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## Product Information

Page 1 / 1

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### Product: Ultrasint TPU01 for HP Jet Fusion printer

Revision: 17.03.2020

Version: 2.0

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#### Results of the testing as required by the ISO10993-1:2018 to be conducted for the intact skin assessment:

**Cytotoxicity Testing- XTT:** Positive Result  
(ISO 10993-5 (2009))

**In vitro Skin Irritation Testing- Human Skin Model:** Negative Result  
(ISO 10993-10 (2013); OECD Guideline No. 439)

**In vivo Sensitisation Testing- Local Lymph Node Assay:** Negative Result  
(ISO 10993-10 (2013); OECD Guideline No. 429)

#### Final Assessment: Accepted for the use on intact skin

The measurement of cytotoxic effects indicated a cytotoxic potential on L929 cells by the extract of the test item, however, the 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 assessment shows the grade of acceptability on the intact skin, however it reflects only the test specimen and has to be retested on the final product.

#### 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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