

LOCTITE[®]

3D PRINTING

3D PRINTING MATERIAL SOLUTIONS FOR HEALTHCARE

Loctite Additive Manufacturing

Henkel

Henkel Adhesive Technologies



Introduction

LOCTITE materials have always been on the forefront of Industrial assembly and manufacturing.

As industry further embraces Additive Manufacturing as a production solution, Henkel is again at the forefront with a broad portfolio of photopolymer resins. Covering tough, specialty, high temperature resistant, elastomer, prototyping, and medical resins, the LOCTITE 3D portfolio supports a wide range of industries, applications, and use cases.

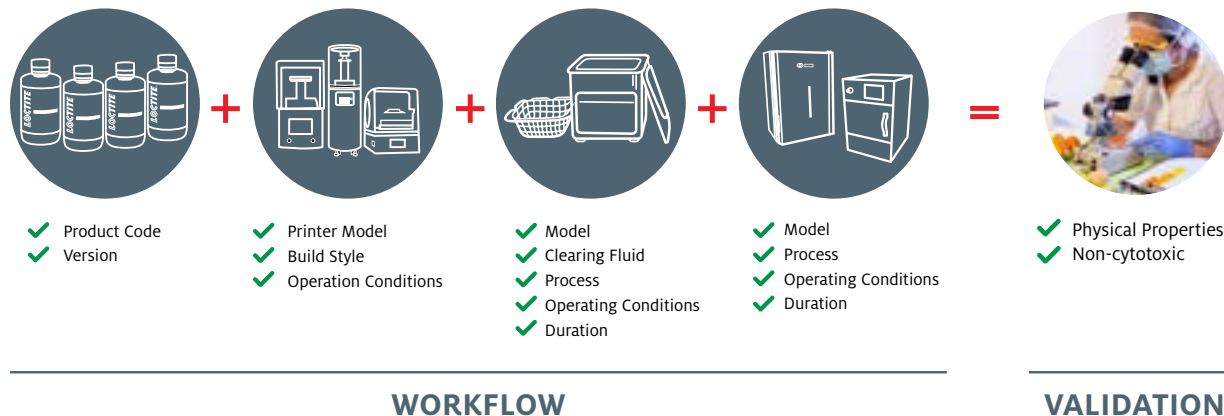
LOCTITE 3D Photopolymer materials have been validated for use on an extensive range of printers giving customers the ability to select a production solution that fits their needs. Among others, our workflow validations and extensive material testing to ASTM standards put LOCTITE in a leading position in open-source materials.

LOCTITE 3D materials are available globally, and with Henkel's legacy of business excellence, customers have the security of working with one of the world's largest industrial materials companies that is committed to bringing LOCTITE Additive Manufacturing solutions to industry.

For more information on material specifications and printer compatibility visit www.LoctiteAM.com

LOCTITE 3D Printing Resins for Healthcare Applications

MEDICAL WORKFLOW VALIDATIONS



LOCTITE Additive Manufacturing delivers high performance photopolymers with a validated workflow to ensure reproducible, repeatable results are generated in accordance with our Technical Data Sheet and test results. For medical device solutions, it is recommended to consult with the LOCTITE 3D Printing team to ensure the use of a workflow that has been validated for the intended use or specific requirements.

BIOCOMPATIBILITY

The biocompatibility of photopolymers in additive manufacturing (AM) needs to take into account the unique parameters of the manufacturing processes, which can influence the physical, chemical, and biological properties of AM-produced devices. The quality of AM-produced devices may consequently vary when identical parts are built using different materials, 3D printers or post processing steps. Here is where the importance of workflow validation comes into focus to ensure replicable biocompatibility results.

Our resins are validated across multiple DLP and LCD printing systems to fit your specific requirements. Biocompatibility (according to ISO 10993-5*, ISO 10993-10* and ISO 10993-23*) is achievable for highlighted resin when they are processed according to a validated workflow.

