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Picture provided by Loctite 3DP & the Ivaldi Group

LOCTITE 3D MED414™

Elastomer
Blue

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Henkel Corporation
loctite3d@henkel.com

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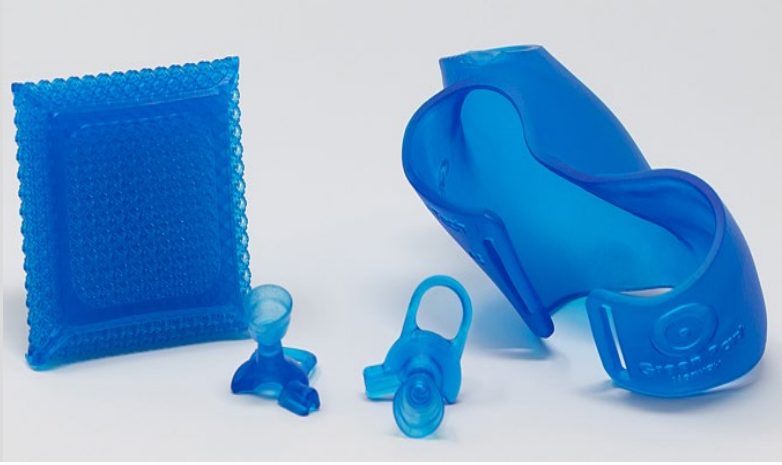


LOCTITE 3D MED414™

LOCTITE 3D MED414 is 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.

LOCTITE 3D MED414 is TPO free and capable of meeting ISO 10993-5 & -10 standards for biocompatibility when processed using a validated workflow. Certificates of Compliance are available upon request.

Benefits:

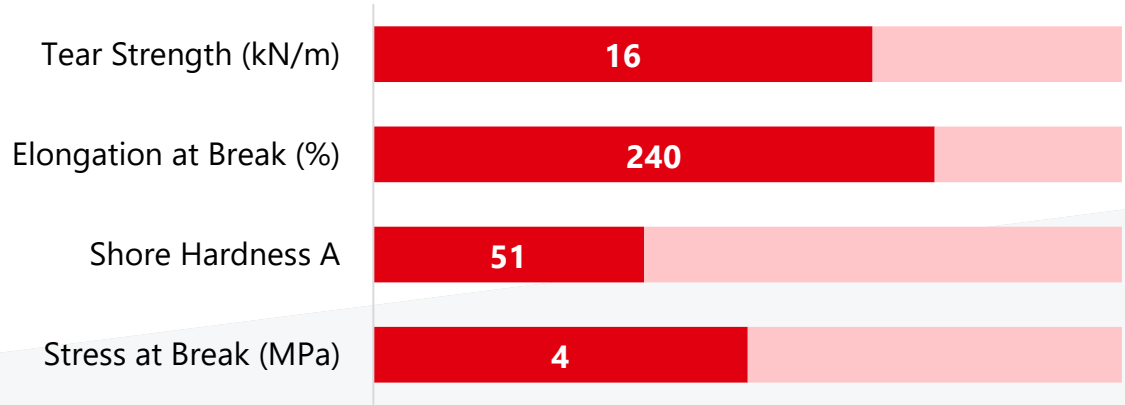
- True elastomeric behavior
- Good balance of strength and elongation
- Good tear resistance & torsional flexibility
- Good print resolution with low shrinkage

Ideal for:

- Custom fit ear device applications for the audiology, noise protection equipment and consumer audiology parts.
- Wearables
- Medical devices
- Medical equipment components

Markets:

Healthcare



**Values shown are linked to LOCTITE MED414 Blue as reference, please refer to the specific mechanical properties for each of the colors shown in this document*

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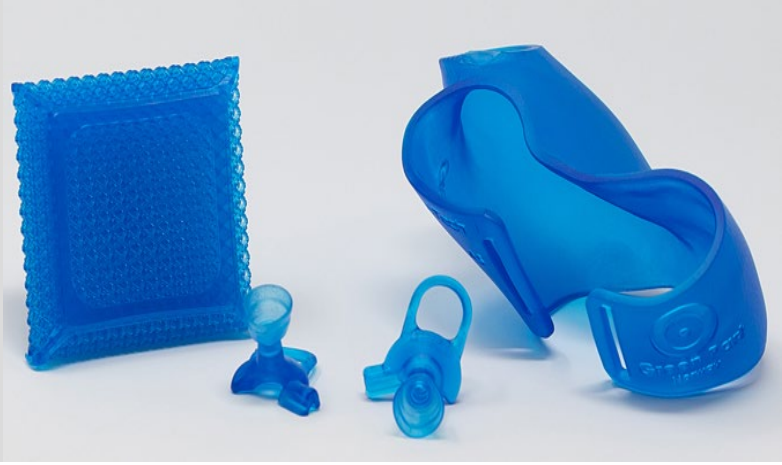

