


# Life Science Grades Product Overview

## Life Science Grades Portfolio



<b>KETRON® PEEK-CLASSIX™ LSG</b>	<b>PEEK</b>
<b>KETRON® PEEK-CA30 LSG</b>	<b>PEEK</b>
<b>KETRON® PEEK-GF30 LSG</b>	<b>PEEK</b>
<b>KETRON® PEEK LSG</b>	<b>PEEK</b>
<b>QUADRANT LSG PPSU</b>	<b>PPSU</b>
<b>DURATRON® LSG PEI</b>	<b>PEI</b>
<b>PSU LSG</b>	<b>PSU</b>
<b>PC LSG</b>	<b>PC</b>
<b>ACETRON® LSG</b>	<b>POM</b>

To meet the challenge, Quadrant Engineering Plastic Products has specifically developed a portfolio of Life Science Grades which are pre-qualified biocompatible materials, cutting costs and giving you a head start on competition.

The QEPP Life Science Grades 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 Testing of Materials.



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# BIOCOMPATIBILITY (USP AND ISO 10993) AND FOOD CONTACT COMPLIANCE (FDA) STATUS OF THE QUADRANT EPP LSG STOCK SHAPES AND THE RESINS USED FOR THEIR MANUFACTURE

GLOBAL NAMES	COMPOSITIONS	USP compliance of the stock shapes	ISO 10993 compliance of the stock shapes	FDA compliance of the resins (****)
KETRON® PEEK-CLASSIX™ LSG white (*)	PEEK white	Class VI (**)	10993-4, -5, -10 & -11 (**)	yes
KETRON® PEEK-CA30 LSG	PEEK + 30%CF	Class VI (**)	10993-4, -5, -10 & -11 (**)	no
KETRON® PEEK-GF30 LSG blue (RAL 5019)	PEEK + 30%GF	Class VI (**)	10993-4, -5, -10 & -11 (**)	no
KETRON® PEEK LSG natural	PEEK natural	Class VI (**)	10993-4, -5, -10 & -11 (**)	yes
KETRON® PEEK LSG black	PEEK black	Class VI (**)	10993-4, -5, -10 & -11 (**)	yes
QUADRANT LSG PPSU black (*)	PPSU black	Class VI (**)	10993-4, -5, -10 & -11 (**)	yes
DURATRON® LSG PEI natural (*)	PEI natural	Class VI (**)	10993-4, -5, -10 & -11 (**)	yes
PSU LSG natural (*)	PSU natural	Class VI (**)	10993-4, -5, -10 & -11 (**)	yes
PC LSG natural (*)	PC natural	Class VI (**)	10993-4, -5, -10 & -11 (**)	yes
ACETRON® LSG natural	POM-C natural	not tested (***)	10993-5 (**)	yes
ACETRON® LSG black	POM-C black	not tested (***)	10993-5 (**)	yes
ACETRON® LSG yellow (RAL 1007)	POM-C yellow	not tested (***)	10993-5 (**)	yes
ACETRON® LSG red (RAL 3027)	POM-C red	not tested (***)	10993-5 (**)	yes
ACETRON® LSG blue (RAL 5005)	POM-C blue	not tested (***)	10993-5 (**)	yes
ACETRON® LSG green (RAL 6016)	POM-C green	not tested (***)	10993-5 (**)	yes
ACETRON® LSG brown (RAL 8016)	POM-C brown	not tested (***)	10993-5 (**)	yes

(\*): according to the resin manufacturer, the resin grade used by QEPP for the manufacture of these stock shapes essentially meets the requirements of USP Class VI. This means that the resin manufacturer in the course of time had successfully one or more resin batches tested by an external accredited testing organisation with respect to its/their biocompatibility in line with the requirements of USP Class VI. However, the batches of this resin are not systematically tested on USP Class VI compliance and hence there are no USP Class VI certificates available for the resin batches used by QEPP for the extrusion of the corresponding LSG stock shapes.

(\*\*): type testing was run by an independent, internationally renowned testing organisation on this QEPP Life Science Grade in order to check its compliance with both United States Pharmacopeia (USP) and ISO 10993-1 guide line requirements for Biocompatibility Testing of Materials (tests were run on specimens machined from rod diameter 50 mm shortly after manufacture).

(\*\*\*): 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 active Drug Master Files (DMF) on these resins are filed in the DMF-Database of the American Food and Drug Administration (FDA).

(\*\*\*\*): this means that the composition of the raw materials used for the manufacture of these LSG stock shapes complies with the requirements of the applicable FDA Food Contact Notification and/or food additive regulation(s).

no: rather than saying "no", one could also say "not tested", "not evaluated" or "not officially evaluated"

## Tests performed by Quadrant EPP on stock shapes

- Systemic Toxicity (acute) - Intracutaneous Reactivity - Implantation test - Sensitisation - Cytotoxicity - Human blood compatibility
- USP-Physicochemical test for plastics - Heavy metal content



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