

# Advanced Engineering Plastics for Life Sciences Applications



A broad range of materials that offer design flexibility and speed development

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QUADRANT

You inspire ... we materialize®

**KETRON® PEEK-CLASSIX™ LSG**  
Body Contact: YES up to 30 days

**LSG PORTFOLIO**  
Body Contact: YES up to 24 hours

**STANDARD PORTFOLIO**  
Body Contact: NO

## Quadrant Portfolio Applicability

### Dental Instruments

- Dental instruments and grips
- Dental drilling and suction equipment
- Isolating parts
- Healing Caps
- Temporary Abutments



### Surgical Instruments & Supplies

- Fixator Equipment
- Surgical Grips
- Targeting Devices
- Isolating parts
- Endoscopic Equipment
- Minimal invasive products



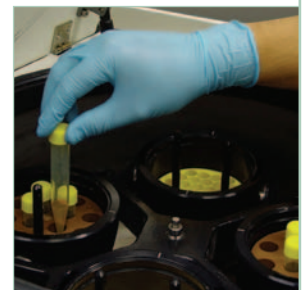
### Pharmaceutical Processing and Packaging

- Applications for tablet production
- Sliding and wear parts for pharma handling and packaging



### Analytical and Diagnostic Equipment

- Trays
- Centrifuges
- DNA Probe Analyzer
- Transport and sliding parts
- Mass spectrometers
- Radiation equipment
- Ultrasound equipment
- X-Ray and MRI devices



### Biotechnology and Laboratory Equipment

- Fermentation of microorganism
- Screening process
- Bio reactors
- Nozzles, adapters, caps
- Optics and lenses



## Stock Shapes for Life Sciences

Quadrant Life Science Grades (LSG) are designed specifically for the Medical, Pharmaceutical and Biotechnology markets. They save OEMs the time and costs associated with biocompatibility testing and regulatory approvals. Key benefits of the Life Science Grades are:

### Performance

Using the cutting edge material portfolio from Quadrant, will replace existing solutions made of stainless steel, Titanium and glass or ceramics through a combination of properties like weight reduction, resistance to commonly used sterilization methods, X-ray transparency, design flexibility, anti-static performance and resistance to high energetic radiation.

### Biocompatibility

The LSG portfolio includes plastics which comply with FDA, ISO 10993 and USP guidelines for biocompatibility testing of materials

### Full Traceability

Quadrant provides OEMs with the assurance of full traceability for its comprehensive LSG product portfolio.

### Global Availability

With production facilities in Europe, North America and Asia, and a presence in 27 countries through its select distribution network, Quadrant guarantees the consistent quality and availability of its products worldwide.

### Quality Assurance

In line with its ISO 9001:2000 certified Quality Assurance System, Quadrant EPP thoroughly monitors and controls the entire manufacturing process of its Life Science Grades



## Quadrant's Values to Market

### Increased Security

- Biocompatibility tested and certified
- Resistance to most common cleaning and sterilization methods
- Full traceability from raw material to stock shape
- Color coding possibilities

### Reduce Time to Market

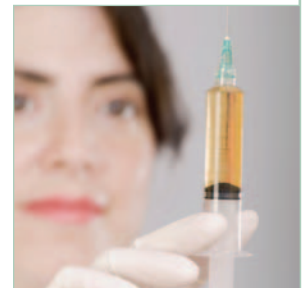
- Certification according regulatory standards saves time for testing
- Extensive technical know how and support from development to market

### Cost Reduction

- Shorter development time using pre-certified products
- Improved device performance
- Better and faster machining when compared to stainless steel and other materials

### Increased Production Speed

- Improved wear performance in unlubricated conditions
- Lower weight which leads to lower inertia forces
- Higher output
- Lower in-use noise levels versus metals



To help the designer meet today's challenges, Quadrant Engineering Plastic Products has specifically developed a portfolio of materials including a group of new, Life Science Grades which are pre-qualified biocompatible materials, helping to save precious time and money. The QEPP Life Science materials successfully passed a series of biocompatibility tests, run in order to check their compliance with both United States Pharmacopeias (USP) and ISO 10993-1 guideline requirements for Biocompatibility.

## Life Science Grades Portfolio



In addition to the Life Science Grade materials, Quadrant manufactures a broad range of materials that offer FDA compliance. This wide range of FDA compliant materials are well suited for production and process equipment in chemically intense analytical instrumentation, and ideal for applications where direct body contact is not required. Quadrant's technical support team can help you select the best material for your application.