PROPERTIES

Mechanical Properties	Measure	Method	Green	Post Processed (Broad Band UV)
Stress at 50% Strain	MPa	ASTM D412	0.7-0.9 [1]	1.6-1.7 [1]
Stress at 100% Strain	MPa	ASTM D412	1.1-1.3 [1]	2.1-2.2 [1]
Stress at 150% Strain	MPa	ASTM D412	1.4-1.7 [1]	2.7-2.8 [1]
Elongation at Break	%	ASTM D412	215-230 [1]	220-240 [1]
Stress at Break	MPa	ASTM D412	2.3-2.6 [1]	3.5-4 [1]
Tear Strength	kN/m	ASTM D624	7.5-8.5 [1]	13.5-16 [1]
Young's Modulus	MPa	ASTM D638	3-5 [1]	9-15 [1]
Tensile Stress at Break	MPa	ASTM D638	1.2-1.5 [1]	2.5-2.8 [1]
Tensile Elongation at Break	%	ASTM D638	160-170 [1]	170-190 [1]
Tensile Stress at Yield	MPa	ASTM D638	*N/A*	*N/A*
Other Properties				
Energy Return	%	Internal	*N/A*	50 [2]
Shore Hardness (5 sec)	A	ASTM D2240	32 [3]	51 [4]
Water Absorption (24 hr)	%	ASTM D570	*N/A*	3.0 [5]
Solid Density	g/cm^3	ASTM D1475	1.06 [6]	1.02 [6]

Liquid Properties	Measure	Method	Value
Viscosity at 25°C (77°F)	cP	ASTM D7867	1600 - 3000 [7]
Liquid Density	g/cm^3	ASTM D1475	1.0 [8]

Biocompatibility	Method	Value
Cytotoxicity	ISO 10993-5	Comply [10]
Sensitization	ISO 10993-10	Comply [11]
Irritation	ISO 10993-23	Comply [11]

"All specimen are printed unless otherwise noted. All specimen were conditioned in ambient lab conditions at 19-23°C / 40-60% RH for at least 24 hours."
ASTM Methods and Parameters: D638-14 Type IV, 50 mm/min, D412-16 (21) Die C Shape, 3 mm thickness, 500 mm/min, D624, 500 mm/min

Internal Data Sources:

[1] GEN1092, [2] FOR42131, [3] FOR43680, [4] FOR42122, [5] FOR42148, [6] FOR42136, [7] GEN794243, [10] FOR52316, [11] FOR157979, [7] FOR42660, [8] FOR42136, [10] GEN250788, [11] FOR157979,

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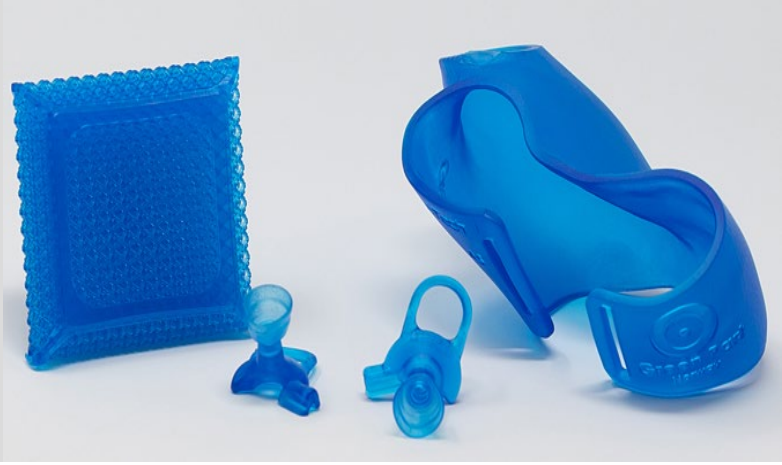

WORKFLOW

Validated workflows need to be followed to achieve properties as provided in the TDS. Examples of validated workflow steps are listed below. Users should defer to the most current workflow information for best results which can be found at https://www.loctiteam.com/printer-validation-settings

