

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:



Our product SMARTIL® PETG NATURAL, has been manufactured with PETG pellets that complies with the following medical-related regulations.

ISO 11607-1:2006

SMARTIL® PETG is in subjective compliance to ISO 11607-1:20 / EN ISO 11607-1: 2009, as it applies to raw materials and not the finished device. Bellow is a table that show the tests conducted to show compliance to ISO 11607-1: 2006.

Test	Pre-sterilization	Post-sterilization	Accelerated Aging (5 years)
Biocompatibility Testing , including: <ul style="list-style-type: none"> • USP Intracutaneous Reactivity • USP Acute Systemic Toxicity • USP Implantation • Cytotoxicity (ISO 10993) • Sensitization (ISO 10993) • Hemocompatibility (ISO 10993) 	Not required	Test for: <ul style="list-style-type: none"> • EtO • Gamma 15 kGy • Gamma 55 kGy 	Not required
Chemical Testing , including: <ul style="list-style-type: none"> • UPS Physicochemical Test – Plastic <661>, Aqueous Extraction in Purified Water (PW) for Total Non-Volatile Residue (NVR), Residue on Ignition (ROI), Heavy Metals (HM) and Buffering Capacity (BC) • USP Physicochemical Test <661>, Alternate Extract in Ethanol (EtOH) for Non-Volatile Residue, Residue on Ignition, Turbidity and UV absorption. • Infrared analysis of extract residues (PW and EtOH) • Infrared analysis of the Test Article • Gas Chromatography with Mass Spectrometry (GC/MS) of extract residues (PW an EtOH) • Differential Scanning Calorimetry (DSC) Characterization 	Tested	Tested for: <ul style="list-style-type: none"> • EtO • Gamma 15 kGy • Gamma 55 kGy 	Tested for: <ul style="list-style-type: none"> • EtO • Gamma 15 kGy • Gamma 55 kGy



Physical Testing , (per AAMI TIR17:2008), including: <ul style="list-style-type: none"> • Tensile properties • Flexural properties • Impact resistance • Hardness • Tear strength • Discoloration 	Required	Tested for <ul style="list-style-type: none"> • EtO 1 cycle • EtO 2 cycles • E-beam 55kGy • Gamma 15 kGy • Gamma 55 kGy 	Tested for: <ul style="list-style-type: none"> • EtO 1 cycle • EtO 2 cycles • E-beam 55kGy • Gamma 15 kGy • Gamma 55 kGy
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ISO 10993

SMARFIL® PETG, complies with ISO 10993 guidelines. Test results of raw materials are shown in the below table.

Test	ISO Guideline	Method	Results
Cell Cytotoxicity	ISO 10993 Part 5	MEM Extraction	Pass
Ames Genotoxicity	ISO 10993 Part 3	Saline	Pass
Hemocompatibility	ISO 10993 Part 4	Direct Contact	Pass
Irritation	ISO 10993 Part 10	Intracutaneous saline/Cottonseed/PET/ETOH	Pass
Sensitization		Guinea Pig Maximization	Pass
Systemic Toxicity	ISO 10993 Part 11	Acute	Pass
		14 day Repeat Dose	
Implant	ISO 10993 Part 6	2 week Intramuscular	Pass

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.