- **ISO 10993-5:2009*** describes test methods to assess the cytotoxicity of medical devices. These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion. These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.
- **ISO 10993-10:2021*** describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce skin sensitization on contact. ISO 10993-10:2010 includes pretest considerations for compositional screening, including in silico and in vitro methods for dermal exposure, details of in vivo sensitization test procedures and key factors for the interpretation of the results.
- **ISO 10993-23:2021*** describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation on contact. The tests are designed to predict and classify the irritation potential of medical devices, materials or their extracts according to ISO 10993-1 and ISO 10993-2.

ISO 13485 CERTIFIED QUALITY STANDARD FOR PRODUCTION FACILITY

Henkel's US laboratory and production facilities in California, USA, which are dedicated to developing and manufacturing resins for 3D printing, have achieved ISO 13485:2016 certification. ISO 13485 is an international quality standard that enables medical device manufacturers to specify and implement process and production controls, in addition to providing them with documentation and traceability. In Henkel's case specifically, it covers the design and manufacturing of biocompatible resins and other materials used to produce non-implantable medical devices.

ISO 13485 certification requires an organization to review many aspects of its operations with the goals of identifying, implementing and complying with industry quality standards and practices. Henkel engaged DQS, Inc., to conduct an audit and document a report which confirms its compliance. Areas of emphasis include:

- Design control: All processes involved with product design are identified and documented, including user needs, workflow, design inputs and outputs, verification and validation
- Process and production controls: Managed with a quality management software, including over 2,000 pages of supporting documents
- Change management control: As problems are uncovered over a product's lifecycle, processes are audited and improved to eliminate or minimize the issue
- Product traceability: Cradle to grave visibility and surveillance from raw material to finished resin and from component to final printed part
- Risk management: Each process is documented and analyzed for risk based on probability and severity

With the ISO 13485 certification, Henkel is well positioned to support medical device manufacturers. Customers in that industry can benefit from additive manufacturing and have peace of mind knowing LOCTITE's portfolio of products and validated workflows are designed, developed and manufactured with quality in mind.



LOCTITE 3D Printing Product Overview

MEDICAL RESINS

		Color	HDT at 0.455 MPa (°C)	Tensile Stress at Break (MPa)	Elongation at Break (%)	Young's Modulus (MPa)	IZOD Impact Notched (J/m)	Shore Hardness (3 sec)	Biocompatibility		
	Ideal For		ASTM D648	ASTM D638 (D412 ¹)	ASTM D638 (D412 ¹)	ASTM D638	ASTM D256	ASTM D2240	ISO 10993-5	ISO 10993-10	ISO 10993-23
MED412	<ul style="list-style-type: none"> Medical devices Medical equipment components 	Clear	40	37	110	1,300	50	70 D	✓	✓	✓
		White	40	28	100	1300	50	68 D	✓	✓	✓
MED413		Clear	70	40	50	1,600	65	76 D	✓	✓	✓
		White	69	44	55	1,800	58	72 D	✓	✓	✓
MED414	Wearables <ul style="list-style-type: none"> PPE Earbuds Medical Devices <ul style="list-style-type: none"> Hearing aid Orthoses 	Blue	-	4	240	15	-	51 A (5 sec)	✓	✓	✓
MED9851	<ul style="list-style-type: none"> Prosthetics Orthotics Eyewear 	Clear	68	45	40	2,300	50	80 D	✓	Pending	✓

For further information please see TDS, contact Technical Service Centre or Customer Service Representative. The physical properties provided in this document are typical results of printed parts and are provided for reference purposes only. All data after post-cure. HDT: Heat Deflection Temperature. ¹ Test method for Elastomer: D412. For additional information please refer to the respective TDS,