PRINTER SETTINGS

LOCTITE 3D MED414 BL is formulated to print optimally on industrial DLP printer. Read the safety data sheet carefully to get details about health and safety instructions. Recommended print parameters:

- Shake resin bottle well before usage
- Temperature: 20°C to 35°C
- Intensity: 3 mW/cm^2, higher intensities can result in reduced surface quality and mechanical properties

Settings: 385nm at 3mW/cm^2	Measure	Method	Value
Layer Thickness	µm	Internal	100
Burn-in Region	s	Internal	30
Transition Region	s	Internal	25
Model Region	s	Internal	12-16

Settings: 385nm at 3mW/cm^2	Measure	Method	Value
E_C	mJ/cm^2	Internal	9 [9]
D_P	mm	Internal	0.13 [9]

Settings: 385nm at 3mW/cm^2	Measure	Method	Exposure time
D_C = 50µm	s	Internal	5.7
D_C = 100µm	s	Internal	7.5

Test parameters:
*Exposure times are calculated without a safety factor

Internal data source:
[9] FOR42274

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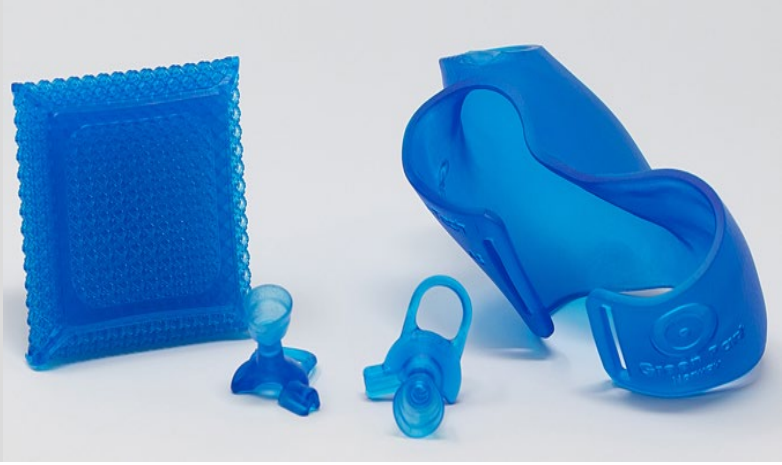

WORKFLOW

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CLEANING

LOCTITE 3D MED414 BL requires post processing to achieve specified properties. Prior to post curing, support structures should be removed from the printed part, and the part should then be washed. Use compressed air to remove residual solvent from the surface of the material between intervals.

Post Process Step	Agent	Method	Duration	Intervals	Additional Info
Cleaning Cycle 1	IPA	Ultra sonic bath	2 min	1	Allow parts to dry between intervals
Cleaning Cycle 2	IPA	Ultra sonic bath	2 min	1	Use fresh IPA
Dry	n.a.	Compressed air	10 to 60 s	2	Air pressure (50psi)
Wait before post curing	n.a.	Ambient condition	60 min	1	Room temperature

POST CURING

LOCTITE 3D MED414 BL requires post curing to achieve specified properties. A wide array of post cure equipment can be used to cure appropriately. See Validation chart for examples of type and time. Exact devices with detailed information can be found by contacting us at www.loctiteAM.com.

UV Curing Unit	UV Source	Intensity	Cure time per side	Additional Settings (Shelf, Output Energy)
Loctite UVALOC 1000	Mercury Arc Bulb (broad spectrum)	50 mW/cm^2 at 380 nm	5min	500 W 2nd Shelf from bottom

STORAGE

Store LOCTITE MED414 BL in the unopened container in a dry location. Optimal Storage: 8°C to 30°. Storage below 8°C or above 30°C can adversely affect product properties. Material removed from containers may be contaminated during use. For this reason, filter used resin with 190µm mesh filter before placing back into proper storage container.

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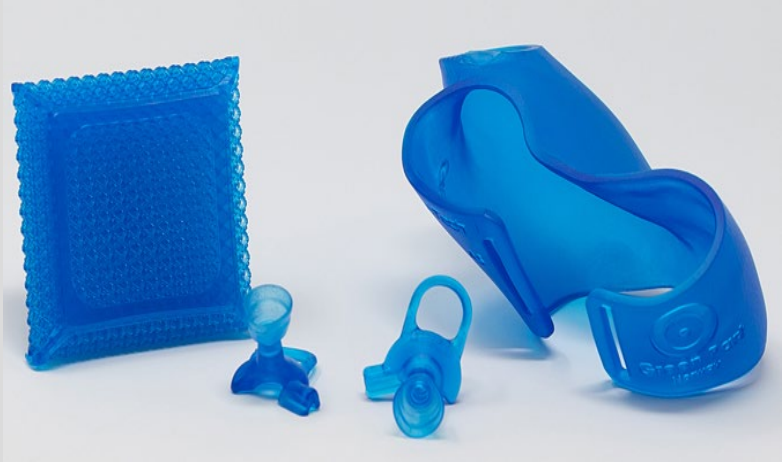

