa	EN ISO 10477, EN ISO 4049

Temporary CB Resin is a Medical Device as defined in the Medical Device Directive (93/42/EEC) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

Restorations printed with Temporary CB Resin have been evaluated in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405:2009/(R)2015, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description [5]
EN ISO 10993-5:2009	Not cytotoxic
ISO 10993-10:2010/(R)2014	Not an irritant
ISO 10993-10:2010/(R)2014	Not a sensitizer
ISO 10993-3:2014	Not genotoxic
ISO 10993-1:2009	Non toxic

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 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

[1] VITA is a registered trademark of a company which is not affiliated with Formlabs Inc.

[2] Material properties may vary based on part geometry, print orientation, print settings, and environmental conditions.

[3] Test samples were printed with a Stainless Steel Build Platform on a Form 2 and Form 3B printer with 50 µm Temporary CB Resin settings. The printed samples were post-processed as recommended in the Instructions for Use.

[4] Data for post-cured samples were measured on 3 point bending test specimens according to EN ISO 10477 and EN ISO 4049 standards.
Screen reader support enabled.

[5] Temporary CB Resin was tested at Eurofins BioPharma Product Testing, Munich GmbH.

Permanent Crown

A validated material for comfortable, aesthetic permanent restorations

Permanent Crown Resin is a tooth-colored, ceramic-filled resin for 3D printing of permanent single crowns, inlays, onlays, and veneers. Permanent Crown Resin produces high strength, long term restorations with accurate and precise fitment. Low water absorption and a smooth finish ensure restorations have a low tendency to age, discolor, or accumulate plaque.

Permanent Crown Resin is only validated for use with the Stainless Steel Build Platform.

Permanent Restorations:

Inlays

Crowns

Veneers

Onlays

V1

FLPCA201 **FLPCB101**
FLPCA301 **FLPCC201**

*** May not be available in all regions**

Prepared 10 . 21 . 2020
Rev. 01 10 . 21 . 2020

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

MATERIAL PROPERTIES DATA

Permanent Crown Resin

VITA[1] CLASSICAL SHADES: A2, A3, B1, C2

	MEASURED VALUES	METHOD
Mechanical Properties		
Density	1.4 - 1.5 g/cm^3	BEGO Standard
Viscosity	2500 - 6000 MPa*s	BEGO Standard
Flexural Strength (post cured) [2, 3, 4]	116 MPa	EN ISO 10477, EN ISO 4049
Flexural Modulus (post cured)	4090 MPa	EN ISO 10477, EN ISO 4049
Water Solubility	0.23 µg/mm^3	EN ISO 4049
Water Sorption	3.6 µg/mm^3	EN ISO 10477

Permanent Crown Resin is a Medical Device as defined in the Medical Device Directive (93/42/EEC) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

Restorations printed with Permanent Crown Resin have been evaluated in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405:2009/(R)2015, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, and passed the requirements for the following biocompatibility risks:

ISO Standard	Description [5]
EN ISO 10993-5:2009	Not cytotoxic
ISO 10993-10:2010/(R)2014	Not an irritant
ISO 10993-10:2010/(R)2014	Not a sensitizer
ISO 10993-3:2014	Not genotoxic
ISO 10993-1:2009	Non toxic

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 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

[1] VITA is a registered trademark of a company which is not affiliated with Formlabs Inc.

[2] Material properties may vary based on part geometry, print orientation, print settings, and environmental conditions.

[3] Test samples were printed with a Stainless Steel Build Platform on a Form 3B printer with 50 µm Permanent Crown Resin settings. The printed samples were post-processed as recommended in the Instructions for Use. Screen reader support enabled.

[4] Data for post-cured samples were measured on 3 point bending test specimens according to EN ISO 10477 and EN ISO 4049 standards. Screen reader support enabled.

[5] Permanent Crown Resin was tested at Eurofins BioPharma Product Testing, Munich GmbH.

Denture Base and Teeth

Long-lasting materials for truly lifelike permanent prosthetics

Formlabs is expanding access to digital dentures with an efficient, cost-effective manufacturing solution. Class II long-term biocompatible Digital Denture Resins enable dental professionals to produce 3D printed full dentures accurately and reliably.

Dentures **Try-ins**

V1

FLDTA101 **FLDTA201** **FLDTA301** **FLDTAS01** **FLDTB101** **FLDTB201**

*** May not be available in all regions**

Prepared 09 . 16 . 2020

Rev. 01 09 . 16 . 2020

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Denture Base	METRIC [1]	METHOD
	Post-Cured [2]	
Mechanical Properties		
Flexural Strength	> 50 MPa	ISO 10477
Density	1.15 g/cm^3 < X <1.25 g/cm^3	ASTM D792-00

Denture Teeth	METRIC [1]	METHOD
	Post-Cured [2]	
Mechanical Properties		
Flexural Strength	> 65 MPa	ISO 20795-1
Density	1.15 g/cm^3 < X <1.25 g/cm^3	ASTM D792-00