LOCTITE 3D Printing Product Overview

MEDICAL COMPATIBLE RESINS

		Color	HDT at 0.455 MPa (°C)	Tensile Stress at Break (MPa)	Elongation at Break (%)	Young's Modulus (MPa)	Flexular Modulus (MPa)	IZOD Impact Notched (J/m)	Shore Hardness (3 sec)	Tear Strength (kN/m)	Biocompatibility		
	Ideal For		ASTM D648	ASTM D638 (D412 ¹)	ASTM D638 (D412 ¹)	ASTM D638	ASTM D790	ASTM D256	ASTM D2240	ASTM D2240	ISO 10993-5	ISO 10993-10	ISO 10993-23
TOUGH													
3172	<ul style="list-style-type: none"> Medical equipment components, Manufacturing aids Jigs and fixtures Housings and covers 	Gray	52	39	100	1,500	1,100	73	63 D	-	✓		✓
3843	<ul style="list-style-type: none"> Medical equipment components Manufacturing aids Jigs and fixtures Housings and covers 	White	60	49	48	1,700	1,700	58	76 D	-	✓		✓
IND405	<ul style="list-style-type: none"> Medical equipment components Manufacturing aids Fluid routing prototypes Consumer goods prototyping 	Clear	53	38	96	1,400	1,300	72	76 D	-	✓		✓
HIGH TEMPERATURE													
IND406	<ul style="list-style-type: none"> Medical equipment components Manufacturing aids Jigs and fixtures Housings and covers 	Black	107	55	25	1,600	1,900	35	79D	-	✓		✓
ELASTOMER													
IND402	<ul style="list-style-type: none"> Grippers Other medical components 	Black	-	7	260	42	-	-	82 A (5 sec)	28			✓
IND475	<ul style="list-style-type: none"> Grippers Other medical components 	White	-	4.6	160	1.1	-	-	62 A (5sec)	13			✓

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LOCTITE 3D MED412

TOUGH HIGH IMPACT RESIN



Scan QR code to access the TDS

Strong, durable material with excellent elongation, impact strength and surface finish. It been designed to enable the manufacture of medical devices and their component parts that require good stiffness and wear resistance.

Benefits

- Capable of meeting ISO 10993-5, -10 & -23 standards for biocompatibility
- Tough with superb elongation
- Good impact strength and surface finish

PROPERTY ¹	METHOD	Clear	White
Color	-	Clear	White
HDT at 0.455 MPa (°C)	ASTM D648	40	40
Tensile Stress at Break (MPa)	ASTM D638	37	28
Elongation at Break (%)	ASTM D638	110	100
Young's Modulus (MPa)	ASTM D638	1,300	1,300
IZOD Impact Notched (J/m)	ASTM D256	50	50
Shore Hardness (D) 3 sec	ASTM D2240	70	68

Note

- When this product is used to create a Regulated Medical Device, either the User assumes all responsibility to use this product only for Henkel supported and approved Indications for Use or the User must take all responsibility to register their indication for Use with the proper regulatory authority.
- Strict adherence to our Instructions for Use and Validated Workflow is critical in assuring a safe, bio compatible and effective printed appliance.
- Henkel resins may not be used in applications that are Class III medical devices and/or involve implantation in the human body.

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Case Study: 3D Printed Nasopharyngeal (NP) Swab

RAPID AGILITY AND INNOVATION



Challenge

- Depleting supplies of NP Swabs impacting ability to test patients for Covid-19 during pandemic.
- Demand on supply resulting in longer lead times.
- Supply chain ability to respond to rapidly changing situation limited.
- Fabrication of material that does not contain any DNA to impact test.

Solution

- Consultative process to address
 - Lattice Structure Design to drive effective nasal secretion collection
 - Post process requirements
 - Sterilization techniques matched to Henkel resin
- LOCTITE 3D MED412 Resin high print accuracy & function (flexural & tensile)
- Ability to validate an FDA approved 3D printed Medical Device in short time frame

Benefit

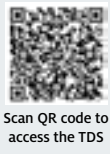
- FDA Registered Device
- Clinically validated for Safety & Conformance
- Able to print thousands of parts per week



Scan QR code for more details

LOCTITE 3D MED413

TOUGH RESIN



High-performance, high modulus material with excellent flexural and tensile physical properties. Stiffness combined with toughness make this material ideal for use in a wide variety of impact resistant medical device applications.

