

## BSE/TSE Certificate

Date: 15 April 2017  
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**To whom it may concern,**

**SMART MATERIALS 3D PRINTING S.L** with address in Polígono Industrial El Retamar Calle Tomillo number 7 Vial G, CP: 23680 Alcalá la Real (Jaén), certifies:

That our product **SMARTFIL ABS MEDICAL**, has been manufactured with ABS pellets that comply with the requirements BSE/TSE regulation.

The pellet used for manufacturing SMARTFIL ABS MEDICAL contains < 2 % of a stearamide and < 0.5 % of a stearic acid salt as releasing agents. These stearates can be made from vegetable oils or tallow.

All tallow derivatives and vegetable oils used in the raw material are manufactured according to at least one of the processing conditions described in chapter 6.4 (Tallow Derivatives) of European 2011/C 73/01 ["Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medical products" (EMA/410/01 Rev. 3—July 2011)].

Thus, we are confident that the use of these stearates as additive in the raw material do **not** pose any BSE/TSE risk and can be considered compliant with the above mentioned note for guidance.

Smart Materials 3d Printing SL guarantees that the raw material has not been altered or modified in the filament manufacturing process.

Throughout the production process, the complete management and control of product traceability is guaranteed from the purchase of the raw material to the delivery to the customer. The follow-up and control is carried out by means of individual marked batch code in each coil.

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

The aforementioned confirmation only applies to the filament delivered by Smart Materials.



Antonio Peláez

**Head of the technical department.**