

LOCTITE®

Biocompatible Solutions

Adhesives for Medical Device Assembly



Excellence is our Passion



LOCTITE Adhesives for Medical Device Manufacturing

Henkel offers long term experience in the medical device market and provides a complete range of LOCTITE adhesives for the medical device industry. Including instant, light cure and structural adhesives along with flexible adhesives and sealants, we offer a broad range of products that are certified to comply with ISO 10993.

What does Henkel offer you for your medical devices?	
Biocompatibility	Medical device adhesives in compliance with the industry's most comprehensive ISO 10993 biocompatibility standards*
Henkel global presence	Local on-site support with global connection
Operational excellence	Solutions for lower overall process cost and increased efficiencies
Technology breadth	Turnkey solutions due to a wide range of adhesives, equipment and services
Sterilisation resistance	Multiple products suitable for your specific sterilisation need (ETO, Gamma radiation, Steam)
Freedom in design	Unrestricted material selection (e.g. color/substrate) and geometry (e.g. size/shape)

* Certificates of Compliance to ISO 10993 (Acute Systemic, Muscle Implantation and Intracutaneous, Cytotoxicity and Hemolysis) are available at www.loctite.com

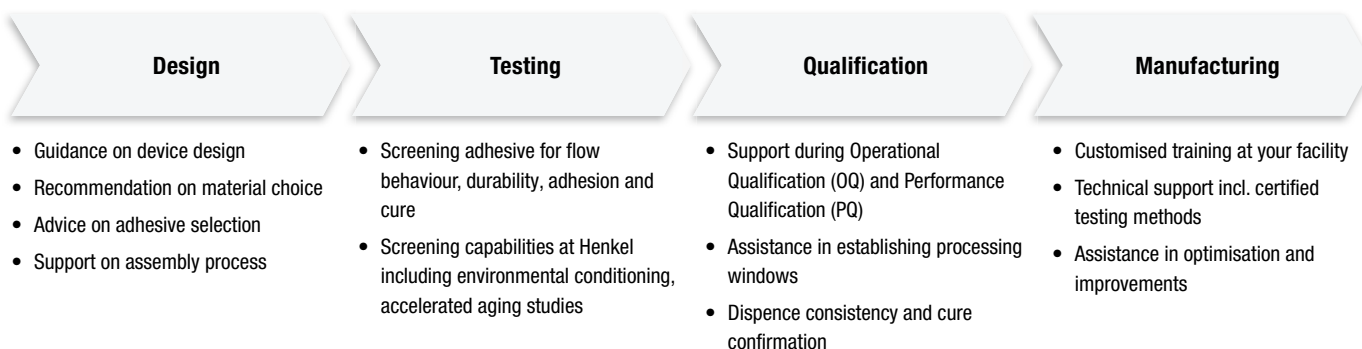


Manufacturing Process and Product Selection

Henkel's approach to new projects is always focused on your specific requirements, the design of your device and individual manufacturing environments. We select compatible solutions for your technology and process based on many different criteria such as design of your device, process fitting, documentation, in-line testing, invisible bondline, curing equipment, strength and many more.

Henkel Value Chain:

All these criteria play a crucial role in finding the best possible adhesive solution. Our adhesive specialists assist you not only in the adhesive selection, but along the entire value chain from design to testing and training.





Cyanoacrylate Adhesives

LOCTITE cyanoacrylates are high-performance, instant adhesives designed for the most challenging applications. They offer excellent adhesion to a wide variety of substrates and are ideal for joining plastics such as ABS, PVC, polycarbonate, styrene, acrylic and thermosets as well as elastomers such as latex, TPU, TPE and PUR. By using the primer LOCTITE 7701, even difficult to bond materials such as polypropylene, polyethylene and other low energy rubbers and plastics can be bonded to obtain maximum adhesion.

Key strengths:

- High speed cure
- High strength
- Adhesion to most materials

Product	Pack Size	Viscosity (mPa·s)	Sterilisation Methods	Max Gap	Properties	Suitable Substrate
4011	20 g, 454 g	100	ETO, Gamma radiation	0.1 mm	Colour: clear Low viscosity	Rubber, urethane, foam, porous and other difficult to bond substrates
4014	20 g, 454 g	3	ETO, Gamma radiation	0.05 mm	Colour: clear Low viscosity Wicking grade	Rubber, plastics, metals
4031	20 g, 454 g	1,300	ETO, Gamma radiation	0.05 mm	Colour: clear High viscosity Low odour, low bloom	Rubber, plastics, metals Appearance sensitive applications
4061	20 g, 454 g	20	ETO, Gamma radiation	0.1 mm	Colour: clear Low viscosity	Rubber, plastics, metals
4081	20 g	5	ETO, Gamma radiation	0.05 mm	Colour: clear Low viscosity Wicking grade Low odour, low bloom	Rubber, plastics, metals Appearance sensitive applications
4541	10 g, 200 g	Gel	ETO, Gamma radiation	0.5 mm	Colour: clear Non migrating gel	Rubber, urethane, foam, porous and other difficult to bond substrates
4601	20 g, 454 g	50	ETO, Gamma radiation	0.1 mm	Colour: clear Low viscosity Low odour, low bloom	Rubber, plastics, metals Appearance sensitive applications
New! 4902	20 g	200	ETO, Gamma radiation	0.1 mm	Colour: clear Highly flexible	For flexible plastics and elastomers