Benefits

- Full Biocompatibility achievable, ISO 10993 -5, -10 &-23
- Parts can function at body temperature
- Outstanding surface finish
- Excellent machineability

PROPERTY ¹	METHOD	Clear	White
Color	-	Clear	White
HDT at 0.455 MPa (°C)	ASTM D648	70	69
Tensile Stress at Break (MPa)	ASTM D638	40	44
Elongation at Break (%)	ASTM D638	50	55
Young's Modulus (MPa)	ASTM D638	1,600	1,800
IZOD Impact Notched (J/m)	ASTM D256	65	58
Shore Hardness (D) 3 sec	ASTM D2240	76	72

Note

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Case Study:

End-Use Part for Head Lice Treatment

REDUCE DEVELOPMENT AND PRODUCTION COSTS



Photos source: Enventys Partners

Challenge

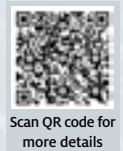
- Designing and manufacturing a new head lice treatment device offering a better user experience with improved ergonomics for technicians.
- Demand for 200-300 devices annually, and each device requiring many plastic components, the costs were unjustified.
- Achieve cost-savings without sacrificing product quality.

Solution

- LOCTITE 3843, IND403 and MED413 matched the requirements for toughness, temperature and color needs, providing high part dimensional stability and an exceptional surface finish.
- The final material is also sterilizable, allowing FloSonix to reusable tips for head lice treatment.

Benefit

- Component consolidation, adding assembly features, and final tuning parameters
- Initial prototyping and end-use manufacturing accomplished on a single printing platform (Origin)



LOCTITE MED414

HIGH ELASTOMERIC RESIN



A high-performance, soft material boasting excellent elongation and tear strength properties. Shore A hardness combined with good tear resistance and strength make this material ideal for use in a wide variety elastomeric medical device and skin contact applications.

Benefits

- Capable of meeting ISO 10993-5, -10 & -23 standards for biocompatibility
- True elastomeric behavior
- Good tear resistance
- Torsional flexibility
- Good balance of strength and elongation

PROPERTY ¹	METHOD	
Color	-	Blue
Tensile Stress at Break (MPa)	ASTM D638	4
Elongation at Break (%)	ASTM D638	240
Young's Modulus (MPa)	ASTM D638	15
Shore Hardness (A) 5 sec	ASTM D2240	51

Note

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Examining an Industry Challenge: Direct Print vs Casted Hearing Protection



Challenge

- Provide a direct print alternative to conventionally casted audiology soft materials for PPE and Hearing Aids.
- Exceed the end part functionality compared to traditional manufacturing.
- Simplify production while reducing costs and time.
- Provide customization for design specific to end user anatomy and needs.

Solution

- Development for high throughput audiology printing
 - Shore A 50 Elastomer
 - Single print process capable of production for multiple end use pairs at once
 - Eliminates need for printing of casting shell and pouring silicone material
- LOCTITE 3D MED414 offers high print accuracy and excellent surface finish.
- Ability to validate ISO 10993 requirements for biocompatibility.

Benefit

- Ease of manufacturing with higher throughput.
- Reduction of waste in production process.
- Ability to provide custom product to customer sooner and at lower cost.

LOCTITE 3D MED9851

TOUGH HIGH IMPACT RESIN



A high performance, high modulus material with excellent tensile and flexural physical properties. Stiffness combined with toughness make this material ideal for a wide variety of impact resistant medical device applications.

