BIOCOMPATIBILITY
CERTIFICATE

HP Inc.
HP 3D600/3D700 Fusing and Detailing Agents and HP 3D High Reusability PA 12
USP Class I-VI and FDA Intact Skin Surface Devices Certification

HP 3D600/3D700 Fusing and Detailing Agents and HP 3D High Reusability PA 12 have met the requirements of USP Class I-VI and US FDA's guidance for Intact Skin Surface Devices. This conclusion is based on following tests and guidelines used:

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

HP believes that the testing referred to above is representative of parts produced with HP 3D600/3D700 Fusing and Detailing Agents and fresh HP 3D High Reusability PA 12 powder[1] on the HP Jet Fusion 3D 3200 and 4200 printers. Based on these results, HP expects that similar articles made from these materials, under similar conditions will meet the compliance requirements of USP Class I-VI and FDA's guidance for Intact Skin Surface Devices.

It is the responsibility of each customer to determine that its use of HP 3D600/3D700 Fusing and Detailing Agents and HP 3D High Reusability PA 12 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. 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 Fusing and Detailing Agents and HP 3D High Reusability PA 12 powder, HP cannot guarantee that the status of HP 3D600/3D700 Fusing and Detailing Agents and HP 3D High Reusability PA 12 powder will remain unchanged 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 Fusing and Detailing Agents and HP 3D HR PA 12, please contact our HP 3D Printing Materials team at 3dmaterials@hp.com.

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[1] Testing performed with 100% fresh powder