

USP 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:

- **USP Class VI: Acute Systemic Injection Test Extracted in Normal Saline, Alcohol in Saline, PEG 400 and Vegetable oil (Cottonseed and Sesame Oil) at 50°C, for 72 hours. Injected in Mouse.** Result: passed
- **USP Class VI: Intracutaneous Irritation Test Extracted in Normal Saline, Alcohol in Saline, PEG 400 and Vegetable oil (Cottonseed or Sesame oil) at 50°C, for 72 hours. Tested with Rabbit.** Result: passed
- **USP Class VI: Intramuscular Implantation Test Implanted in Rabbit for 1 week.** Result: passed

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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