Benefits

- Capable of meeting ISO 10993-5, -10 & -23 standards for biocompatibility
- Parts can function at body temperature or higher
- Good impact strength and surface finish

PROPERTY ¹	METHOD	
Color	-	Clear
HDT at 0.455 MPa (°C)	ASTM D648	68
Tensile Stress at Break (MPa)	ASTM D638	45
Elongation at Break (%)	ASTM D638	40
Young's Modulus (MPa)	ASTM D638	2,300
IZOD Impact Notched (J/m)	ASTM D256	50
Shore Hardness (D) 3 sec	ASTM D2240	80

Note

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Case Study:

3D Printed Eyewear Frames

EXCELLENT PERFORMANCE
AND CUSTOMIZATION



Challenge

- Provide a digital solution to the manufacture of frames for lifestyle and prescription eyewear.
- Reduce timeline and customer cost for customized eyewear.
- Match performance criteria for conventionally manufactured eyewear with ISO12870 and ISO10993 requirements.
- Provide customization for design and color options.

Solution

- Development for high throughput eyewear printing
 - Unique design and production with partners
 - Post process requirements
 - Service Bureau and point of care production
- LOCTITE 3D MED9851 Resin high print accuracy & function (flexural & tensile).
- Ability to validate ISO12870 ophthalmic requirements compliant material for direct printing of frames.

Benefit

- Ease of design and appearance customization
- Clinically validated for Safety & Conformance
- Ability to reduce costs and turn around time for end customer

TOUGH RESIN

LOCTITE 3D 3172

TOUGH & HIGH IMPACT RESIN



Scan QR code to access the TDS

LOCTITE 3D 3843

TOUGH RESIN



Scan QR code to access the TDS

Durable photopolymer resin that enables functional parts production where high stiffness with a good surface finish and high impact resistance are required. Parts manufactured with this resin can be machined, tapped or polished.

Benefits

- For gray color: capable of meeting ISO 10993-5 & -23 standards for biocompatibility
- Tough & durable
- Superior impact strength
- Nice surface finish, machine-able

PROPERTY ¹	METHOD	
Color	-	Gray
HDT at 0.455 MPa (°C)	ASTM D648	52
Tensile Stress at Break (MPa)	ASTM D638	39
Elongation at Break (%)	ASTM D638	100
Young's Modulus (MPa)	ASTM D638	1,500
Flexular Modulus (MPa)	ASTM D256	1,100
IZOD Impact Notched (J/m)	ASTM D256	73
Shore Hardness (D) 3 sec	ASTM D2240	63

Semi-flexible resin with moderate temperature resistance, high impact strength, and versatility for a broad range of applications. Ideal for a wide variety of tooling applications on the production floor.

Benefits

- For white color: capable of meeting ISO 10993-5 & -23 standards for biocompatibility
- Moderate heat resistance, HDT 60° C
- Tough with outstanding surface finish
- Superior strength and impact resistant

PROPERTY ¹	METHOD	
Color	-	White
HDT at 0.455 MPa (°C)	ASTM D648	60
Tensile Stress at Break (MPa)	ASTM D638	49
Elongation at Break (%)	ASTM D638	48
Young's Modulus (MPa)	ASTM D638	1,700
Flexular Modulus (MPa)	ASTM D256	1,700
IZOD Impact Notched (J/m)	ASTM D256	58
Shore Hardness (D) 3 sec	ASTM D2240	76

Note

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TOUGH RESIN

LOCTITE 3D IND405

HIGH IMPACT, HIGH ELONGATION RESIN



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Rigid, high elongation and high tough one-part material with excellent surface finish properties. Properties are comparable to an unfilled thermoplastic like Polypropylene (PP).

