

# EPO-TEK® Biocompatible/Medical Device Grade Products



## Comprehensive listing

Epoxy	† MED-301	Clear, low viscosity, room temp cure, used for potting
	† MED-301-2	Clear, low viscosity, long pot life, room temp cure
	* MED-301-2FL	More flexible version of MED-301-2
	* MED-302-3M	Clear, medium viscosity, room temp cure, low outgassing with low water absorption
	* MED-302-3M-R	REACH compliant version of MED-302-3M
	* MED-320	Black, opaque, thixotropic paste, room temp cure, potting, low fluorescence
	* MED-323LP	Medium viscosity, long pot life with high Tg
	† MED-353ND	Medium viscosity, high Tg, high strength (worldwide standard for endoscopes)
	† MED-353ND-T	Smooth thixotropic paste, high temperature resistance and strength
	* MED-354	Medium viscosity, long pot life (3 days) with high Tg
	* MED-354-T	Thixotropic paste, long pot life (3 days) with high Tg
	* MED-375	Medium viscosity, high Tg, long pot life with low outgassing
	† MED-377	Low viscosity, long pot life, high Tg, low outgassing, used with fiber optic bundles
	† MED-H20E	Smooth thixotropic paste, ECA with high thermal conductivity and high reliability
† MED-OD2002	Viscous liquid, high Tg with low modulus and good toughness, autoclave resistant	
* MED-T7110	Thixotropic paste, TCA with low viscosity	
UV	† MED-OG116-31	Viscous liquid, thixotropic, high Tg, UV curing with excellent chemical resistance
	† MED-OG198-54	Clear, low viscosity, UV shadow curable with high Tg

\* Certified ISO 10993-5 Cytotoxicity

† Certified ISO 10993-4,5,6,10,11

*Additional Products In Testing, Please Inquire*

Contact our **Medical Device Adhesive Experts** for technical discussions and assistance in finding the best adhesive solution for your bonding challenges at:

**+1.978.667.3805 or med@epotek.com**

For ordering, please contact us at:

**Epoxy Technology, Inc.**

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**epotek.com**

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Now Available

# EPO-TEK® Biocompatible Medical Device Grade Products

Epoxy Technology, Inc. (EPO-TEK®), a global leader in specialty adhesives since 1966, has a full line of Optical, Thermally Conductive (TCA), Electrically Conductive (ECA), UV and UV Hybrid Adhesives.



Now, many of our adhesives have undergone additional specialized **ISO 10993** testing to be classified as **biocompatible/medical grade** adhesives, which we call our EPO-TEK® “**MED**” line.

**ISO 10993 (Biocompatibility Testing of Adhesives)** is used to determine how compatible a material is within a biological environment. It is also used to predict any potentially harmful effects on the human body. We test our medical grade adhesives to this high worldwide standard.



## ISO 10993 Compliant Products - (“MED”) Testing Passing ISO 10993-4, 5, 6, 10, 11

Epoxyes	<b>MED-301</b>	Clear, low viscosity, room temp cure, used for potting
	<b>MED-301-2</b>	Clear, low viscosity, long pot life, room temp cure
	<b>MED-353ND</b>	Medium viscosity, high Tg, high strength (worldwide standard for endoscopes)
	<b>MED-353ND-T</b>	Smooth thixotropic paste, high temperature resistance and strength
	<b>MED-377</b>	Low viscosity, long pot life, high Tg, low outgassing, used with fiber optic bundles
	<b>MED-H20E</b>	Smooth thixotropic paste, ECA with high thermal conductivity and high reliability
<b>MED-OD2002</b>	Viscous liquid, high Tg with low modulus and good toughness, autoclave resistant	
UV	<b>MED-OG116-31</b>	Viscous liquid, thixotropic, high Tg, UV curing with excellent chemical resistance
	<b>MED-OG198-54</b>	Clear, low viscosity, UV shadow curable with high Tg

## ISO 10993-5 Compliant Products - (“MED”) Testing Passing ISO 10993-5 Cytotoxicity

Epoxyes	<b>MED-301-2FL</b>	More flexible version of MED-301-2
	<b>MED-302-3M</b>	Clear, medium viscosity, room temp cure, low outgassing with low water absorption
	<b>MED-320-3M-R</b>	REACH compliant version of MED-302-3M
	<b>MED-320</b>	Black, opaque, thixotropic paste, room temp cure, potting, low fluorescence
	<b>MED-323LP</b>	Medium viscosity, long pot life with high Tg
	<b>MED-354</b>	Medium viscosity, long pot life (3 days) with high Tg
	<b>MED-354-T</b>	Thixotropic paste, long pot life (3 days) with high Tg
	<b>MED-375</b>	Medium viscosity, high Tg, long pot life with low outgassing
	<b>MED-T7110</b>	Thixotropic paste, TCA with low viscosity

# ISO 10993 Testing Information & Certification

All of our medical grade adhesives are ISO 10993 tested.

