

Product Information

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Product:

Ultrasint TPU01 for HP Jet Fusion printer + vapour smoothing

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3D printed test items of the above stated product have fulfilled the requirements of tests as stated below:

Cytotoxicity Testing- Neutral red: Pass

(EN ISO 10993-5 (2009))

In vitro Skin Irritation Testing- Human Skin Model: Pass

(EN ISO 10993-10 (2013))

In vivo Sensitisation Testing- Local Lymph Node Assay: Pass

(prEN ISO 10993-10 (2020))

Sampling preparation: The test specimens were dry ice blasted and handled only with disposable medical gloves. The test specimens were wrapped in aluminum foil for shipment for vapour smoothing externally with an AMT Post Pro 3D.

According to our testing institutes the test result show no indication against the use of the test specimen in skin contact application. Please note, that the biocompatibility tests indicated above 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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