BIOCOMPATIBILITY
STATEMENT

HP Inc.
HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 12
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 12 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 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 results from the above-referenced testing are representative of parts produced on the HP Jet Fusion 4210 and 4200 3D Printing Solutions over the range of available printmodes with HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 12 Material. HP 3D High Reusability PA12 fresh and recycled (80% recycled/20% fresh) powders were used for the Cytotoxicity test. HP 3D High Reusability PA12 100% fresh powder was used for the Sensitization and Irritation, Acute Systemic Toxicity, and Muscle Implantation tests. 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 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 12 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 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 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 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 12 powder, HP cannot guarantee that the status of HP 3D600/3D700/3D710 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 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D High Reusability PA 12, please contact our HP 3D Printing Materials team at 3dmaterials@hp.com.

4AA7-0331ENW, October 2019

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