ISO 10993 testing was written to establish a worldwide rigorous set of standards for the medical industry. There are many tests involved in this standard for predicting a reaction to an adhesive within biological media. All EPO-TEK® medical device grade adhesives (“MED”) are subjected to testing by an independent outside testing laboratory to determine ISO 10993 compliance before they are added to our special “MED” line of products.

Two levels of testing may be performed on our products: ISO 10993-5 Cytotoxicity testing, or ISO 10993-4,5,6,10,11 testing.



## ISO 10993 Adhesive Tests

### ISO 10993-4 Hemocompatibility

#### *Hemolysis Complete (Direct and Indirect) - ASTM*

In-vitro assay that determines the test articles' ability to destroy red blood cells by measuring the hemolysis index after 3 hours of incubation.

### ISO 10993-5 Cytotoxicity

#### *MEM Elution Cytotoxicity*

An in-vitro reactivity test involving mouse L929 fibroblast cell cultures. An extract of the test article is prepared within Minimum Essential Media (MEM) where the cells are allowed to grow for 48 hours.

### ISO 10993-6 Implantation

#### *Implant/Muscle/2 weeks*

This 2 week muscle implantation test gauges the bioreactivity of a test article when implanted into the muscle of a rabbit. The effects are observed *macro and microscopically* through tissue comparison versus a control.

### ISO 10993-10 Sensitization

#### *Kligman Maximization/2 Extracts/35 Animals/Concurrent(+) Controls*

This test measures the allergenic or sensitizing potential of a test article in guinea pigs. Test article extracts are prepared using sodium chloride & cottonseed oil, applied to an injection site and observed for 48 hours.

### ISO 10993-10 Irritation/Intracutaneous Reactivity

#### *Intracutaneous Injection/2 Extracts*

This test was designed to evaluate any biological reaction in response to test article extract injections in rabbits. The injection sites are observed over 72 hours for any type of tissue reaction.

### ISO 10993-11 Acute Systemic Toxicity

#### *Acute Systemic Injection/2 Extracts*

Extracts are prepared with the test article in a sodium chloride and cottonseed oil solution. These extracts are then injected intravenously into mice who are observed for 72 hours for any biological reaction.

Each “MED” product shipment will receive detailed documentation

- Certificate of Compliance for ISO 10993 testing from an independent outside laboratory
- Certificate of Analysis from EPO-TEK® Quality department for each specific lot
- Comprehensive MED Data Sheet
- MED Safety Data Sheet SDS





# Common Applications Using EPO-TEK® Medical Device Grade Adhesives



## Imaging Systems

- X-Ray Equipment (Scintillator Grids)
- CT Scan
- MRI
- Ultrasound (PZT Connections)
- OCT
- Nuclear Medicine

### EPO-TEK® MED Adhesive:

MED-301  
MED-301-2  
MED-301-2FL  
MED-353ND  
MED-H20E  
MED-OG198-54  
MED-OG116-31  
MED-T7110



### EPO-TEK® MED Adhesive:

MED-301  
MED-353ND  
MED-H20E  
MED-OG198-54  
MED-T7110

## Diagnostics/Scientific Equipment

- Patient Monitoring
- Lab on a Chip
- Sensors
- Gluco Sensors
- Point-of-Care-Instrumentation

## Surgical Tools

- Catheters
- Special Dental Equipment
- Electro Surgical Tools
- Fiber Optic Lasers
- Cryo Ablation
- Neurovascular

### EPO-TEK® MED Adhesive:

MED-301  
MED-301-2FL  
MED-353ND  
MED-353ND-T  
MED-OG116-31  
MED-OG198-54  
MED-H20E



### EPO-TEK® MED Adhesive:

MED-301  
MED-301-2  
MED-302-3M  
MED-320-3M-R  
MED-323LP  
MED-353ND-T  
MED-H20E  
MED-OG116-31

## Implantable/Non-Implantable Devices

- ICD/CRM/Pacemakers
- Ophthalmic & Neurostimulators
- Insulin Pumps
- Cochlear
- Hearing Aids
- Skeletal/Spinal/Ortho
- LVAD

## Endoscopes & Optical Systems

- Fiber-optic Bundles
- Light Guides/Camera
- Attachment of Probes
- Guide Wire Tips
- Capsule Endoscopy

### EPO-TEK® MED Adhesive:

MED-301  
MED-301-2  
MED-301-2FL  
MED-320  
MED-323LP  
MED-353ND  
MED-377  
MED-OD2002



*Additional Products In Testing, Please Inquire*