Light Cure Cyanoacrylate Adhesives, Activators and Primers for Cyanoacrylates

This range of adhesives combines the advantages of the cure on demand light cure technology with the features of instant adhesives. This benefit is especially useful for applications where a secondary moisture cure is required, allowing the adhesive to cure completely in shadowed areas (where light cannot reach). Exposure to low intensity UV or visible light provides tack-free surfaces in less than five seconds.

Key strengths:

- Very high speed cure
- “On demand” cure, combined with shadow cure
- Low stress cracking, low blooming

Light Cure Cyanoacrylates

Product	Pack Size	Viscosity (mPa-s)	Sterilisation Methods	Max Depth of Cure	Properties	Suitable Substrate
4304	20 g, 454 g	20	ETO, Gamma radiation	4 mm	Colour: light amber	Rubber, plastic, metals
4305	20 g, 454 g	900	ETO, Gamma radiation	4 mm	Colour: light amber	Rubber, plastic, metals
4306	20 g, 454 g	20	ETO, Gamma radiation	4 mm	Fluorescent	Rubber, plastic, metals
4307	20 g, 454 g	900	ETO, Gamma radiation	4 mm	Fluorescent	Rubber, plastic, metals

Primer for Cyanoacrylates

Product	Pack Size	Viscosity (mPa-s)	Sterilisation Methods	Max Gap	Properties	Suitable Substrate
7701	35 g, 300 g	1.25	ETO, Gamma radiation	N/A	Liquid	Polyolefins e.g. polyethylene, polypropylene, thermoplastic elastomers and other difficult to bond substrates

Activators for Cyanoacrylates

Product	Pack Size	Viscosity (mPa-s)	Sterilisation Methods	Max Gap	Properties	Suitable Substrate
713	40 g	1	ETO, Gamma radiation	N/A	Very fast fixture	Accelerates the fixturing time with all instant adhesives
7451	40 g, 360 g	3	ETO, Gamma radiation	N/A	Fast fixture	Accelerates the fixturing time with all instant adhesives

Light Cure Acrylic Adhesives

These products offer the most extensive variety of properties of all light cure chemistries. Upon exposure to suitable UV and/or visible light, acrylics produce tough, durable thermoset polymers. Cured properties range from hard and rigid to soft and flexible. Easily automated, fluorescent versions allow in-line detection of the adhesive.

Key strengths:

- High speed cure/"on demand" cure by light cure system
- High strength
- Designed for automated dispensing & curing applications

Product	Pack Size	Viscosity (mPa-s)	Sterilisation Methods	Max Depth of Cure	Properties	Suitable Substrate
AA 3011 LC	1 l	100	ETO, Gamma radiation	4 mm	Colour: clear	Stainless steel, thermoset and thermoplastics
AA 3081 LC	1 l, 15 l	100	ETO, Gamma radiation	4 mm	Colour: clear Fluorescent	Stainless steel, thermoset and thermoplastics
AA 3211 LC	25 ml, 1 l	10,000	ETO, Gamma radiation, Steam	13+ mm	Colour: clear	Polycarbonate, acrylic and other thermoplastics where a flexible joint is desired
AA 3936 LC	25 ml	10,000	ETO, Gamma radiation, Steam	13+ mm	Colour: clear Fluorescent	Polycarbonate, acrylic and other thermoplastics where a flexible joint is desired
AA 3301 LC	25 ml	150	ETO, Gamma radiation, Steam	13+ mm	Colour: clear	Metals and plastics, best on rigid and flexible PVC, giving a flexible joint
AA 3921 LC	25 ml, 1 l	150	ETO, Gamma radiation, Steam	13+ mm	Colour: clear Fluorescent	Metals and plastics, best on rigid and flexible PVC, giving a flexible joint
AA 3311 LC	25 ml, 1 l	300	ETO, Gamma radiation, Steam	13+ mm	Colour: clear	Metals and plastics, best on rigid and flexible PVC, giving a flexible joint
AA 3922 LC	25 ml, 1 l	300	ETO, Gamma radiation, Steam	13+ mm	Colour: clear Fluorescent	Metals and plastics, best on rigid and flexible PVC, giving a flexible joint
AA 3321 LC	25 ml, 1 l	5,000	ETO, Gamma radiation, Steam	13+ mm	Colour: clear	Metals and plastics, best on rigid and flexible PVC, giving a flexible joint
AA 3926 LC	25 ml, 1 l	5,000	ETO, Gamma radiation, Steam	13+ mm	Colour: clear Fluorescent	Metals and plastics, best on rigid and flexible PVC, giving a flexible joint
AA 3341 LC	25 ml, 1 l	450	ETO, Gamma radiation, Steam	13+ mm	Colour: clear Fluorescent	Best on highly plasticised PVC, giving a flexible joint
AA 3345 LC	1 l	1,500	ETO, Gamma radiation, Steam	4 mm	Colour: clear	Glass and metals
AA 3971 LC	1 l, 15 l	300	ETO, Gamma radiation	13+ mm	Colour: clear Fluorescent	Stainless steel, thermoset and thermoplastics
AA 3972 LC	15 l	4,500	ETO, Gamma radiation	13+ mm	Colour: clear Fluorescent	Stainless steel, thermoset and thermoplastics



