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Biocompatibility product Information

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Product: Ultrafuse® TPU 85A

Revision: 6/7/2022

Version: 1.2

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Ultrafuse® TPU 85A material is 3D printed as test specimens and successfully passed the requirements of the stated tests below:

- **Cytotoxicity XTT Test - Neutral red** (ISO 10993-5:2009)
The extract of the product Ultrafuse® TPU 85A resulted in a cell vitality of more than 70% in comparison to the negative control and can therefore be considered to be not cytotoxic.
- **Skin Irritation Test** (ISO10993-10:2013)
All human skin models EpiDermTM have values which are above the threshold for irritation when exposed to Ultrafuse® TPU 85A for 18hr under experimental conditions. Therefore, Ultrafuse® TPU 85A is not irritant to skin according to UN GHS and EU CLP regulation.
- **Skin Sensitisation Test - Local Lymph Node Assay KretinoSens** (ISO10993-12:2018)
The extracts of the product Ultrafuse® TPU 85A resulted in an induction of the luciferase activity of less than 1.5 times compared to the DMSO control and is therefore to be assessed as non-sensitizing.

The performed biocompatibility tests were recorded on test specimen of the above referenced product to show compatibility of the material in general. The biocompatibility tests listed are not part of any continuous production protocol. The test assessments reflect only the test specimen and have to be retested on the final product. It remains the responsibility of the device manufacturers and/or end-users to determine the suitability of all printed parts for their respective application.

For notice:

We give no warranties, expressed or implied, concerning the suitability of above-mentioned product for use in any medical device and pharmaceutical applications.

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