

REGULATORY GUIDELINE FOR 3D-PRINTED MEDICAL DEVICES

Medical Devices Branch

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The Health Sciences Authority (HSA) is issuing this guideline to provide clarity on three-dimensional (3D)-printed medical devices, as well as the regulatory approach and regulatory requirements for these medical devices.

This guideline reflects HSA's current thinking, existing policies and practices. This should not be misconstrued as new regulatory controls for these medical devices.



- 3D printing, or Additive Manufacturing (AM) is a process of building an object layer by layer, based on a digital model. It is the opposite of conventional subtractive manufacturing.
- Types of medical devices commonly manufactured using 3D printing:
 - Non-invasive prosthetics (such as prosthetic limbs)
 - Dental devices
 - Surgical tools and guides
 - Implantable devices (such as orthopedic implants)



- Commonly used AM technologies in medical devices are:
 - Powder bed fusion: uses energy source (laser or electron beam) to melt a layer of powder
 - Stereolithography: uses a vat of liquid material that is selectively cured
 - Fused filament fabrication: melts a solid filament at point of deposition
 - Liquid-based extrusion: eject a liquid, which then solidifies through light exposure or chemical process
- With 3D printing, designs can be altered rapidly without the need for re-tooling and complex devices can be created and built as a single piece.



- Medical devices manufactured using 3D printing technology are subject to the current regulatory framework and requirements as those manufactured using traditional manufacturing techniques, based on risk classification of the device.
- 3D-printed medical devices must comply with the Essential Principles of Safety and Performance as described in [GN-16](#): Guidance on Essential Principles for Safety and Performance of Medical Devices.
- Regulatory controls are based on intended use/indications for use and technological characteristics within the existing risk-based framework for medical devices, regardless of the manufacturing process.



This document is applicable to all medical devices manufactured by Additive Manufacturing (3D printing), excluding *in-vitro* diagnostic medical devices (IVD MDs).



CATEGORISATION OF 3D-PRINTED DEVICES

Mass-produced vs. Custom-made MDs

Generally, 3D-printed medical devices may be categorized into either “mass-produced” or “custom-made” medical devices:

Mass-produced medical devices

- Standard-sized device; or
- Mass-produced device which could be adapted to an individual; or
- **Patient-matched medical device**
[new terminology]

Custom-made medical devices

- Made at the request of a qualified practitioner and in accordance with the specifications of the qualified practitioner regarding the **design characteristics or construction** of the medical device;
- Intended to be used only in relation to a particular individual; and
- Not adapted from a mass-produced medical device

Reference: Health Products (Medical Devices) Regulation 2010

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Categorisation of
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Patient-matched
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Flowchart 1

CATEGORISATION OF 3D-PRINTED DEVICES

Custom-made MDs

Custom-made medical devices are typically intended *for special clinical circumstances* when mass-produced devices are inadequate for the needs of a particular individual.

With 3D printing, it is now possible to mass produce patient-matched medical devices (including higher risk implantable products) based on patient CT scans, on a *commercial scale*. Therefore, it is important to differentiate such patient-matched devices from custom-made medical devices.



CATEGORISATION OF 3D-PRINTED DEVICES

Patient-matched MDs

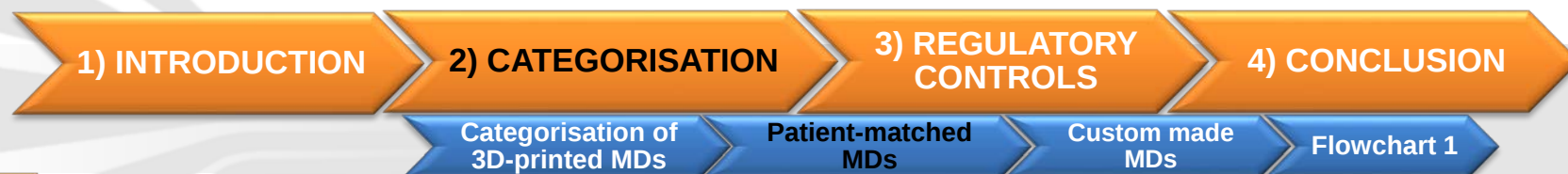
Patient-matched medical devices can be mass-produced and are described as follows:

- A medical device manufactured within a specified design envelope^{*} and typically produced in a batch[^] through a process that is capable of being validated and reproduced
- The device is matched to a specific patient's anatomy within the design envelope

^{*}Design envelope: Refers to various parameters including minimum and maximum dimensions/size (e.g. length, breadth, thickness, angle), mechanical performance limits etc. relevant to a medical device.

Note: Design/specifications of the patient-matched medical device must remain within the validated parameters of the specified design envelope.

