

To whom it may concern

Biocompatibility

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

| Test | Reference | Results |
|--|---|--|
| USP Class VI with Histopathology | USP 39 NF 34 | passed the test |
| Physicochemical Test for Plastics | USP <381> | passed the test |
| Analysis for Metals | ICP-OES Elemental testig after acid digestion | not detected at the detection limit |
| Rabbit Pyrogen (Material Mediated) 30-minute intervals between 1 and 3 hours observation | ISO 10993-11 ISO 10993-12 ISO/IEC 17025/2005 | non-pyrogenic |
| Systemic Injection 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 |
| In Vitro Hemocompatibility | ISO 10993-4 | passes the test |
| Short Term Intramuscular Implantation 14-days exposure | ISO 10993-6 ASTM F 981-93 | non-toxic |
| Rabbit blood Hemolysis | ASTM F756-13 | non- hemolytic |

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| MEM Elution – Cytotoxicity 48-hours exposure | USP 39 NF 34 | non-cytotoxic |
| L929 Neutral Red Uptake -NRU - Cytotoxicity | ISO 10993-5 ISO 10993-12 | non-cytotoxic |
| Kligman Maximisation < 30-days Cottonseed Oil (CSO) 0,9% sodium chloride USP solution extract | ISO 10993-10 ISO 10993-12 | no evidence of sensitization |
| Intracutaneous Injection 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 |
| Ames Assay 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.

It is the responsibility of the end manufacturer to ensure that the final product is suitable for its intended use.

The above mentioned information and results apply to pellet (raw material).

Spectrum Group Sp. z o.o. ensures that the raw material has not been modified in the filament manufacturing process.