

## LSG material selection

# Biocompatibility pre-assessment table – Medical

Materials	Tests / Compliance							USP Class VI Conclusion from tests 3, 4 and 5	Body Contact Duration Intended applications of which the duration of contact with human body tissue is limited to.
	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, Ultra Pure Water extract, 70°C/24h		
<b>Ketron® LSG PEEK grades</b>									
Ketron® LSG PEEK-CLASSIX™ white	●	●	●	●	●	●	●	●	≤ 30d
Ketron® LSG PEEK natural, black	●	●	●	●	●	●	●	●	≤ 24h
Ketron® LSG Food Grade PEEK natural	●	●	●	●	●	●	●	●	≤ 24h
Ketron® LSG PEEK red	●	○	●	●	●	○	●	●	≤ 24h
Ketron® LSG PEEK blue	●	○	●	●	●	○	●	●	≤ 24h
Ketron® LSG PEEK green	●	○	●	●	●	○	●	●	≤ 24h
Ketron® LSG PEEK yellow	●	○	●	●	●	○	●	●	≤ 24h
Ketron® LSG CA30 PEEK	●	●	●	●	●	●	●	●	≤ 24h
<b>Sultron® LSG PPSU grades</b>									
Sultron® LSG R5100 PPSU black BK937	●	●	●	●	●	●	●	●	≤ 24h
Sultron® LSG R5500 PPSU black BK937	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG Food Grade R5100 PPSU black BK937	●	●	●	●	●	●	●	●	≤ 24h
Sultron® LSG R5100 PPSU bone NT15	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU bone NT15	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU blue BU1027	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU brown BN1164	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU green GN1007	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU orange OR1145	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU red RD1018	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU yellow YL1337	●	○	●	●	●	○	●	●	≤ 24h
Sultron® LSG R5500 PPSU grey GY1037	●	○	●	●	●	○	●	●	≤ 24h
<b>Duratron® LSG grades</b>									
Duratron® LSG PEI natural	●	●	●	●	●	●	●	●	≤ 24h
Duratron® LSG PEI black	●	○	●	●	●	○	●	●	≤ 24h
Duratron® LSG PEI blue	●	○	○	○	○	○	●	○	≤ 24h
<b>Sultron® LSG PSU grades</b>									
Sultron® LSG PSU natural NT	●	●	●	●	●	●	●	●	≤ 24h
<b>Altron™ LSG PC grades</b>									
Altron™ LSG PC	●	●	●	●	●	○	●	●	≤ 24h
<b>Proteus® LSG PP grades</b>									
Proteus® LSG HP PP-H	●	○	●	●	●	○	●	●	None
Proteus® LSG HS PP-H white, black	●	○	○	○	○	○	●	○	None
<b>Proteus® LSG HDPE grades</b>									
Proteus® LSG HDPE	●	○	●	●	●	○	●	●	≤ 24h

**Note:** To see the disclaimer, please see page. 3.

● Shape tested (incl. raw materials)  
○ Shape testing pending/planned

○ Raw material tested  
○ Not tested

d Days  
h Hours

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# Biocompatibility pre-assessment table – Bioprocessing

Materials	Tests / Compliance				
	USP Class VI Conclusion from tests 3, 4 and 5	Animal Free Origin (AFO) or EMA/410/01 Rev.3 (Absence of BSE/TSE)	Food Contact – FDA Ref.: USA FDA 21 CFR 177 and 178	Food Contact – EU Ref.: Commission Regulation (EU) No 10/2011	
<b>Ketron® LSG PEEK grades</b>					
Ketron® LSG PEEK-CLASSIX™ white	●	■	◇	◇	
Ketron® LSG PEEK natural, black	●	■	◆	◇	
Ketron® LSG Food Grade PEEK natural	●	□	◆	◆	
Ketron® LSG PEEK red	●	□	◇	◇	
Ketron® LSG PEEK blue	●	■	◇	◇	
Ketron® LSG PEEK green	●	■	◇	◇	
Ketron® LSG PEEK yellow	●	■	◇	◇	
Ketron® LSG CA30 PEEK	●	□	◇	◇	
<b>Sultron® LSG PPSU grades</b>					
Sultron® LSG R5100 PPSU black BK937	●	■	◆	◇	
Sultron® LSG R5500 PPSU black BK937	●	■	◆	◇	
Sultron® LSG Food Grade R5100 PPSU black BK937	●	■	◆	◆	
Sultron® LSG R5100 PPSU bone NT15	●	■	◆	◇	
Sultron® LSG R5500 PPSU bone NT15	●	■	◆	◇	
Sultron® LSG R5500 PPSU blue BU1027	●	■	◇	◇	
Sultron® LSG R5500 PPSU brown BN1164	●	■	◇	◇	
Sultron® LSG R5500 PPSU green GN1007	●	■	◇	◇	
Sultron® LSG R5500 PPSU orange OR1145	●	■	◇	◇	
Sultron® LSG R5500 PPSU red RD1018	●	■	◇	◇	
Sultron® LSG R5500 PPSU yellow YL1337	●	■	◇	◇	
Sultron® LSG R5500 PPSU grey GY1037	●	■	◆	◇	
<b>Duratron® LSG grades</b>					
Duratron® LSG PEI natural	●	■	◆	◇	
Duratron® LSG PEI black	●	■	◆	◇	
Duratron® LSG PEI blue	●	■	◆	◇	
<b>Sultron® LSG PSU grades</b>					
Sultron® LSG PSU natural NT	●	■	◆	◇	
<b>Altron™ LSG PC grades</b>					
Altron™ LSG PC	●	■	◆	◇	
<b>Proteus® LSG PP grades</b>					
Proteus® LSG HP PP-H	●	□	◆	◇	
Proteus® LSG HS PP-H white, black	○	□	◇	◇	
<b>Proteus® LSG HDPE grades</b>					
Proteus® LSG HDPE	●	■	◆	◇	

● Shape tested (incl. raw materials)    ● Raw material tested    ■ Animal Free Origin (AFO)    □ Not compliant    ◇ Raw material compliant  
 ● Shape testing pending/planned    ○ Not tested    □ Absence TSE/BSE    ◆ Shape compliant    ◇ Not compliant

**Note:** To see the disclaimer, please see page. 3.

# Disclaimers

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