Plug into our resources at [www.quadrantplastics.com](http://www.quadrantplastics.com) or 800.366.0300.

Quadrant's Life Science Grades resist against a broad range of chemicals.

CHEMICAL RESISTANCE* AGAINST ↓	LIFE SCIENCE GRADES									
	KETRON® PEEK-CLASSIX™ LSG	KETRON® PEEK-CA30 LSG	KETRON® PEEK-GF30 LSG	KETRON® PEEK LSG	TECHTRON® HPV PPS	RADEL® PPSU	ULTEM® 1000 PEI	PSU 1000	PC 1000	ACETRON® GP
weak acids	A	A	A	A	A	A	A	A	L	
strong acids	L	L	L	L	L	U	U	U	U	
weak alkalis	A	A	A	A	A	A	A	L	A	
strong alkalis	A	A	A	A	A	U	L	U	A	
water	A	A	A	A	A	A	A	A	A	
hot water (80 - 90°C)	A	A	A	A	A	A	A	L	A	
esters	A	A	A	A	L	L	U	U	A	
ketones	A	A	A	A	U	U	U	U	A	
aromatic hydrocarbons	A	A	A	A	L	U	U	U	A	
aliphatic hydrocarbons	A	A	A	A	A	A	A	A	A	

\* = at normal room temperature (15 - 25°C), unless otherwise stated  
A = Acceptable Use, L = Limited Use, U = Unacceptable

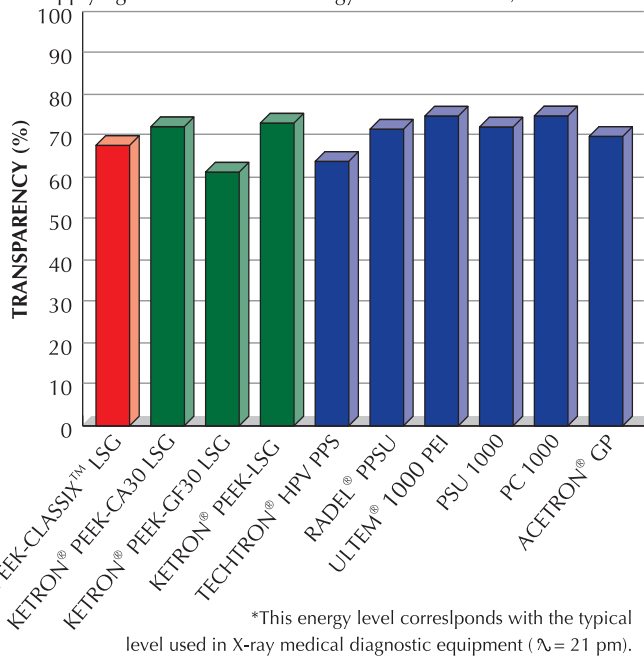
Quadrant's Life Science Grades are compatible with the most commonly used sterilization methods.

LIFE SCIENCE GRADES ↓	COMPATIBILITY WITH SOME COMMONLY USED STERILIZATION METHODS				
	Ethylene Oxide Gas	Steam 121°C/134°C	Dry Heat 160°C	Plasma	Gamma Irradiation
KETRON® PEEK-CLASSIX™ LSG	VG	VG / VG	VG	VG	VG
KETRON® PEEK-CA30 LSG	VG	VG / VG	VG	VG	VG
KETRON® PEEK-GF30 LSG	VG	VG / VG	VG	VG	VG
KETRON® PEEK LSG	VG	VG / VG	VG	VG	VG
TECHTRON® HPV PPS	VG	VG / G	VG	G	VG
RADEL® PPSU	VG	VG / VG	VG	VG	G
ULTEM® 1000 PEI	G	VG / G	VG	G	G
PSU 1000	G	VG / G	G	G	G
PC 1000	G	P / NS	NS	G	G
ACETRON® GP	G	G / P	NS	G	NS