Benefits

- For clear color: capable of meeting ISO 10993-5 & -23 standards for biocompatibility
- High impact resistance with high elongation
- Easy to print
- Tough and durable

PROPERTY ¹	METHOD	
Color	-	Clear
HDT at 0.455 MPa (°C)	ASTM D648	53
Tensile Stress at Break (MPa)	ASTM D638	38
Elongation at Break (%)	ASTM D638	96
Young's Modulus (MPa)	ASTM D638	1,400
Flexular Modulus (MPa)	ASTM D256	1,300
IZOD Impact Notched (J/m)	ASTM D256	72
Shore Hardness (D) 3 sec	ASTM D2240	76

HIGH TEMPERATURE RESIN

LOCTITE 3D IND406

OUR TOUGHEST HIGH TEMPERATURE RESIN



Scan QR code to access the TDS

Tough resin designed for interior applications in Automotive, due to its high surface quality, dimensional accuracy and temperature resistance.

Benefits

- Capable of meeting ISO 10993-5 & -23 standards for biocompatibility
- High heat deflection temperature, HDT >100 °C
- Tough and durable
- Good surface finish

PROPERTY ¹	METHOD	
Color	-	Black
HDT at 0.455 MPa (°C)	ASTM D648	107
Tensile Stress at Break (MPa)	ASTM D638	55
Elongation at Break (%)	ASTM D638	25
Young's Modulus (MPa)	ASTM D638	1,600
Flexular Modulus (MPa)	ASTM D256	1,900
IZOD Impact Notched (J/m)	ASTM D256	35
Shore Hardness (D) 3 sec	ASTM D2240	79

Note

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ELASTOMER RESIN

LOCTITE 3D IND402

HIGH REBOUND ELASTOMERS



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Single component elastomer material with high elongation and high resilience, excellent tensile strength and high energy return while also not requiring thermal post processing.

Benefits

- Capable of meeting ISO 10993-23 standards for biocompatibility
- True elastomeric behavior
- Excellent interlayer adhesion
- Good rebound performance

PROPERTY ¹	METHOD	
Color	-	Black
Tensile Stress at Break (MPa)	ASTM D412	7
Elongation at Break (%)	ASTM D412	260
Young's Modulus (MPa)	ASTM D638	42
Shore Hardness (A) 5 sec	ASTM D2240	82
Tear Strength (kN/m)	ASTM D256	28

Note

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LOCTITE 3D IND475

EASY TO PRINT



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An industrial strength UV resin that cures to a soft, elastomeric material. IND475 is suitable for applications where resilience, snap back, and tear resistance is desired, such as lattice structures and functional prototyping. This single component resin is easy to print of a variety of platforms, making it a superior material for elastomeric applications.

Benefits

- For white color: capable of meeting ISO 10993-23 standards for biocompatibility
- True elastomeric behavior
- Fast printing with low shrinkage behavior
- High resilience and energy return
- Exceptional durability compression forces

PROPERTY ¹	METHOD	
Color	-	White
Tensile Stress at Break (MPa)	ASTM D412	4.6
Elongation at Break (%)	ASTM D412	160
Young's Modulus (MPa)	ASTM D638	1.1
Shore Hardness (A) 5 sec	ASTM D2240	62
Tear Strength (kN/m)	ASTM D256	13

SUMMARY

- Every application has its own unique requirements, and we are here to support your journey towards additive manufacturing at industrial scale
- LOCTITE offers you a broad material portfolio of tough, specialty, high temperature resistant, elastomer, prototyping, and medical resins for a broad range of leading DLP and LCD systems
- We work with industry leaders and equipment manufacturers to ensure our materials are validated within a qualified industrial workflow
- LOCTITE materials allow you to produce functional, repeatable and reliable parts



Value for You



Promise of LOCTITE Branding

We leverage decades of industrial experience of solving real manufacturing challenges, across markets



Technology Experts

We are the photopolymer technology experts



Trusted Eco-System Partners

We work with ecosystem partners like service bureaus, OEM printer partner and experts in post processing to ensure production of functional, repeatable and reliable parts



Validation

Unlocking Customer Readiness with validated

- Workflows
- Materials properties/ customization
- Parts design
- Quality management system

LOCTITE®

3D PRINTING

Test your application with our materials.

Contact our engineers to get support:

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Learn more about our application cases.

Visit LoctiteAM.com



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