SUPPLEMENTARY PRINTER SETTINGS

LOCTITE 3D MED414 BL requires detailed attention to interactions between the material and the hardware in use. Mechanical process settings must be optimized for each printer based on the hardware and software capabilities. Due to the low durometer and high elasticity of the material, printed parts may sway during tray release, build head movement, and upon re-entering the resin. For this reason, the user must consider many variables while printing. Some applicable print process considerations and respective guidelines are discussed below. Critical considerations include adhesion behavior at the print interface, model geometry, and model print orientation.

Lift Height Between Layers: Larger parts may require larger lift heights due to overall elongation magnitude.

- Small parts (<25 mm height): 10-15 mm
- Medium parts (25 - 100 mm height): 20-25 mm
- Large parts (>100mm height): 25-30 mm

Build Head Movement Rates: Thicker parts allow for more rapid rates due to overall part rigidity compared to printing forces.

- Low Thickness (<5 mm thickness): 3-5 mm/second
- Medium Thickness (5-10 mm thickness): 3-10 mm/second
- High Thickness (>10 mm thickness): 3-20 mm/second

Time Delay Before Layer Exposure:

- Generally, 5-8 seconds is sufficient due to the resin's high viscosity. Parts with thin features may require longer times for the small features to return to the correct position as they normalize with the resin's viscosity forces.

Support Structures:

- Place supports on non-critical model surfaces if possible. Support structure placement and geometry is model-dependent based on model layer surface area. General recommendations are provided.
- Support Thickness: 0.2-0.8 mm diameter
- Support Contact Area: 25-75% support thickness

Other:

- Ensure the printer is level. Gravitational forces may influence sway and part positioning due to the low durometer.
- Build heads with mechanical adhesion features such as perforations will improve print success for parts with large surface areas. Additionally, if build head adhesion failures are observed during a print, consider generating a base with a larger surface area or increasing base and burn-in layer exposure times.

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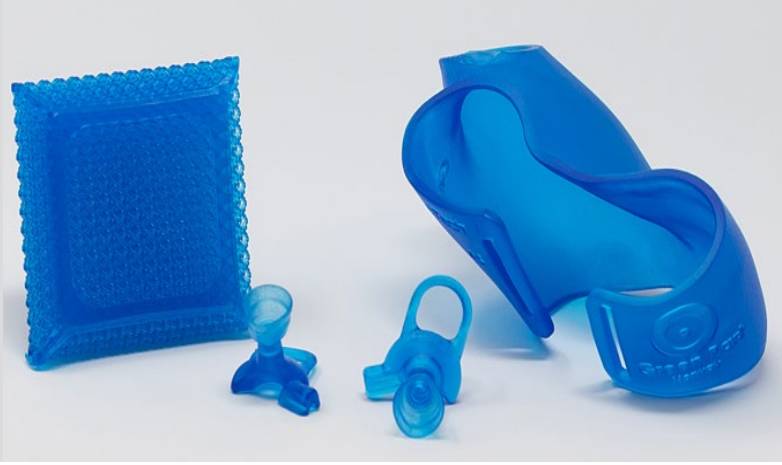

ADDITIONAL DEVELOPMENT OPTIONS

Colors: LOCTITE 3D MED414 BL formula is made with additional pigment colors

LIMITATIONS

Vat Printer: LOCTITE 3D MED414 BL formula shows limited path forward for Vat printers.

LCD printers: LOCTITE 3D MED414 BL formula may be compatible with LCD Printers using long exposure times.

BIOCOMPATIBILITY

Printed parts were prepared in accordance with the instructions provided in this document and submitted to an external lab for evaluation in accordance with ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

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 of use with the proper regulatory authority. Strict adherence to our information for use and validated production workflows (printer, washing, and post processing procedures), is critical in assuring a safe, biocompatible and effective printed appliance.