[^]Refer to <IMDRF 2018 Final Document – Definitions for Personalised Medical Devices> for definition



CATEGORISATION OF 3D-PRINTED DEVICES

Patient-matched MDs

Example 1 :

Acetabular guide designed to assist a surgeon with pre-operatively planned placement of the acetabular cup component of a total hip replacement:

- The guide is based upon CT images of a ***patient's specific anatomy*** and pre-operatively planned placement of the acetabular cup.
- The device manufacturing processes, as well as the pre-operative planning process upon which **design of the patient-matched guide is based**, are validated within a certain range of anatomical parameters.
- The guide is produced under the responsibility of the manufacturer in consultation with, and input from, the surgeon.



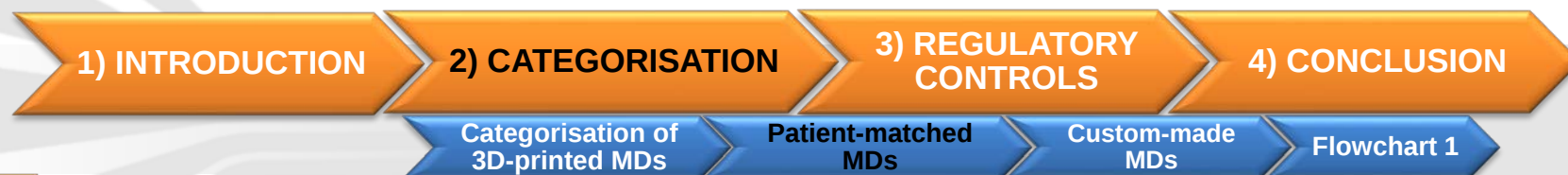
CATEGORISATION OF 3D-PRINTED DEVICES

Patient-matched MDs

Example 2 :

An **externally worn orthosis** to shape the skull of an infant to prevent plagiocephaly, based on 3D external images of the **patient's head**.

In this example the images are produced by a prosthetist and sent to a manufacturer. The manufacturer produces, under its responsibility, a **patient specific helmet within validated parameters**.



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Custom-made MDs

Custom-made medical devices must fulfill all of the criteria below:

- Made at the request of a qualified practitioner and in accordance with the specifications of the qualified practitioner regarding the ***design characteristics or construction**** of the medical device;
- Intended to be used only in relation to a particular individual; *and*
- Not adapted from a mass-produced medical device.

Reference: Health Products (Medical Devices) Regulation 2010

***Design characteristics or construction** is defined as:

Unique design specifications, including mechanical performance necessary to produce custom-made devices and which are based on an individual's specific anatomico-physiological features and/or pathological condition.



CATEGORISATION OF 3D-PRINTED DEVICES

Custom-made MDs

Example of custom-made medical device:

Acetabular cup implant requested by an orthopedist who, **in addition** to DICOM-compliant scan images, sends **specific requirements for bridging the areas of acetabular bone loss in acetabulum reconstruction** to a 3D printing implant manufacturer. These include the **thickness and trajectory of the cup mounting flange**, and the **number, type and positions of fixation screws**.

