

BIOCOMPATIBILITY (USP AND ISO 10993) STATUS OF THE QUADRANT EPP LSG STOCK SHAPES

A comprehensive biocompatibility type testing programme was run by an independent, internationally renowned and accredited testing organisation on the Quadrant LSG stock shapes in order to check their compliance with both United States Pharmacopeia (USP) and ISO 10993-1 guideline requirements for Biocompatibility Testing of Materials.

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. Sensitization 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. Acute 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 Tests for Plastics Ref.: USP <661> Containers	
Ketron® CLASSIX™ LSG PEEK white	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG CA30 PEEK	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG GF30 PEEK blue (RAL 5019)	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG PEEK natural & black	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® R5100 LSG PPSU black BK937	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® R5100 LSG PPSU natural NT15 (ivory)	✓	NT ⁽⁴⁾	✓	✓	NT ⁽⁴⁾	NT ⁽⁴⁾	✓	NT ⁽⁴⁾
Quadrant® R5500 LSG PPSU black BK937, blue BU1027, brown BN1164, green GN1007, grey GRY1037, natural NT15 (ivory), orange OR1145, red RD1018, yellow YL1337	✓	NT ⁽⁴⁾	NT ⁽⁴⁾	NT ⁽⁴⁾	NT ⁽⁴⁾	NT ⁽⁴⁾	✓	NT ⁽⁴⁾
Duratron® LSG PEI natural	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® LSG PSU natural	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® LSG PC natural	✓	✓	✓	✓	✓	✓	✓	✓
Acetron® LSG natural & black	✓	NT	NT	NT	NT	NT	✓	NT ⁽³⁾
Proteus® H LSG natural (white)	✓	NT	✓	✓	✓	NT	NT	✓
Proteus® LSG HS PP white & black	✓	NT	NT	NT	NT	NT	✓	NT

✓ This test was carried out and the material passed the test.

NT Not Tested

- All tests were run on test specimens machined from stock shapes shortly after manufacture.
- 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 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 that are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days*).** They should not be used either for the manufacture of critical components of medical devices that are essential to the continuation of human life.
*: '30 days' applies to Ketron® CLASSIX™ LSG PEEK white only.
- Please note that the virgin, natural coloured POM Copolymer resins used in the manufacture of the Acetron® LSG natural & black stock shapes meet the requirements of USP Class VI (according to biocompatibility tests carried out on behalf of the resin suppliers).
- An abbreviated biocompatibility type testing programme was run on these Quadrant® LSG PPSU products, which are colour variations of Quadrant® R5100 LSG PPSU black BK937. A comprehensive biocompatibility type testing programme was run on Quadrant® R5100 LSG PPSU black BK937.

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