ISO 10993 and US FDA Intact Skin Surface Devices Statement

HP 3D400 Fusing, Detailing, and Bright Fusing Agents and HP 3D High Reusability CB PA 12

Original HP 3D400 Fusing, Detailing, and Bright Fusing Agents and HP 3D HR CB PA 12 material ("HP Agents & CB PA 12 Material") have met the US Food and Drug Administration's ("FDA") guidance and ISO 10993-1 standard for Intact Skin Surface Devices. This conclusion is based on the following guidelines and tests conducted at a certified third-party laboratory:

1. **Cytotoxicity** – ISO 10993-5, Biological evaluation of medical devices – part 5: Tests for in vitro cytotoxicity.
2. **Sensitization and irritation** – ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
3. **Acute systemic toxicity** – ISO 10993-11, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.
4. **Pyrogenicity** – USP, General Chapter <151>, Pyrogen test. Recommended in ISO 10993-11, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.

The results from the above-referenced testing are representative of parts produced on the HP Jet Fusion 540 3D printers over the range of available printmodes with HP Agents & CB PA12 Material. The only post processing that the parts underwent were sand blasting, a soak in isopropanol for 30 minutes, and a rinse in deionized water. Based on these results, HP expects that similar parts made from the HP Agents & CB PA 12 Material under recommended operating conditions as per the site preparation guide will be suitable for applications described in FDA's and ISO 10993's guidance for Intact Skin Surface Devices.

It is the responsibility of each customer to determine that its use of HP Agents & CB PA 12 Material is safe and technically suitable to the customer's intended applications and consistent with the relevant regulatory requirements (including FDA requirements) applicable to the customer's final product. Customers should conduct their own testing to ensure that this is the case. Results may vary if the testing is performed under different conditions than those existing at testing time and/or those required testing conditions that applied for the purposes of the biocompatibility tests referenced above. Because of possible changes in the relevant industry standards, FDA guidance, and other legal or regulatory requirements, as well as possible changes in HP Agents & CB PA 12 Materials, HP cannot guarantee that the status of HP Agents & CB PA 12 Material will remain unchanged or that it will qualify for or comply with FDA's and/or ISO 10993's guidance for Intact Skin Surface Devices in any particular use.

For additional information about HP 3D400 Fusing, Detailing, and Bright Fusing Agents and HP 3D HR CB PA 12, please contact our HP 3D Printing Materials team at 3dmaterials@hp.com.

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