BIOCOMPATIBILITY
STATEMENT

HP Inc.
Original HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 11
USP Class I-VI and FDA Intact Skin Surface Devices Statement

HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 11 have met the requirements of USP Class I-VI and US Food and Drug Administration's (FDA) guidance for Intact Skin Surface Devices. This conclusion is based on following tests and guidelines 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. **Muscle implantation** – USP, General Chapter <88>, Biological Reactivity Tests, In vivo – Muscle implantation

The results from the above-referenced testing are representative of parts produced on the HP Jet Fusion 3D 4200/4210 printers over the range of available printmodes with HP 3D700/710 Fusing and Detailing Agents and HP 3D HR PA11[1] 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 articles made from HP 3D700/710 Fusing and Detailing Agents and HP 3D HR PA11[1] material under recommended operating conditions as per the site preparation guide will meet the compliance requirements of USP Class I-VI and will be suitable for applications described in FDA's guidance for Intact Skin Surface Devices.

It is the responsibility of each customer to determine that its use of HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 11 powder 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. HP 3D High Reusability PA11 powder is not intended to be used in medical device applications that constitute a non-temporary implant (i.e., that, in whole or in part, may be in contact with a patient's skin, body fluids or tissues for more than 30 days). 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 HP's laboratories at testing time and those that applied for the purposes of the biocompatibility tests as 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 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 11 powder, HP cannot guarantee that the status of HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 11 powder will remain uncharged or that it will qualify for USP Class I-VI Certification and or comply with FDA's guidance for Intact Skin Surface Devices in any particular use.

For additional information about HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 11, please contact our HP 3D Printing Materials team at 3dmaterials@hp.com.

1. Testing performed with 100% fresh powder.

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