

ISO 10993 Biocompatibility statement

Product name: **Ultrasint® PA11** ID-Number: 955638

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

- **Cytotoxicity Testing- XTT:** passed
(ISO 10993-5 (2009))
- **In vitro Skin Irritation Testing- Human Skin Model:** passed
(ISO 10993-10 (2013); OECD Guideline No. 439)
- **In vivo Sensitisation Testing- Local Lymph Node Assay:** passed
(ISO 10993-10 (2013); OECD Guideline No. 429)

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 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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