Epoxy Adhesives

LOCTITE epoxies provide high peel and shear strength on a wide variety of metals and plastics. When cured, these crosslinking thermoset polymers offer superior thermal and chemical resistance, as well as high cohesive strength and minimal shrinkage. LOCTITE epoxy two-part systems are packaged in side-by-side cartridges, allowing them to be dispensed as easily as any one-part system.

Key strengths:

- Very high strength
- Wide variety of materials
- Withstands ETO, gamma & steam sterilisations

One Component Heat Cured

Product	Pack Size	Viscosity (mPa·s)	Sterilisation Methods	Max Gap	Properties	Suitable Substrate
EA 9535	1 l	18,000	ETO, Gamma radiation, Steam	1 mm	Colour: white fluorescent Low temperature cure (>80 °C)	Metals, ceramics, glass, rigid plastics

Two Components

Product	Pack Size	Viscosity (mPa·s)	Sterilisation Methods	Max Gap	Properties	Suitable Substrate
EA M-21HP	50 ml	37,000 (mixed)	ETO, Gamma radiation, Steam	1 mm	Colour: off-white tough	Metals, ceramics, glass, rigid plastics
EA M-31CL	50 ml, 200 ml	6,000 (mixed)	ETO, Gamma radiation, Steam	0,5 mm	Colour: clear Low viscosity	Metals, ceramics, glass, rigid plastics
EA M-121HP	50 ml	11,000 (mixed)	ETO, Gamma radiation, Steam	1 mm	Colour: amber Peel resistant	Metals, ceramics, glass, rigid plastics

Silicone Adhesive

LOCTITE silicones cure to soft, flexible, thermoset elastomers when exposed to UV light. Due to its light cure mechanism, this product enables fast fixturing which results in enhanced productivity.

Key strengths:

- High flexibility
- Fast fixture
- Withstands ETO, gamma & steam sterilisations

Product	Pack Size	Viscosity (mPa·s)	Sterilisation Methods	Max Gap	Properties	Suitable Substrate
SI 5248	300 ml	50,000	ETO, Gamma radiation, Steam	6 mm	Colour: clear/translucent Flowable	Extrudable and mouldable silicones, stainless steel, glass and aluminium

In addition to the products listed above, we have a full range of general industry adhesives commonly used in the medical devices market. Please visit www.loctite.com



Dispensing Equipment

The state-of-the-art combination of modular LOCTITE equipment modules guarantees dispensing at highest reliability standards, as required for medical goods. The equipment modules have been proven in many medical assembly lines throughout the world, proving excellent compatibility to LOCTITE adhesives.

Standalone system

System designed for single user manual workstations. Suitable for dispensing microdots, drops or beads of low to high viscosity products.



LOCTITE 97009 / LOCTITE 97201

Line integrated system

System designed for integration into automated assembly lines. It can be externally triggered by a PLC or robot control. Suitable for dispensing microdots, drops or beads of low to high viscosity products.



LOCTITE 97152 / LOCTITE 97108 / LOCTITE 97201

Peristaltic Dispenser

System designed for single use workstations. Air-pressure-free dispensing, easy to clean. Suitable for dispensing microdots, drops or beads of low to high viscosity products, especially for cyanoacrylates.



LOCTITE 98548

Jet Valve Dispenser

System designed for integration into automated assembly lines. Suitable for contact-less dispensing of microdots, drops or beads of low to high viscosity products, especially for light cure acrylics.



New!