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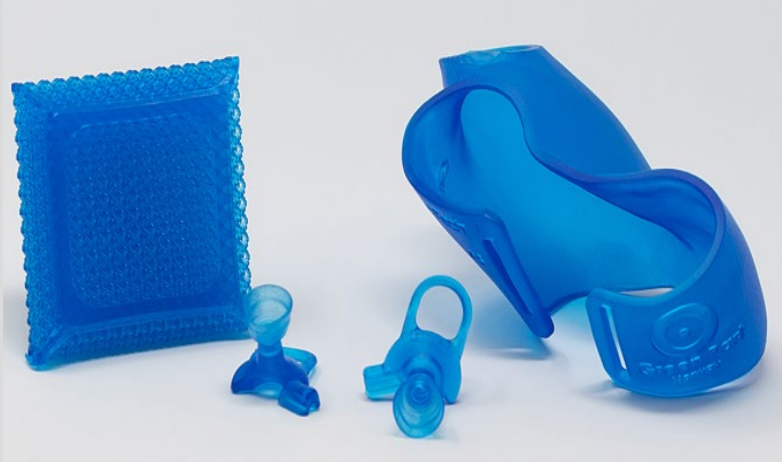
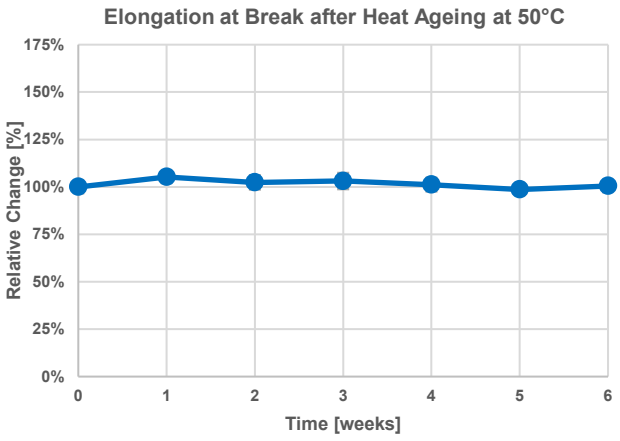
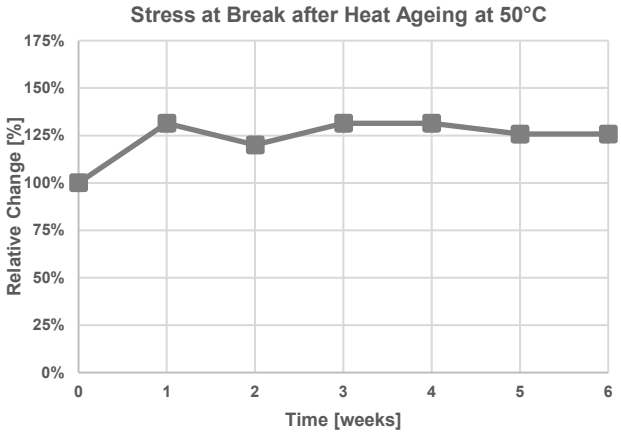


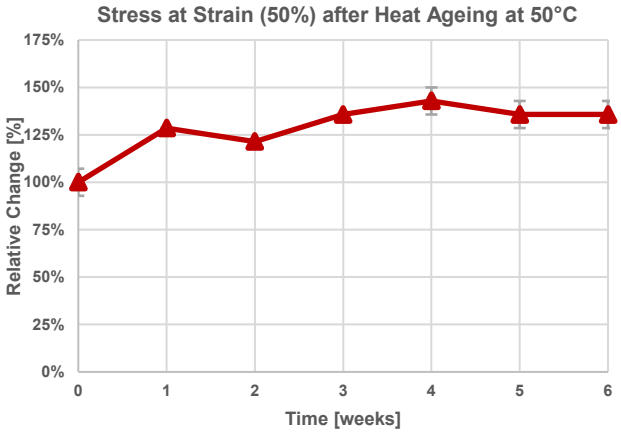
AGEING AND ENVIRONMENTAL EFFECTS – HEAT AGEING

