FAQ

3D-PRINTED MEDICAL DEVICES

Medical Devices Branch

July 2021

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1. Is there any prescribed timeline for registration of patient-matched medical device?

Please take note that unlike custom made medical devices, all Class B, C and D patient-matched medical devices are required to be registered on Singapore Medical Device Register (SMDR).

Companies supplying patient-matched medical devices locally should submit their product registration application to HSA by 01 August 2022 to continue supplying their devices here.

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2. Is 3D printer and software regulated as a medical device?

3D printer and 3D printer software (with no diagnostic and/or therapeutic function) are generally considered as manufacturing equipment and not medical devices.

Manufacturing activities are covered under the Quality Management System (such as ISO13485 or equivalent) for the manufacturing of the medical device.

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3. Is the raw materials for 3D printing regulated as a medical device?

Raw materials for 3D printing, as with any other traditional manufacturing raw materials, are not medical devices. However, choice of raw materials will affect the Safety and Performance of a medical device (Guidance GN-16). These are controlled under the Quality Management System (such as ISO 13485 or equivalent) for the manufacture of the medical device.

Some dental materials, however, may be approved for a specific intended use (i.e. material used to manufacture partial or full crowns and bridges) are regulated *as a medical device*, regardless of it being used in manufacturing by 3D printing or conventional methods. The material in its finished form should be tested for safety and performance for its proposed used.

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4. Is a 3D printed anatomical model regulated as a medical device?

Currently, 3D anatomical models intended for:

- Education or teaching purposes,
- Use during patient consultation, or
- To aid in doctor's preparation for surgery

are not regulated as medical device and is not subjected to medical device regulatory controls.

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5. Are there any international standards for 3D printed medical devices?

International standards that are applicable to medical devices in general are also applicable to 3D printed medical devices, to demonstrate compliance with the Safety and Performance Requirements (GN-16 Guidance on Essential Principles for Safety and Performance of Medical Devices).

An example is the International standard ISO 10993 series which can be used by manufacturers to demonstrate conformance to the Safety and Performance Requirements, for biocompatibility of their medical devices.

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6. Are there any international standards for Additive Manufacturing/ 3D printing?

Currently, there are several published ISO standards, ASTM standards and standards jointly developed by ISO/ASTM (**Appendix A**) on Additive Manufacturing which relates to terminology, design, materials and processes, test methods and etc.

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7. There is a change in the manufacturing method for the registered medical device from conventional to additive manufacturing. Can the change be effected via Change Notification?

Yes, the change can be effected via a Change Notification submission.

Please refer to the guidance document (GN-21 Guidance on Change Notification for Registered Medical Devices) for more information.

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8. The registered medical device is not manufactured using additive manufacturing method. Can a new model manufactured using additive manufacturing be added to the existing listing via Change Notification based on FAMILY grouping?

For existing registered medical devices manufactured via conventional method, a new model manufactured via additive manufacturing would not fulfil the FAMILY Grouping criteria (GN-12 Guidance on Grouping of Medical Devices for Product Registration - General Grouping Criteria) due to the difference in manufacturing process between the registered and new models.

Hence, the new model cannot be added to the existing listing (of FAMILY grouping) via Change Notification. A new pre-market Product Registration will be required for the new model.

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9. Can I submit a pre-market application with the same design but different materials used in 3DP?

In order to qualify for a FAMILY grouping, medical devices should be manufactured using same material. Differences in the materials is not within the scope of permissible variants for FAMILY grouping.

Hence, it does not fulfil our FAMILY grouping criteria (GN-12 Guidance on Grouping of Medical Devices for Product Registration - General Grouping Criteria) and separate pre-market applications will be required.

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10. Can I submit a pre-market application for two devices with the same design and materials but different 3D printing methods?

Different 3D printing methods such as Selective Laser Melting (SLM) and Electron Beam Melting (EBM) are considered as different manufacturing process.

Medical devices with the same design and material, but manufactured using different manufacturing processes (example: SLM and EBM), do not fulfil our FAMILY grouping criteria (GN-12 Guidance on Grouping of Medical Devices for Product Registration - General Grouping Criteria) and two separate pre-market applications will be required,

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11. There is a change in the Additive manufacturing process (i.e. changes to the 3D printer software, printer or printing process) for the registered medical device. Is Change Notification submission required?

Whether a change notification submission is required will be based on if the change in manufacturing process would result in a change in specifications of the registered device.

Please refer to Flowchart 1.1 of the guidance (GN-21 Guidance on Change Notification for Registered Medical Devices) for more information.

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12. Can patient-matched medical devices and non patient-matched medical devices be grouped together as a FAMILY grouping?

If both patient-matched medical devices and non patient-matched medical devices fulfils the FAMILY grouping requirements as per Guidance GN-12 (GN-12 Guidance on Grouping of Medical Devices for Product Registration - General Grouping Criteria), these devices can be submitted together as a FAMILY.

One of the grouping criteria under GN-12 for FAMILY grouping is “common manufacturing process”. If the patient matched medical devices is manufactured via additive manufacturing, but the non patient-matched medical device is not manufactured via additive manufacturing, it will not fulfil the “common manufacturing process” criteria for grouping.

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13. What are the regulatory requirements for custom-made medical device?

Custom-made medical devices do not require product registration, however, dealers (Importers and Manufacturers) need to notify HSA on their updated list of custom-made devices.

Dealers dealing with custom-made medical device are subject to the dealer's licencing requirements and post-market obligations.

For more information, please refer to our website available here.

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14. Should dealers keep a record of custom-made medical devices?

Dealers must keep records of the requesting qualified practitioner's prescription or equivalent as evidence that the device was custom-made based on the qualified practitioner's request and specifications for his patient.

Standard record keeping requirement (example: keeping of distribution and complaint records) for dealers will also apply.

These records may be requested by HSA for verification purposes. For more information, please refer to our website available here.

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APPENDIX A
Common Standards for Additive Manufacturing

Terminology	Title
ISO/ASTM 52900-15	Standard Terminology for Additive Manufacturing - General Principles- Terminology
ISO/ASTM 52921-13	Standard Terminology for Additive Manufacturing – Coordinate Systems and Test Methodologies

Test Methods	Title
F2971-13	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing
F3122-14	Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes

Design	Title
ISO/ASTM 52915-16	Standard Specification for Additive Manufacturing File Format (AMF) Version 1.2

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APPENDIX A
Common Standards for Additive Manufacturing

Materials & Processes	Title
F2924-14	Standard Specification for Additive Manufacturing Titanimum-6 Aluminium-4 Vanadium with Powder Bed Fusion
F3001-14	Standard Specification for Additive Manufacturing Titanimum-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
F3049-14	Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes
F3055-14a	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion
F3056-14e1	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
F3091/ F3091M-14	Standard Specification for Powder Bed Fusion of Plastic Materials

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