

# BIOCOMPATIBILITY CERTIFICATE



**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 Certification**

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 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 3D600/3D700/3D710 Fusing and Detailing Agents and fresh HP 3D High Reusability PA 12 powder<sup>1</sup> on the HP Jet Fusion 3D 4210 and 4200 Printing Solutions. 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 3D600/3D700/3D710 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 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 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](mailto:3dmaterials@hp.com).

---

<sup>1</sup> Testing performed with 100% fresh powder.

---

© Copyright 2017, 2018 HP Development Company, L.P.

Nothing herein should be construed as constituting an additional warranty. The only warranties for HP products and services are set forth in the express warranty statements accompanying such products and services and/or in a written agreement between you and HP. HP believes that the information herein is correct based on the current state of scientific knowledge and as the date of its publication, however, to the maximum extent permitted by law HP EXPRESSLY DISCLAIMS ANY REPRESENTATIONS AND WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, AS TO THE ACCURACY, COMPLETENESS, NON-INFRINGEMENT, MERCHANTABILITY AND/OR FITNESS FOR A PARTICULAR PURPOSE (EVEN IF HP IS AWARE OF SUCH PURPOSE) WITH RESPECT TO ANY INFORMATION PROVIDED. Except to the extent that exclusion is prevented by law, HP shall not be liable for technical or editorial errors or omissions, and damages or losses of any kind or nature that result from the use of or reliance upon this information, which is subject to change without notice. The HP Jet Fusion 3D products have not been designed, manufactured or tested by HP for compliance with legal requirements for specific 3D printed parts and their uses, and recipients are responsible for determining the suitability of HP Jet Fusion 3D products for their uses, ensuring compliance with applicable laws and regulations, and being aware that other safety or performance considerations may arise when using, handling or storing the product.