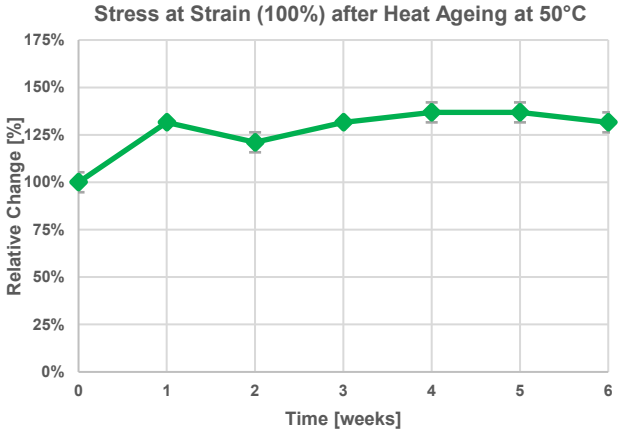
LOCTITE 3D MED414 BL was heat aged without load according to ASTM D3045. Test samples were exposed for a defined time at 50°C and conditioned for 24 hours at 22°C before mechanical testing. Control samples were stored at a constant 22°C. All samples were printed in the same print job using a validated workflow. Mechanical testing was conducted according to ASTM D412 at standard lab conditions (22°C). "0 weeks" represents non-aged samples stored at 22°C and tested 24 hours after post-processing.

Based on temperature dependence of reaction rates a test time of 6 weeks at 50°C can be interpreted as approximately 12 months at ambient temperature.









Test parameters:
ASTM D412: Type Die C, Pull speed: 500 mm/min, 22°C

Internal Data Sources:
FOR220974, FOR220970

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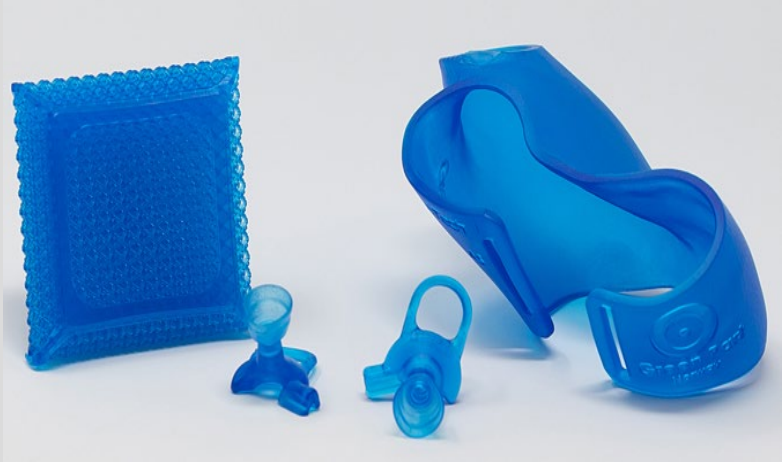
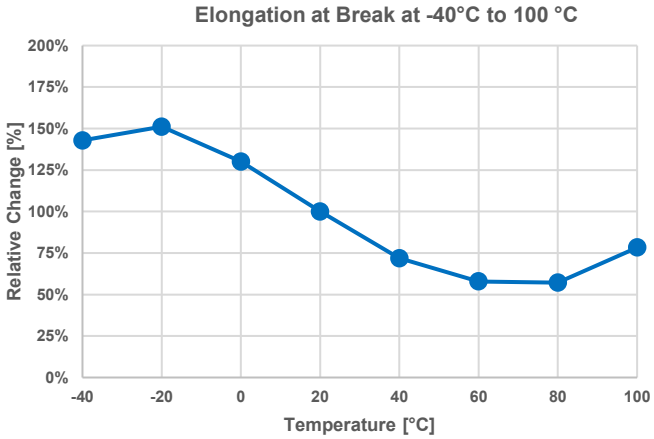
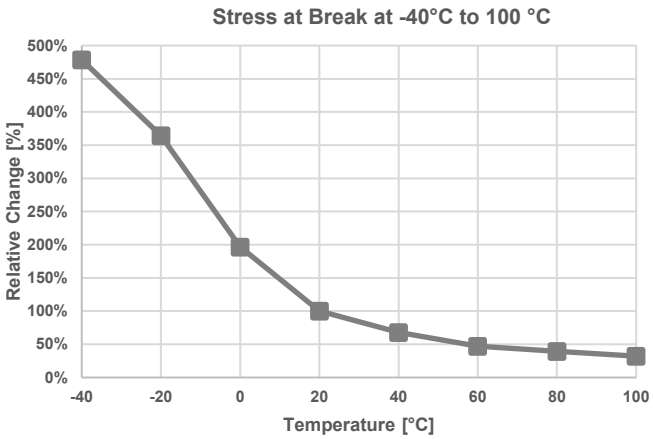


THERMAL INFLUENCE ON MECHANICAL PROPERTIES

LOCTITE 3D MED414 BL has been tested according to ASTM D412 at varied environmental temperatures, from -40°C to 100°C. All samples were printed in the same print job using a validated workflow. Mechanical testing was conducted according to ASTM D412. Before each test series samples were conditioned for 60 minutes at the specific test temperature.