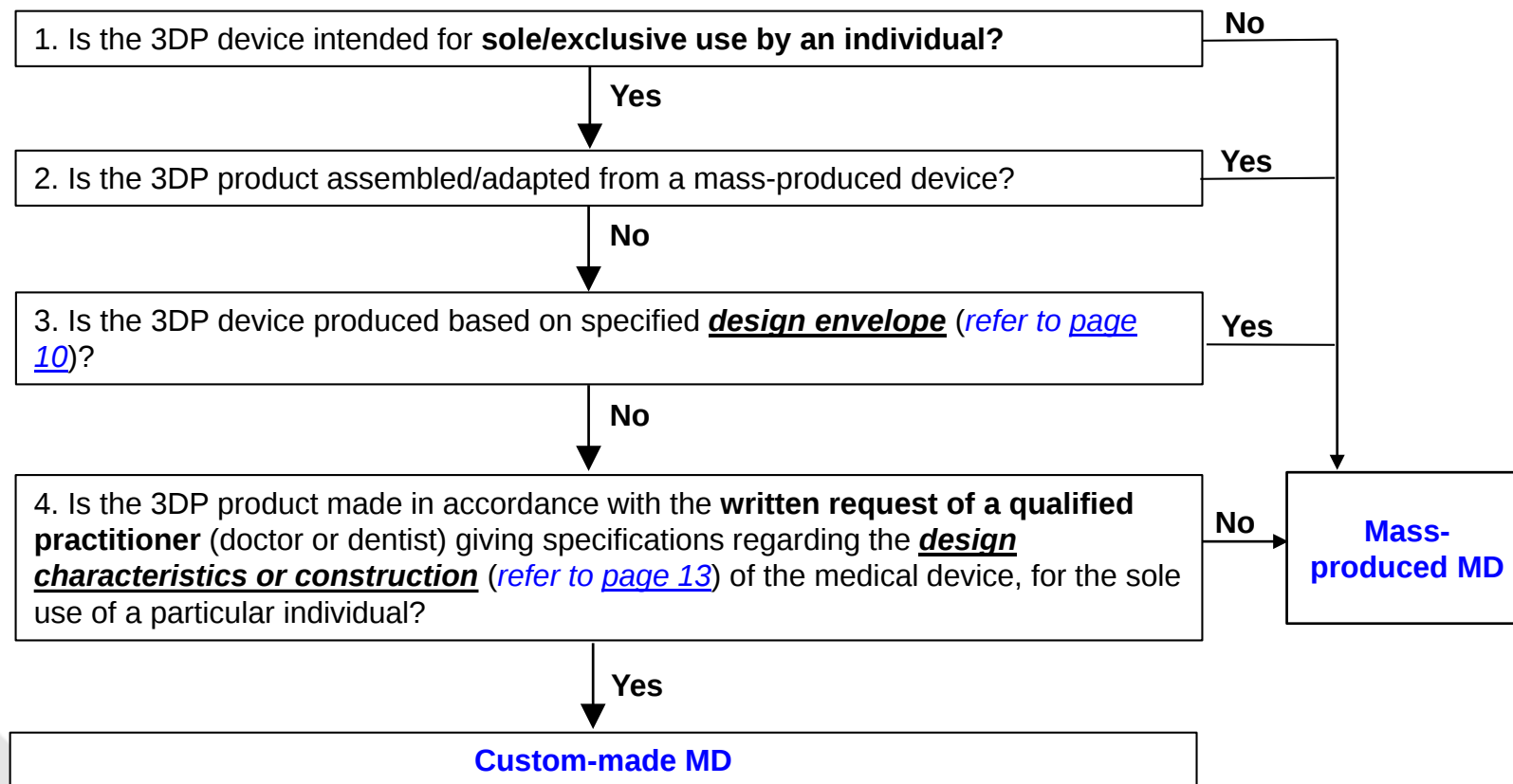
In this example, these requirements are ***outside of the manufacturer's validated parameters*** of the specified [design envelope](#) for this type of device:

- the required dimensions for bridging exceed those that have been validated under worst case parameters; and
- the number and location of screw holes are also beyond the limits modeled and/or tested.



CATEGORISATION OF 3D-PRINTED DEVICES

Flowchart 1



REGULATORY CONTROLS

Mass-produced medical devices

Subject to the following medical device regulatory controls:

- **Dealer's license requirements**
- **Post-market obligations**
- **Product Registration (except for Class A MDs)**

Custom-made medical devices

Subject to the following medical device regulatory controls:

- **Dealer's license requirements**
- **Post-market obligations**

Note: Where the medical device is manufactured within the Private Hospitals and Medical Clinics (PHMC) facility for their patient use, please contact the Medical Devices Branch (MDB) for further advice.

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Product Registration

- As with all medical devices, 3D-printed devices are classified into different risk classification (Class A to Class D) as per [GN-13: Guidance on the Risk Classification of General Medical Devices](#), depending on the nature of the device and its intended functions. In order to supply mass-produced 3D-printed medical devices in Singapore, the Registrant is required to register the Class B, C and D devices with HSA.
- Product registration submission requirements and process will be per [GN-15: Guidance on Medical Device Product Registration](#).
- Similarly, 3D-printed medical devices undergo changes as part of their product life cycle as well. Please refer to [GN-21: Guidance on Change Notification for Registered Medical Devices](#) to determine whether a Change Notification submission to HSA is required for specific proposed changes to a medical device that is registered on the Singapore Medical Device Register (SMDR).



- Basic considerations for **all** 3D-printed devices is as described in [Table A](#). However, not all considerations described will be applicable to every device as this would be dependent on the AM technology, device type and material used.
- Mass produced 3D-printed device requires product registration and the basic considerations in Table A are mapped against [TR-01](#): Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT. The type and amount of technical documents for product registration submission will vary depending on the intended use, risk classification and evaluation route of the device.
- For custom-made MDs and Class A MDs which do not require product registration, manufacturers should still take note and comply with the applicable considerations presented in Table A for their device.



