

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:

1

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

### **USP <661>**

SMARTFIL® PETG, complies with the compositional requirements and specifications of USP <661> requirements, including multiples internal reflectance, thermal analysis, water vapor permeation, color extraction, heavy metals, and absorbance @ 575 nm against ethylene glycol. It was found acceptable in all test and thus meets all the requirements of USP <661>.

SMARTFIL® PETG may be used in contact with solid and liquid pharmaceutical dosage forms, except where its use would be inappropriate, such as for heat sterilization or where solvents attack the resin. Therefore, it is the responsibility of our customers to determine that their use of our products is safe, lawful, and technically suitable in their intended applications.

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.*

