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Product information on skin contact

Ultrasint® PP nat 01 Product name: ID-Number: 932238

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

- Cytotoxicity Testing- Neutral red: Pass (ISO 10993-5 (2009))
- In vitro Skin Irritation Testing-Human Skin Model: Pass
- (OECD Guideline No. 439)
- In vivo Sensitisation Testing- Local Lymph Node Assay: Pass (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.

Fornotice:

We give no warranties, expressed or implied, concerning the suitability of above-mentioned product for use in any medical device and pharmaceutical applications.

Disclaimer.

The declaration is exclusively for our customers and respective competent authorities. It is not intended for publication either in printed or electronic form (e.g., via Internet) by others. Thus, neither partial nor full publication is allowed without written permission by BASF 3D Printing Solutions GmbH.

The aforementioned data or information is based on our current knowledge and experience. In view of the many factors that may affect processing and application of our product, these data do not relieve processors from carrying out their own investigations and tests; neither do these data imply any guarantee of certain properties. nor the suitability of the product for a specific purpose. Any descriptions, drawings, photographs, data, proportions, weights etc. given herein may change without prior information and do not constitute the agreed contractual quality of the product. It is the responsibility of the recipient of our products to ensure that any proprietary rights and existing laws and legislation are observed. This statement does not constitute the legally binding Safety Data Sheet.

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