

ATRON® ERTACETAL® CE

Engineering Plastic Solutions
for Life Science Industry



Global Leader in Engineering Plastics

FLUOROSINT® TECHTRON® SYMALIT®
ATRON® ERTACETAL®
OLE® TIVAR® KETRO
KETRON® TECHTRON®
ALYTE® ERTALON®
® SYMALIT®



QUADRANT

You inspire ... we materialize®

You inspire ... we materialize

Quadrant history:

The first engineering polymer shapes for machining.

Quadrant today:

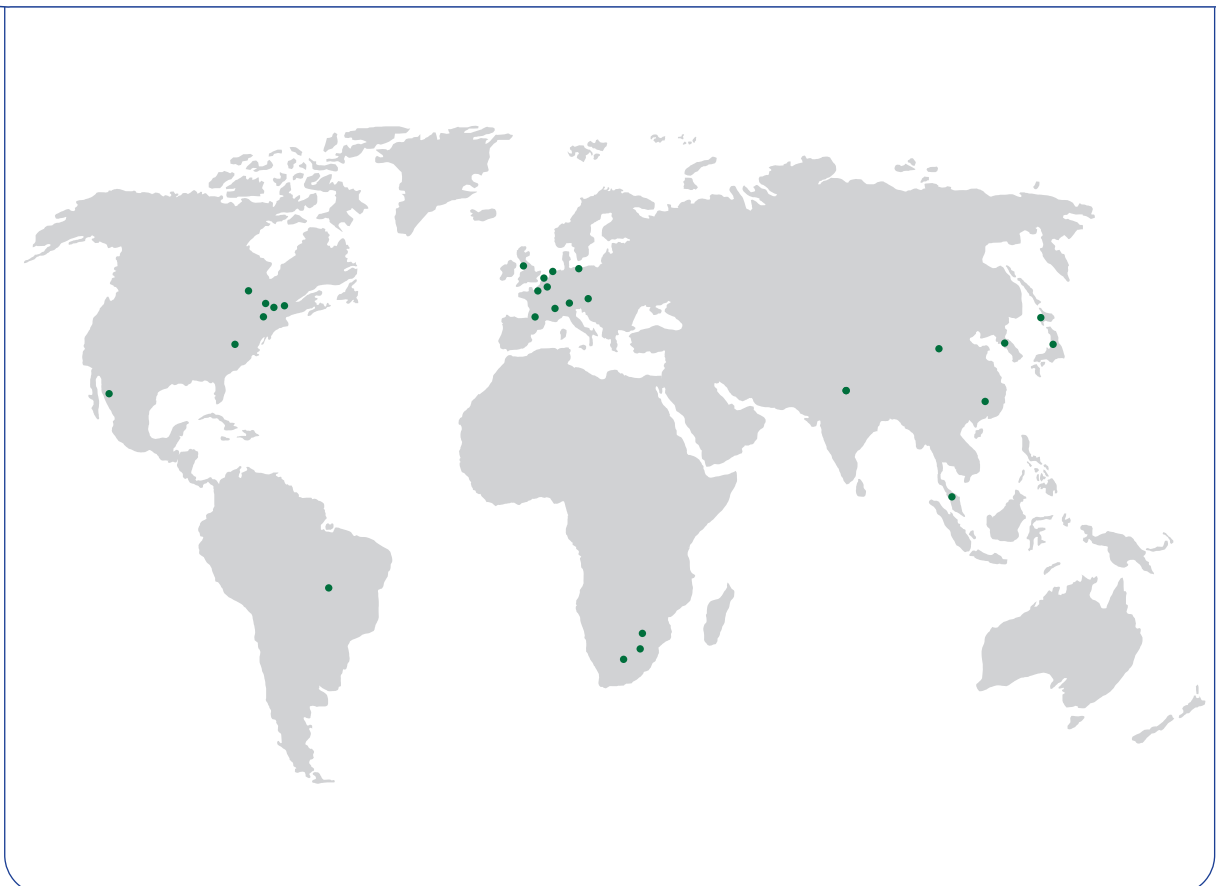
The broadest range of engineering polymer shapes allowing the most effective material choice.

Quadrant tomorrow:

New products for new needs, developed by QEPP's global product and application development team.

For over 60 years, the companies that today form Quadrant have been developing new materials to meet changing demands of customers around the world. The innovative, collaborative spirit between our people and our customers has shaped our success and led to the industry's broadest range of engineering plastic shapes for machining. Our investment in innovation will only increase in the years ahead, to support your requirements for higher levels of performance, productivity and value.

