



smart materials 3D

To whom it may concert:

SMART MATERIALS 3D PRINTING SL with **CIF B23735681** and address **POL. IND. EL RETAMAR, C/ TOMILLO, 7, VIAL – G 23680- ALCALA LA REAL (JAEN)** certifies:

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Our product **MEDICAL SMARTIL**, has been manufactured with ABS pellets that meet with the biocompatibility USP Class VI plastics and ISO 10993-1 requirements up to 30 days in human contact.

TESTS	Reference	Results
Heavy Metals , 24-hours	ISO/IEC 17025/2005	passed the test
Physicochemical Test for Plastics, 24-hours	USP <661> ISO/IEC 17025/2005	passed the test
Analysis for Metals – ICP	EPA Method 601110A	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
Hemolysis – Human Blood	ISO 10993-4	non - he molytic
MEM Elution – Cytotoxicity 48-hours exposure	ISO 10993-5 ISO 10993-12 ISO/IEC 17025/2005	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 biocompatibility testing, sample plaques were sterilized by Gamma Irradiation at 6.0 Mrad Dosage and ethylene oxide.

Smart Materials 3d printing SL ensures that the raw material has not been added or modified in the filament manufacturing process.

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

The above mentioned confirmation only applies for the filament delivered by Smart Materials 3D.



Sr. Antonio Peláez
Technical department manager.