Test parameters:
ASTM D412: Type Die C, Pull speed: 500 mm/min

Internal Data Sources:
FOR137768

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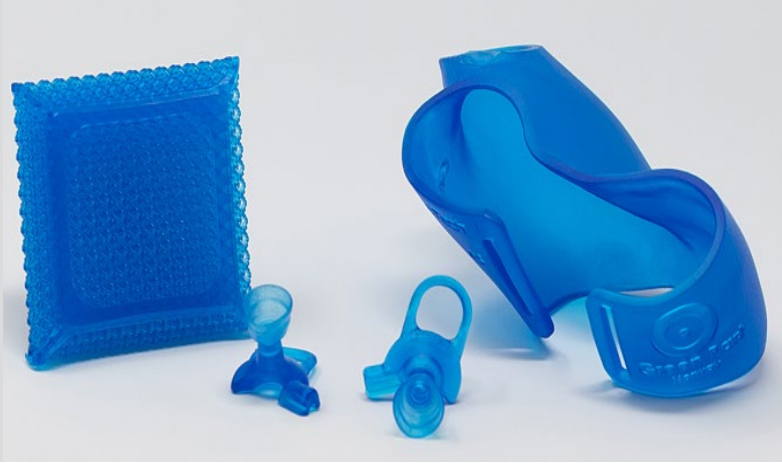
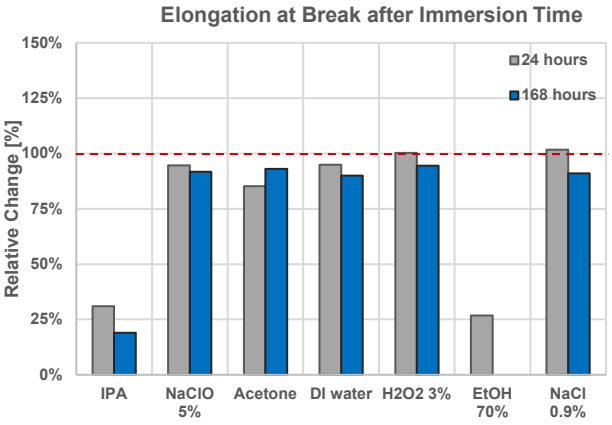
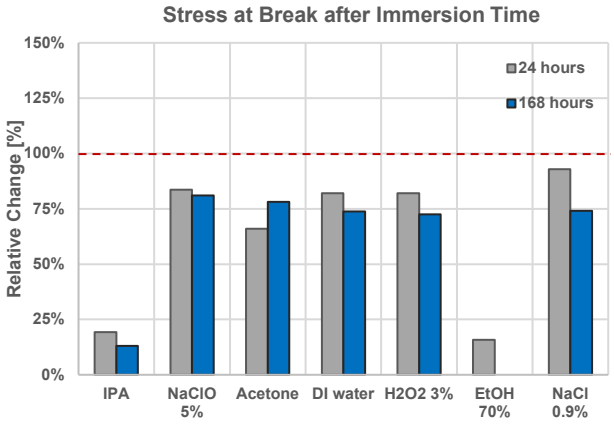


AGEING AND ENVIRONMENTAL EFFECTS – MEDICAL CHEMICAL RESISTANCE

LOCTITE 3D MED414 BL has been tested after chemical ageing according to ASTM D543. The influence of chemicals was tested by measuring mechanical properties after different test times (Immersion test for 24 and 168 hours). Exposed samples were stored in containers and fully immersed in different chemicals. Samples were stirred every 24 hours using a shaker. After removal, exposed samples were washed and conditioned for 24 hours at 22°C before mechanical testing. All samples were printed using a validated workflow. Mechanical testing was conducted according to ASTM D412 at standard lab conditions (22°C).

The 100% value represents the initial weight 24 hours after post-processing.