Denture Base and Teeth resins were tested for biological evaluation of medical devices at WuXi Apptec, 2540 Executive Drive, St. Paul, MN, and is certified biocompatible per EN-ISO 10993-1:2009/ AC:2010:

ISO Standard	**Description**
EN-ISO 10993-3:2014	Not mutagenic
EN-ISO 10993-5:2009	Not cytotoxic
EN-ISO 10993-10:2010	Not an irritant
EN-ISO 10993-10:2010	Not a sensitizer
EN-ISO 10993-11:2006	Non toxic

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

Denture Base ISO Standards	**Description**
EN-ISO 22112:2017	Dentistry - Artificial teeth for dental prostheses
EN-ISO 10477	Dentistry - Polymer-based crown and veneering materials (Type 2 and Class 2)

Denture Theeth ISO Standards	**Description**
EN-ISO 20795-1:2013	Dentistry - Base Polymers - Part 1: Denture Base Polymers

[1] Material properties can vary with part geometry, print orientation, print settings, and temperature.

[2] Data refers to post-cured properties obtained after exposing green parts to 108 watts each of Blue UV-A (315 – 400 nm), in a heated environment at 80 °C (140 °F) and 1hr, with six (6) 18W/78 lamps (Dulux blue UV-A)

Soft Tissue Starter Pack

A color-customizable soft model material for working digital prosthetic cases

Create flexible gingiva masks for use in combination with rigid dental models. Confidently check implant prosthetics by adding removable soft tissue components to your model production. Use the Soft Tissue Starter Pack to create your own Soft Tissue Resin in customizable dark, medium, and light pink shades.

The Soft Tissue Starter Pack uses Flexible 80A Resin as a flexible base material.

Please note: Adding Color Pigments to Flexible 80A Resin to create Soft Tissue Resin will alter some of its mechanical properties.

Soft tissue for implant models

Gingiva masks

*** May not be available in all regions**

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To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.

MATERIAL PROPERTIES DATA **Soft TissueStarter Pack (Flexible 80A Resin)**

	METRIC [1]		IMPERIAL [1]		METHOD
	Green	Post-Cured [2]	Green	Post-Cured [2]	
Tensile Properties					
Ultimate Tensile Strength [3]	3.7 MPa	8.9 MPa	539 psi	1290 psi	ASTM D 412-06 (A)
Stress at 50% Elongation	1.5 MPa	3.1 MPa	218 psi	433 psi	ASTM D 412-06 (A)
Stress at 100% Elongation	3.5 MPa	6.3 MPa	510 psi	909 psi	ASTM D 412-06 (A)
Elongation at Break	100%	120%	100%	120%	ASTM D 412-06 (A)
Tear Strength [4]	11 kN/m	24 kN/m	61 lbf/in	137 lbf/in	ASTM D 624-00
Shore Hardness	70A	80A	80A	80A	ASTM 2240
Compression Set (23 °C for 22 hours)	Not Tested	3%	Not Tested	3%	ASTM D 395-03 (B)
Compression Set (70 °C for 22 hours)	Not Tested	5%	Not Tested	5%	ASTM D 395-03 (B)
Ross Flex Fatigue at 23 °C	Not Tested	>200,000 cycles	Not Tested	>200,000 cycles	ASTM D1052, (notched), 60° bending, 100 cycles/minute
Ross Flex Fatigue at -10 °C	Not Tested	>50,000 cycles	Not Tested	>50,000 cycles	ASTM D1052, (notched), 60° bending, 100 cycles/minute
Bayshore Resilience	Not Tested	28%	Not Tested	28%	ASTM D2632
Thermal Properties					
Glass transition temperature (Tg)	Not Tested	27 °C	Not Tested	27 °C	DMA

[1] Material properties can vary with part geometry, print orientation, print settings, and temperature.

[2] Data was obtained from parts printed using Form 3, 100 µm, Flexible 80A settings, washed in Form Wash for 10 minutes and post-cured with Form Cure at 60 °C for 10 minutes.

[3] Tensile testing was performed after 3+ hours at 23 °C, using a Die C specimen cut from sheets.

[4] Tear testing was performed after 3+ hours at 23 °C, using a Die C tear specimen directly printed.

SOLVENT COMPATIBILITY

Percent weight gain over 24 hours for a printed and post-cured 1 x 1 x 1 cm cube immersed in respective solvent:

Solvent	24 hr weight gain, %	Solvent	24 hr weight gain, %
Acetic Acid 5%	0.9	Mineral oil (Light)	0.1
Acetone	37.4	Mineral oil (Heavy)	< 0.1
Bleach ~5% NaOCl	0.6	Salt Water (3.5% NaCl)	0.5
Butyl Acetate	51.4	Skydrol 5	10.7
Diesel Fuel	2.3	Sodium Hydroxide solution (0.025% PH 10)	0.6
Diethyl glycol Monomethyl Ether	19.3	Strong Acid (HCl conc)	28.6
Hydraulic Oil	1.0	Tripropylene glycol monomethyl ether	13.6
Hydrogen peroxide (3%)	0.7	Water	0.7
Isooctane (aka gasoline)	1.6	Xylene	64.1
Isopropyl Alcohol	11.7		