

# BIOCOMPATIBILITY CERTIFICATE

To whom it may concern:

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 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
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	ICP-OES Elemental testing 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 - haemolytic
MEM Elution – Cytotoxicity 48-hours exposure	USP 39 NF34	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.

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

## BIOCOMPATIBILITY CERTIFICATE

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.

SMART MATERIALS 3D PRINTING S.L



Antonio Peláez Moya  
*Director General*

## BIOCOMPATIBILITY CERTIFICATE

### ANNEX I MANUFACTURE OF FILAMENT FOR 3D PRINTING – VALIDATION TEST

<b>Manufacturer:</b>	Smart Materials 3D Printing SLU
<b>Address:</b>	Pol. Ind. El Retamar C/Tomillo 7, 23680 Alcalá la Real, Jaén, España
<b>Product description:</b>	Filament Smartfil ABS Medical
<b>Color:</b>	Natural
<b>Inspection date:</b>	26/07/2018

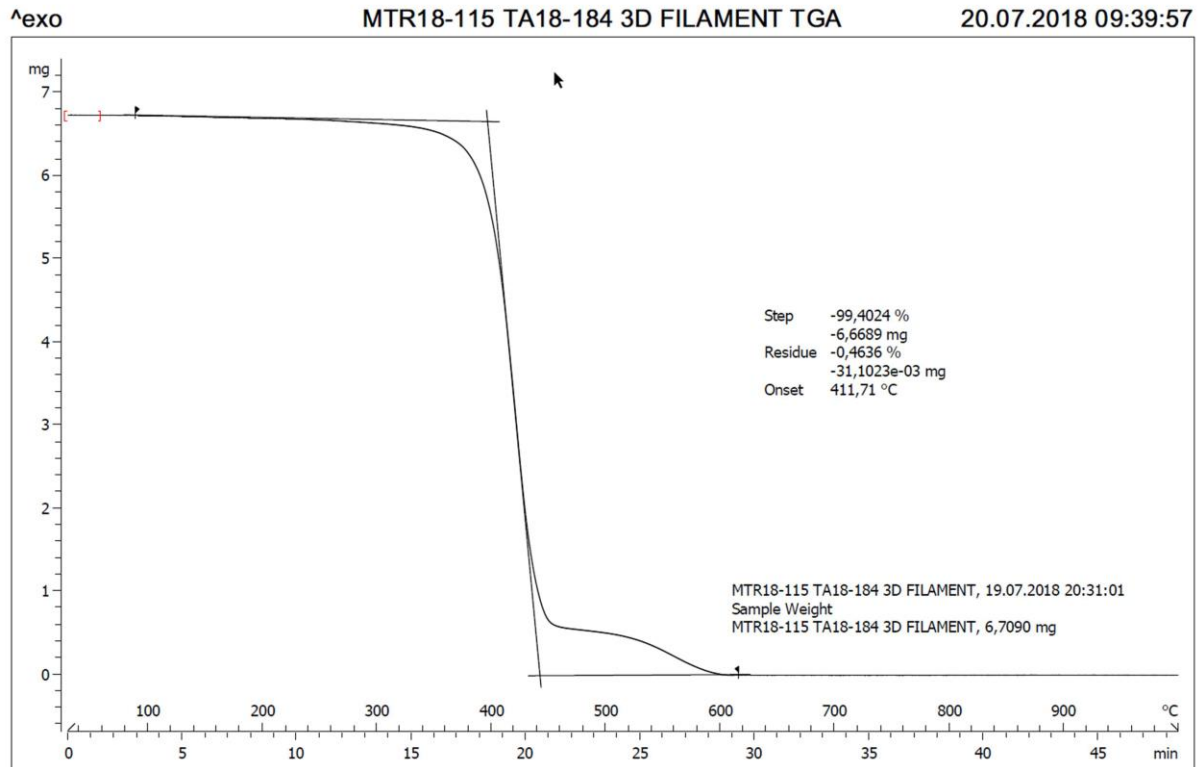
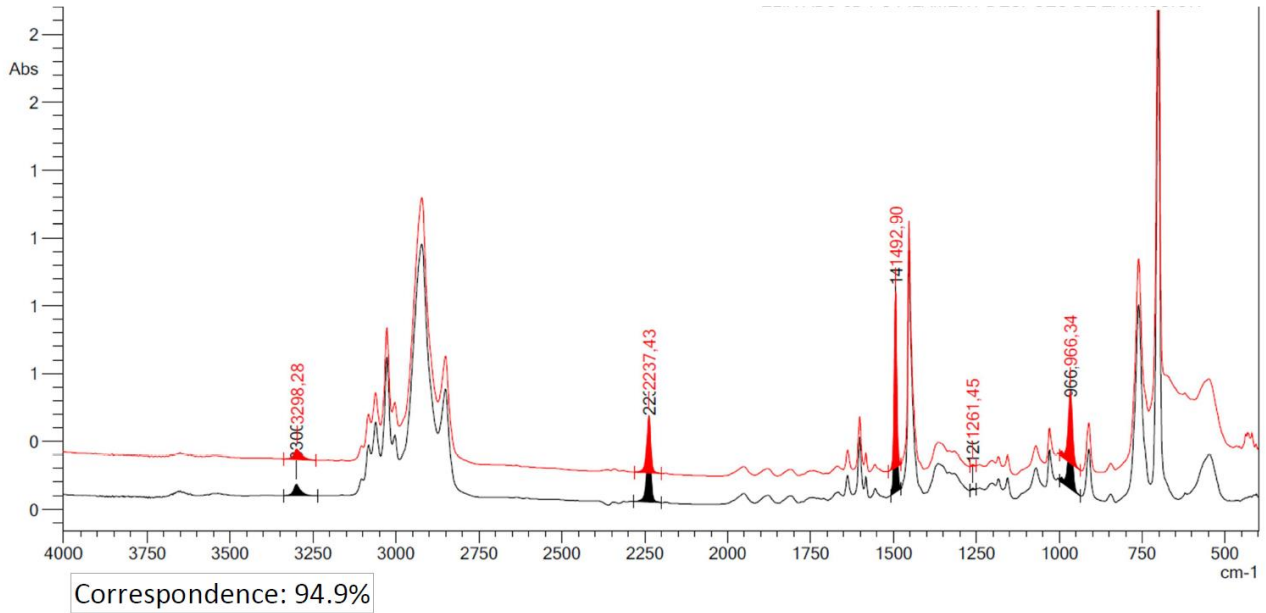
PRODUCT	FILAMENTO SMARTFIL ABS MEDICAL 1.75 mm	
TEST	ESPECIFICACIONES	RESULT
Physical Appearance	--	Correct
Diameter Accuracy	1.75 mm (+- 0,03mm)	Correct
<i>Comparison analysis: processed materials (filament) vs virgin resin</i>		
Color	Color difference DE<1	Natural color (N/A)
Infrared Spectroscopy (IR)	Correspondence > 90 % No additional peaks detected.	Correct Correct
Thermogravimetric (TGA)	Correspondence Thermal Stability. No additional residue detected.	Correct Correct
Differential Scanning Calorimetry (DSC)	Correspondence TG	Correct
Process degradability (GC)	Total monomers increase < 50% Specific monomer increase (ACN/BUT) No additional monomers detected	Correct Correct Correct
Migration/Extractable Test (GC)	No additional peaks identified	Correct

Result of the validation:      **SATISFACTORY**

# BIOCOMPATIBILITY CERTIFICATE

## RESULTS – DETAILED INFORMATION

VIRGIN RESIN  
FILAMENT PROCESSED



# BIOCOMPATIBILITY CERTIFICATE