Test parameters:
ASTM D412: Type C, 22°C, Pull speed: 500 mm/min
ASTM D543: Samples immersed in different chemicals were stored at 22°C. Properties of media used: pH(H_2O_2 3%) = 2; pH(NaClO 5%) = 13

Internal Data Sources:
FOR713415, FOR713417, FOR713574, FOR713576, FOR716029, FOR716030, FOR716031

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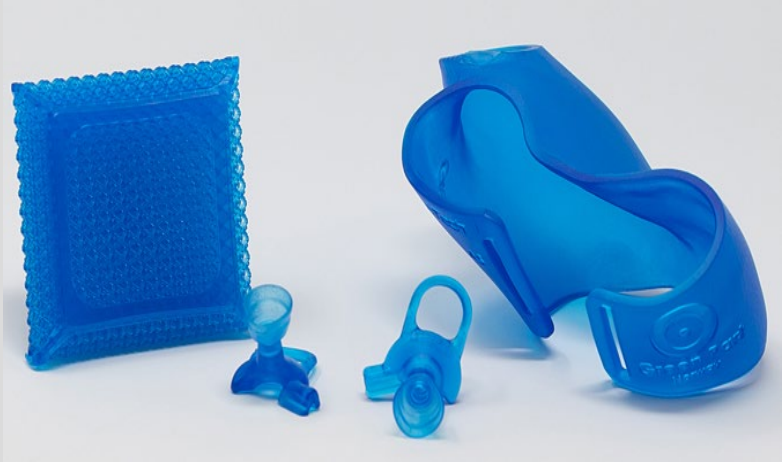
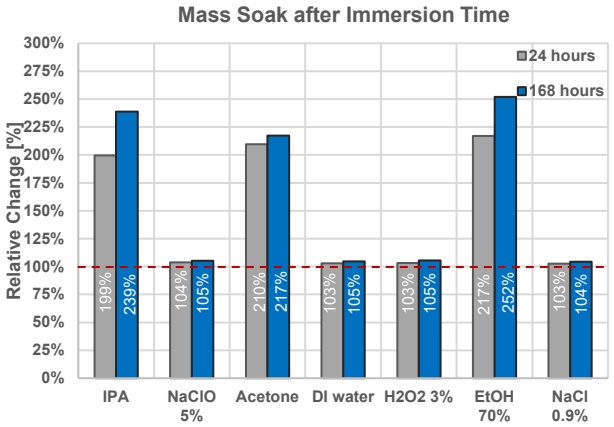


AGEING AND ENVIRONMENTAL EFFECTS – MEDICAL CHEMICAL MASS SOAK

LOCTITE 3D MED414 BL has been tested after chemical ageing according to ASTM D543. The influence of chemicals was tested by measuring the mass change after different test times (Immersion test for 24 and 168 hours). Exposed samples were stored in containers and fully immersed in different chemicals. Samples were stirred every 24 hours using a shaker. After removal exposed samples were washed, dried and immediately weighed. All samples were printed using a validated workflow.

The 100% value represents the initial weight 24 hours after post-processing.



Test parameters:
ASTM D543: Samples immersed in different chemicals were stored at 22°C. Properties of media used: pH(H_2O_2 3%) = 2; pH(NaClO 5%) = 13

Internal Data Sources:
FOR713415, FOR713417, FOR713574, FOR713576, FOR716029, FOR716030, FOR716031

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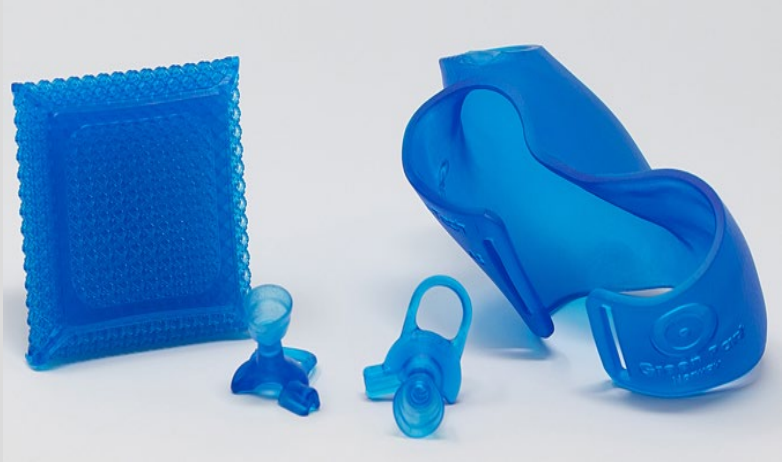

NOTE

The information provided in this Technical Data Sheet (TDS) including the recommendations for use and application of the product are based on our knowledge and experience of the product as at the date of this TDS. The product can have a variety of different applications as well as differing application and working conditions in your environment that are beyond our control. Henkel is, therefore, not liable for the suitability of our product for the production processes and conditions in respect of which you use them, as well as the intended applications and results. We strongly recommend that you carry out your own prior trials to confirm such suitability of our product.
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