LOCTITE 1850212



Curing Equipment

Four major effects must be taken into consideration when designing a successful light cure application: emission spectrum of the cure system, light intensity, transmission properties of substrate and required cure characteristics. As a manufacturer of both the chemistry and the curing equipment, Henkel knows how to match cure applications to the correct adhesive as well as the correct curing system. LOCTITE LED cure systems are high intensity, long lifetime systems designed for curing LOCTITE light cure adhesives. Using modern LED technology these systems provide “cool” radiation in narrow bandwidth.

LED Spot Cure

LOCTITE LED Spot Cure, designed for radiation of one to four spots with very high intensity of UVA light.



LOCTITE 97079

LED Flood Cure System

LOCTITE LED Flood Cure, designed for homogeneous radiation of areas (100 x 100 mm) of high intensity.



LOCTITE 97070 (UVA); LOCTITE 97071 (UV VIS)

Cure chamber for LED flood

Cure chamber for convenient use of light cure radiation systems, especially in manual workstations. It is designed to be combined with the LED flood systems 97070 and 97071.



LOCTITE 97360

Dosimeter

The Dosimeter-Radiometer measures light dose (energy) and light intensity of the UV curing equipment and is a self-contained one channel device. LOCTITE 98787 for UV A light, LOCTITE 98770 for UV VIS light.



LOCTITE 98787 (UVA); LOCTITE 98770 (UV VIS)



Biocompatibility

Each of the medical device adhesives listed in this brochure is tested according to the Henkel Medical Device Adhesive Testing Protocol. In addition, Henkel employs strict manufacturing and quality controls to ensure continuity of compliance.

Henkel medical device adhesives are tested according to:

- Intracutaneous injection (ISO 10993-10)
- Systemic injection (ISO 10993-11)
- Muscle implantation (ISO 10993-6)
- Cytotoxicity (MEM elution) (ISO 10993-5)
- Hemocompatibility (ISO 10993-4)
- Physicochemical (USP)

Frequently Asked Questions & Answers:

What is ISO 10993?

ISO 10993 is an international standard created to facilitate international harmonisation of test methods for biocompatibility evaluation of medical devices.

What is the difference between ISO 10993 and USP?

ISO 10993 standards offer compliance at a global level. USP offers compliance to the United States Pharmacopeia, which historically was created first.

Is there a regulation requiring Henkel to revalidate its medical device adhesives to ISO 10993 on a regular basis?

There is no specific regulatory requirement regarding revalidation of our medical device adhesives. Henkel, as the industry leader, believes the revalidation is an important service to our customers in assuring continuity of compliance.

What controls does Henkel have in place after the product has been tested to ISO 10993?

While Henkel has no specific regulatory obligations under ISO 10993, we perform the following:

- Each batch of LOCTITE medical device adhesive is validated by Henkel's Quality Control Department to include all raw material inputs, intermediates and raw material manufacturers, as well as compliance to the product performance specification.
- Ensure that no changes will be made to composition materials, nor significant changes to our processes, without notifying customers who have a specification on file with the Henkel Quality Department requesting such notification.

Adhesive Property Comparison

Performance Considerations	Adhesive Category			
	Cyanoacrylates	Epoxies	Light Cure Acrylics	Silicones
Benefits	Broad adhesion profile Fast cure	High durability	Cure “on demand” Rapid cure	High flexibility
Bondline Appearance	Invisible	Visible	Invisible	Opaque
Temperature Resistance				
Typical for the Category	-40 °C to 80 °C	-40 °C to 150 °C	-40 °C to 150 °C	-40 °C to 180 °C
Sterilisation resistance				
ETO	High	High	High	High
Gamma	High	High	High	High
Steam	No	High	Medium	High
Repeated Sterilisation	No	High	Low	Medium
Adhesion to Substrates				
Metals	Good	Excellent	Good	Good
Plastics	Excellent	Fair	Excellent	Good
Glass	Not recommended	Excellent	Excellent	Good
Elastomers	Excellent	Fair	Good	Good
Properties of Cured Product				
Shear Strength	High	High	High	Low
Peel Strength	Low	Medium	High	High
Tensile Strength	High	High	High	Low
Elongation / Flexibility	Low	Low	Medium	High
Hardness	Rigid	Rigid	Semi-Rigid	Soft
Process Considerations				
Number of Components	1	1 or 2	1	1
Typical Bond Gap	Tight	Medium	Small	Medium
Fixture Time				
Typical	30 seconds	5 hours	10 seconds	10 minutes
Fastest	5 seconds	15 to 20 minutes	2 seconds	60 seconds
Full Cure Time	24 hours	1/2 to 72 hours	10 to 60 seconds	72 hours

Henkel AG & Co. KGaA
Adhesive Technologies
Henkelstraße 67
40589 Düsseldorf
Germany
www.loctite.com
www.henkel.com

└

┐