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Biocompatibility product Information

Product: Ultrafuse® PLA PRO1

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Ultrafuse® PLA PRO1 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® PLA PRO1 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 10 volunteers exhibited no dermal changes in the test zone at 24h, 48h and 72h when exposed to Ultrafuse® PLA PRO1.

- **Skin Sensitisation Test - Local Lymph Node Assay KretinoSens** (ISO10993-10:2020)
  The extracts of the product Ultrafuse® PLA PRO1 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.

F o r n o t i c e:
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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