Advanced Engineering Plastics for Life Sciences Applications





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

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

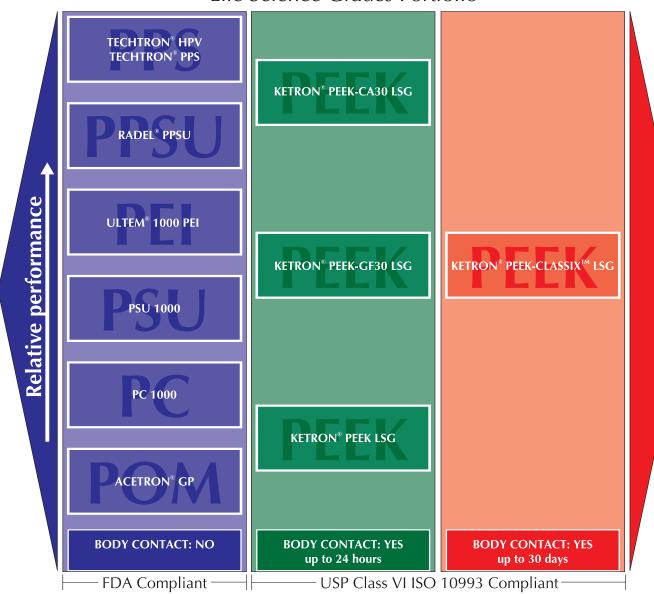






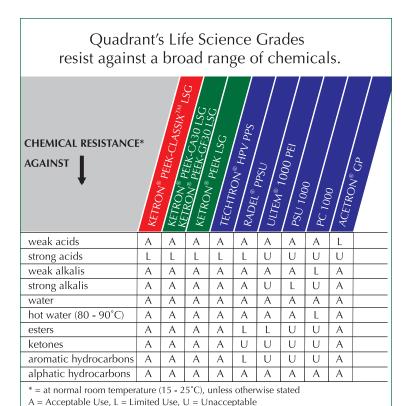
To help the designer meet today's challenges, Quadrant Engineering Plastic Products has specifically developed a portfolio of materials including a group of new, Life Science Grades which are pre-qualified biocompatible materials, helping to save precious time and money. The QEPP Life Science materials 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

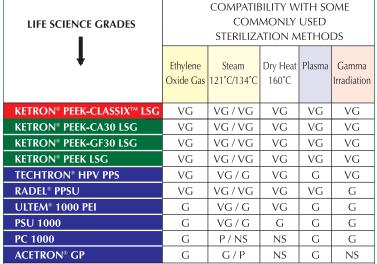


In addition to the Life Science Grade materials, Quadrant manufactures a broad range of materials that offer FDA compliance. This wide range of FDA compliant materials are well suited for production and process equipment in chemically intense analytical instrumentation, and ideal for applications where 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 or 800.366.0300.



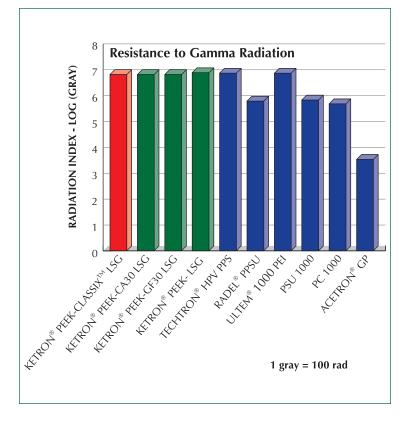
Quadrant's Life Science Grades are compatible with the most commonly used sterilization methods.



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

to High Energy Radiation (measured at 23°C on 12 mm thick test plates, applying radiation with an energy level of 59 keV*)										
	100									
	90									
	80									
(%)	70									
ζζ	60									
4REN	50									
IRANSPARENCY (%)	40									
TRA	30									
	20									
	10									
	0									
	KAY.	E PE								
	SIT	By Ey King His St. 100, St. Sc Tol.								
, <u>, , , , , , , , , , , , , , , , , , </u>	YP 64	the state of the s								
® Strip	ر م	Of the tax								
20x E	. E	*This energy level correslponds with the typical								
E.		*This energy level corresiponds with the typical level used in X-ray medical diagnostic equipment ($\lambda = 21 \text{ pm}$).								
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Transparency of the OFPP Life Science Grades



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

TESTS MATERIALS	1. Cytotoxicity Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test	2. Sensitisation Ref.: ISO 10993-10, Magnusson & Kligman 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 Hemolysis (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	USP Class VI (conclusion from tests 3, 4 and 5)	
KETRON® PEEK-CLASSIX™ LSG	1	1	1	1	1	1	1	Т	✓	
KETRON® PEEK-CA30 LSG	✓	1	✓	✓	✓	1	✓	Т	✓	
KETRON® PEEK-GF30 LSG	1	1	1	1	1	1	✓	Т	✓	
KETRON® PEEK-LSG	1	1	1	1	1	1	1	Т	/	
TECHTRON® HPV PPS										
RADEL® PPSU		FDA COMPLIANT								
ultem® 1000 pei										
PSU 1000				ED	COM					
PC 1000										
ACETRON® GP	CETRON® GP									
1. 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)										

✓: 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

Learn more online at www.quadrantplastics.com

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

EUROPE

Quadrant FPP AG HardstraSSe 5 CH-5600 Lenzburg Tel +41 (0) 62 8858150 Fax +41 (0) 62 8858181 e-mail: info@qplas.com

NORTH AMERICA

2120 Fairmont Avenue PO Box 14235 - Reading, PA 19612-4235 Tel 800 366 0300 / +1 610 320 6600 Fax 800 366 0301 / +1 610 320 6868 e-mail: americas.epp@qplas.com

ASIA-PACIFIC

108 Tai To Tsuen, Ping Shan Yuen Long - N.T. Hong Kong Tel +852 (0) 24702683 Fax +852 (0) 24789966 e-mail: asia.epp@qplas.com

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