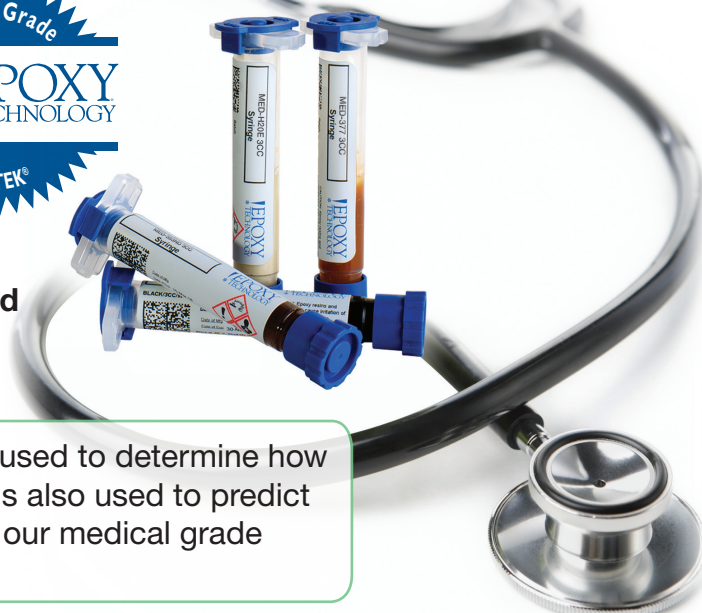


Now Available

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

Category	Product Name	Description
Epoxies	MED-301	Clear, low viscosity, room temp cure, used for potting
	MED-301-2	Clear, low viscosity, long pot life, room temp cure
	MED-353ND	Medium viscosity, high Tg, high strength (worldwide standard for endoscopes)
	MED-353ND-T	Smooth thixotropic paste, high temperature resistance and strength
	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
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

ISO 10993-5 Compliant Products - (“MED”)

Testing Passing ISO 10993-5 Cytotoxicity

Category	Product Name	Description
Epoxies	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 Black	High Tg, high temperature, black - colored epoxy
	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-T7110	Viscous liquid, TCA with low viscosity
	MED-T905BN-3	Thermally conductive and electrically insulating epoxy for potting and heat sink applications
	MED-HYB-353ND	UV hybrid curing epoxy, high temperature, very high strength and moisture resistance

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
MED-T905BN-3



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 Black
MED-353ND-T
MED-OG116-31
MED-OG198-54
MED-H20E



EPO-TEK® MED
Adhesive:

MED-301
MED-301-2
MED-302-3M
MED-302-3M-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-353ND Black
MED-HYB-353ND
MED-377
MED-OD2002



Additional Products In Testing, Please Inquire

EPO-TEK® Biocompatible/Medical Device Grade Products



Comprehensive listing

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	† 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:

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14 Fortune Drive • Billerica, MA 01821
Tel: 978-667-3805 • Fax: 978-663-9782
customerservice@epotek.com

epotek.com

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