Quadrant Engineering Plastics - Global Scope



Quadrant's Values to the Life Science Market

INCREASED SECURITY

- Biocompatibility tested and certified Life Science Grades portfolio
- Resistance to most common cleaning and sterilisation methods
- Full traceability from raw material to stock shape
- Colour 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 performance
- Better and faster machining in comparison to stainless steel and other materials
- Value in use

INCREASED PRODUCTION SPEED

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



Engineering Plastic Solutions 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 due to a combination of properties like weight reduction, resistance to commonly used sterilisation 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

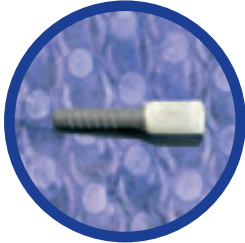
With production facilities in Europe, North America and Asia, and a presence in 27 countries through its select distribution network, Quadrant guarantees the consistent quality and availability of its products worldwide.

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.



Typical Applications for the Life Science Industry



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
- Filling and dosing equipment for pharmaceuticals
- Sealing and handling for blister packaging
- Mixing equipment for cremes and ointments



Analytical and Diagnostic Equipment

- Trays
- Centrifuges
- DNA probe analyser
- 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

Quadrant's Life Science Grades Biocompatibility Testing

MATERIALS	TESTS (1)(2)								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 Hemolysis (in vitro)	7. USP-Physicochemical Test for Plastics Ref.: USP <661> Containers, Ultra Pure Water Extract, 70° C/24h	8. Heavy metal content (mg/kg) Testing the content of cadmium, chromium, lead and mercury by means of ICP-MS	
KETRON® PEEK-CLASSIX™ LSG white	✓	✓	✓	✓	✓	✓	✓	✓	✓
KETRON® PEEK-CA30 LSG	✓	✓	✓	✓	✓	✓	✓	✓	✓
KETRON® PEEK-GF30 LSG blue (RAL 5019)	✓	✓	✓	✓	✓	✓	✓	✓	✓
KETRON® PEEK LSG natural/black	✓	✓	✓	✓	✓	✓	✓	✓	✓
TECHTRON® HPV LSG	✓	✓	✓	✓	✓	✓	✓	✓	✓
RADEL® PPSU LSG black	✓	✓	✓	✓	✓	✓	✓	✓	✓
ULTEM* PEI LSG natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
PSU LSG natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
PC LSG natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
ACETRON® LSG	✓	NT	NT	NT	NT	NT	✓	✓	NT (3)

✓ This test was carried out and the material passed the test
 NT Not tested

(1) All tests were run on test specimens machined from rod diameter 50 mm shortly after manufacture.

(2) Quadrant EPP performs testing on its Life Science Grades in order to facilitate evaluation by its customers of their biocompatibility with regard to the requirements applicable to the specific use of the finished product. Quadrant EPP does not possess expertise in evaluating the suitability of its tested materials for use in specific medical, pharmaceutical, or biotechnological applications. **It remains the customer's sole responsibility to test** specific medical, pharmaceutical, or biotechnological applications. **It remains the customer's sole responsibility to test and assess the suitability of Quadrant's Life Science Grades for its intended applications, processes and uses.**

(3) Please note that the virgin, natural coloured POM Copolymer resins used in the manufacture of all ACETRON® LSG stock shapes meet the requirements of USP Class VI (according to biocompatibility tests carried out on behalf of the resin suppliers), and that active Drug Master Files (DMF) on these resins are filed in the DMF-Database of the American Food and Drug Administration (FDA).

Compatible with common sterilisation methods

LIFE SCIENCE GRADES	Ethylene oxide gas	Steam 121°C / 134°C	Dry heat 160°C	Plasma	Gamma irradiation
KETRON® PEEK-CLASSIX™ LSG white	++	++ / ++	++	++	++
KETRON® PEEK-CA30 LSG	++	++ / ++	++	++	++
KETRON® PEEK-GF30 LSG blue (RAL 5019)	++	++ / ++	++	++	++
KETRON® PEEK LSG natural/black	++	++ / ++	++	++	++
TECHTRON® HPV LSG	++	++ / +	++	+	++
RADEL® PPSU LSG black	++	++ / ++	++	++	+
ULTEM* PEI LSG natural	+	++ / +	++	+	+
PSU LSG natural	+	++ / +	+	+	+
PC LSG natural	+	- / --	--	+	+
ACETRON® LSG	+	+ / -	--	+	--

++: very good
 +: good
 -: poor
 --: not suited

You inspire ... we materialize®

YOU INSPIRE:

Our best successes come from close working relationships with our customers – but not just on solving application problems with our materials properties. The more we understand about what’s important to your company, what it takes to compete, what determines your success and value with your customers for your equipment.