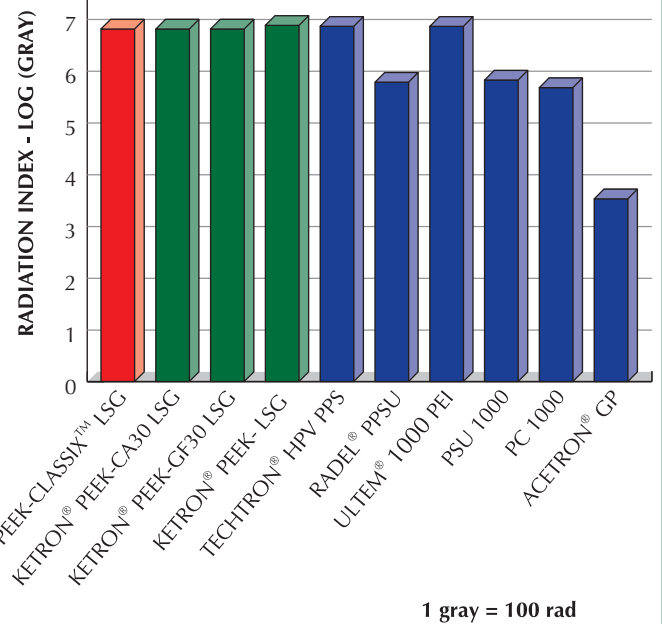
VG = Very Good, G = Good, P = Poor, NS = Not Suited

### Transparency of the QEPPLife Science Grades to High Energy Radiation

(measured at 23°C on 12 mm thick test plates, applying radiation with an energy level of 59 keV\*)



### Resistance to Gamma Radiation



These charts summarize some of the key, relevant performance criteria. Significant additional information is available through Quadrant's website and in Quadrant's printed literature available on-line and through our Technical Services department at 800.366.0300.

A comprehensive biocompatibility type testing program was run by an independent, internationally renowned testing organization on the QEPP Life Science Grades (1) in order to check their compliance with both United States Pharmacopeia (USP) and ISO 10993-1 guideline requirements for Biocompatibility Testing of Materials.

The test results reproduced in the table below indicate that, under the experimental conditions utilized in the testing, the examined QEPP Life Science Grades meet the requirements of the USP and ISO guidelines that are referenced (2). The table below also lists the results of heavy metal content tests run by means of Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

### Quadrant's Life Science Grades Biocompatibility Testing

MATERIALS	TESTS								USP Class VI (conclusion from tests 3, 4 and 5)
	1. Cytotoxicity Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test	2. Sensitisation Ref.: ISO 10993-10, Magnusson & Klignan Maximization Method	3. Intracutaneous Reactivity Ref.: ISO 10993-10 and USP <88> Biological Reactivity Tests, In Vivo - Intracutaneous Test	4. Systemic Toxicity Ref.: ISO 10993-11 and USP <88> Biological Reactivity Tests, In Vivo - Systemic Injection Test	5. Implantation Test Ref.: USP <88> Biological Reactivity Tests, In Vivo - Implantation Test (7 days)	6. Human blood compatibility Ref.: ISO 10993-4, indirect (in vitro)	7. USP-Physicochemical Test for Plastics (3) Ref.: USP <661> Containers, Ultra Pure Water Extract, 70° C/24h	8. Heavy metal content (mg/kg) (4) Testing the content of cadmium, chromium, lead and mercury by means of ICP-MS	
KETRON <sup>®</sup> PEEK-CLASSIX <sup>™</sup> LSG	✓	✓	✓	✓	✓	✓	✓	T	✓
KETRON <sup>®</sup> PEEK-CA30 LSG	✓	✓	✓	✓	✓	✓	✓	T	✓
KETRON <sup>®</sup> PEEK-GF30 LSG	✓	✓	✓	✓	✓	✓	✓	T	✓
KETRON <sup>®</sup> PEEK-LSG	✓	✓	✓	✓	✓	✓	✓	T	✓
TECHTRON <sup>®</sup> HPV PPS	<b>FDA COMPLIANT</b>								
RADEL <sup>®</sup> PPSU									
ULTEM <sup>®</sup> 1000 PEI									
PSU 1000									
PC 1000									
ACETRON <sup>®</sup> GP									

✓: This test was carried out by an independent international renowned testing organization and the material met the guideline requirements (more detailed information available on request)

NT: Not Tested

T: Tested

(1) All tests were run on test specimens machined from rod diameter 50 mm shortly after manufacture • (2) See disclaimer



Quadrant has extensive product and machining resources available online. Our website is a portal to a wealth of technical data and the easiest way to engage our application specialists.

Our team stands ready to help offer solutions to your toughest problems.

## Quadrant Engineering Plastic Products Worldwide

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