

To whom it may concern

## Biocompatibility

### Spectrum Filaments ABS Medical

**Spectrum Filaments ABS Medical** 3D printing filament, has been manufactured using ABS pellets, which meet biocompatibility USP Class VI and ISO 10993-1 requirements up to 30 days in human contact.

Test	Reference	Results
<b>USP Class VI with Histopathology</b>	USP 39 NF 34	passed the test
<b>Physicochemical Test</b> for Plastics	USP <381>	passed the test
<b>Analysis for Metals</b>	ICP-OES Elemental testig after acid digestion	not detected at the detection limit
<b>Rabbit Pyrogen</b> (Material Mediated) 30-minute intervals between 1 and 3 hours observation	ISO 10993-11 ISO 10993-12 ISO/IEC 17025/2005	non-pyrogenic
<b>Systemic Injection</b> 72-hours exposure 0,9% sodium chloride USP solution extract Cottonseed Oil (CSO) Ethanol in saline, 1:20 solution extract Polyethylene glycol 400 extract	ISO 10993-11 ISO 10993-12 ISO/IEC 17025/2005	non-toxic
<b>In Vitro Hemocompatibility</b>	ISO 10993-4	passes the test
<b>Short Term Intramuscular Implantation</b> 14-days exposure	ISO 10993-6 ASTM F 981-93	non-toxic
<b>Rabbit blood Hemolysis</b>	ASTM F756-13	non- hemolytic

<b>MEM Elution</b> – Cytotoxicity 48-hours exposure	USP 39 NF 34	non-cytotoxic
<b>L929 Neutral Red Uptake -NRU -</b> Cytotoxicity	ISO 10993-5 ISO 10993-12	non-cytotoxic
<b>Kligman Maximisation</b> < 30-days Cottonseed Oil (CSO) 0,9% sodium chloride USP solution extract	ISO 10993-10 ISO 10993-12	no evidence of sensitization
<b>Intracutaneous Injection</b> 72-hours exposure 0,9% sodium chloride USP solution extract Cottonseed Oil (CSO) Ethanol in saline, 1:20 solution extract Polyethylene glycol 400 extract	ISO 10993-10 ISO 10993-12 ISO/IEC 17025/2005	negligible irritant
<b>Ames Assay</b> Salmonella typhimurium and Escherichia coli Reverse Mutation Assay	ISO 10993-3 ISO 10993-12	non-mutagenic

Prior to testing the sample plaques were sterilized by Gamma Irradiation at 25.0 to 40.0 KGy dosage at Steris Corp. Tests conducted by Toxikon, Bedford MA, USA in accordance with Good Laboratory Practice.

**Above mentioned information and results apply to pellet (raw material).**

Spectrum Group Sp. z o.o. guarantees that the base raw material has no additives and has not been modified in the filament production process.