Let’s work together on your ideas and these success factors, where our materials can help you better compete in your industry.



REGULATION APPLIANCE LOW SYSTEM COST
BIOCOMPATIBILITY RELIABILITY YIELD CONFIDENCE
OUTPUT TRACEABILITY COMPETITIVENESS
CONSISTENCY PRODUCTIVITY SERVICE LOW MAINTENANCE
ELECTRICAL INSULATION ANTI-STATIC PERFORMANCE

WE MATERIALIZE:

Challenge us with your application requirements. Tell us what it takes for you to compete and deliver value in your industry. That gives us the opportunity to work with your engineers to provide the best combination of technical support, material and finished part performance for your equipment – within your overall cost targets.

Consider how these benefits of Quadrant materials can improve your application reliability, equipment efficiency and bottom line.

STERILISATION RESISTANCY X-RAY
TRANSPARENCY LSG PORTFOLIO CERTIFICATION
LONG WEAR LIFE USP AND ISO 10993 TESTING
STATIC MANAGEMENT RELIABLE AND
APPROVED QUALITIES IONIC FULL
TRACEABILITY HIGH QUALITY RESINS
PREDICTABLE DIMENSIONS TECHNICAL AND
LOGISTICAL SERVICES SELF-LUBRICATING

Distributed by:



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 EPP AG
Hardstrasse 5
CH-5600 Lenzburg
Tel +41 (0) 62 8858409
Fax +41 (0) 62 8858181
e-mail: europa.epp@qplas.com

NORTH AMERICA

Quadrant EPP USA, Inc.
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

Quadrant EPP Asia Pacific Ltd
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

BELGIUM • CHINA • FRANCE • GERMANY • HONG KONG • HUNGARY • INDIA • ITALY • JAPAN • KOREA • MEXICO • POLAND
SOUTH AFRICA • SWITZERLAND • THE NETHERLANDS • UNITED KINGDOM • UNITED STATES OF AMERICA

Quadrant Engineering Plastic Products performs testing on its Life Science Grades in order to facilitate evaluation by its customers of their biocompatibility with regard to the requirements applicable to the specific use of the finished product.

Quadrant EPP does not possess expertise in evaluating the suitability of its tested materials for use in specific medical, pharmaceutical, or biotechnological applications. **It remains the customer's sole responsibility to test and assess the suitability of Quadrant's Life Science Grades for its intended applications, processes and uses.**

Quadrant Engineering Plastic Products makes no warranties or representations whatsoever that its materials are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in implantable medical device applications and in applications that are essential to the restoration or continuation of a bodily function important to the continuation of human life.

Quadrant's Life Science Grades should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours (30 days), or are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days), or as critical components of medical devices that are essential to the continuation of human life

*: '30 days' applies to KETRON® PEEK-CLASSIX™ LSG white only.

By accepting delivery of the Quadrant Life Science Grade product, the customer acknowledges the foregoing conditions.

All information supplied by or on behalf of Quadrant Engineering Plastic Products in relation to its products, whether in the nature of data, recommendations or otherwise, is supported by research and believed reliable, but Quadrant Engineering Plastic Products assumes no liability whatsoever in respect of application, processing or use made of the aforementioned information or products, or any consequence thereof. The buyer undertakes all liability in respect of the application, processing or use of the aforementioned information or product, whose quality and other properties he shall verify, or any consequence thereof. No liability whatsoever shall attach to Quadrant Engineering Plastic Products for any infringement of the rights owned or controlled by a third party in intellectual, industrial or other property by reason of the application, processing or use of the aforementioned information or products by the buyer.

ACETRON®, ERTACETAL®, ERTALON®, ERTALYTE®, FLUOROSINT®, KETRON®, NYLATRON®, SEMITRON®, SYMALIT®, TECHTRON® and TIVAR® are registered trademarks of the Quadrant Group.
PEEK-CLASSIX™ is a trademark of Invibio Ltd.
RADEL® is a registered trademark of Solvay Advanced Polymers.
ULTEM® is a trademark of SABIC Innovative Plastics IP B.V.