REGULATORY CONTROLS

Considerations for 3D-printed MDs

Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.2 Device Description	Design Consideration • Design specifications such as dimensional ranges and design parameters (e.g. performance limits), as applicable should be specified for the final device/component which is 3D-printed. • Critical device features (such as location and thickness of porous features) to be identified as these may have reduced mechanical properties. • For patient-matched medical devices, accuracy of the geometrical features and compatibility with the anatomy are important. Therefore the manufacturer should establish clinically acceptable geometrical tolerances for the design features and include this information in product labelling, where applicable.

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Considerations for 3D-printed MDs

Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.2 Device Description	Design Consideration - Name or CAS number of starting material, additives or processing agents used. - Material specification for the starting material used in 3D printing: Certificate of Analysis (CoA) or equivalent. Applicable material standards and test methods (e.g. ASTM, ISO etc.) should be referenced.

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Considerations for 3D-printed MDs

Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.2 Device Description	Design Consideration Examples of material specifications for the starting material may include, but not limited to: • Solid phase: Particle size and size distribution for powders or filament diameter and diametric tolerances for filaments, composition and purity (for alloys), mix ratio (for composites) • Liquid phase - viscosity or viscoelasticity, and pH • Polymer or monomer mixture - composition, purity, water content (if applicable), chemical structure, molecular weight and melting point.

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Considerations for 3D-printed MDs

Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.2 Device Description	Design Consideration For patient-matched medical device produced based on <u>specified design envelope</u>: - The pre-determined range for these parameters, including but not limited to dimensions or size, and performance limits etc, relevant to a medical device which could be modified, should be specified. <u>Annex 2 for GN-17 List of Configurations</u> should include information on the validated parameters <i>of the specified design envelope</i>: refer to page 31.

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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.3 Summary of Design Verification and Validation Documents	Device Validation Consideration Biocompatibility is recommended to be evaluated according to international standards such as ISO10993-1 ¹ based on nature of contact, using final finished device ² . If biocompatibility is not evaluated according to ISO10993-1, or if the testing identifies a concern, additional material chemistry information or testing may be required to ensure there are no unintentionally formed chemical entities that could pose a risk to patient health.

¹ISO10993 Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process

²Final finished device: finished device subjected to all post-processing, cleaning and sterilization steps (as applicable).



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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.3 Summary of Design Verification and Validation Documents	Device Validation Consideration - Type of mechanical or performance validation applicable would depend on the device type and it may include: tensile strength, fatigue, or abrasive wear etc. - Performance testing should be conducted on final finished device¹ or representative test coupons, with rationale provided on the determined worst case. A test coupon is a representative test sample of the device or component. The build orientation and location can affect the device mechanical properties and should be considered during the performance testing.

¹Final finished device: finished device subjected to all post-processing, cleaning and sterilization steps (as applicable).



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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.3 Summary of Design Verification and Validation Documents	Device Validation Consideration - Removal of manufacturing material residues to acceptable levels that do not adversely affect device safety and performance. Validation should consider the worst case scenario. - Sterilization process validation should account for the device's complex geometry under worst case conditions (e.g. greatest amount of residual manufacturing materials, largest surface area, greatest porosity and most internal voids).

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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.4 Device Labelling	Labelling and expiration date For patient-matched medical device produced based on a specified design envelope: • Elements of labelling should include sufficient information to identify or to trace the individual. • Labeling should recommend patient to be assessed for potential anatomical changes prior to the procedure/ surgery, to ensure the compatibility of the device with the anatomy. • Due to possible time-dependent changes to patient anatomy, expiration date of the device may be based on the patient imaging date (as provided by the healthcare professional), rather than the standard methods of determining device shelf life.

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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.6 Manufacturer Information	Manufacturing Consideration - Information on the Additive manufacturing method (e.g. laser sintering, direct metal laser sintering and stereolithography). - All manufacturing activities for the medical device including the additive manufacturing and post-manufacturing processes should be performed within an ISO 13485-compliant quality management system.

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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.6 Manufacturer Information	Manufacturing Consideration - Additive Manufacturing Process flow chart (including critical pre-printing steps eg. software workflow and the post printing processing steps). - For patient matched medical device, if the workflow uses data from imaging modalities such as CT, ultrasound etc., the minimum image requirements (such as file types, resolution etc) used for matching should be clearly established and communicated to the healthcare provider for image acquisition.

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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.6 Manufacturer Information	Manufacturing Consideration Information on material re-use process (as applicable). Examples of material re-use process includes filtering reused material, a limit on the percent of reused material, or monitoring for changes in chemistry, oxygen, or water content.

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Table A: Basic considerations for all 3D-printed devices

TR-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT	Basic Considerations, as applicable
4.6 Manufacturer Information	Manufacturing Consideration - For patient matched medical device: - Validation of software components used in the processing of patient imaging data, design development and production of the device, as applicable. - The manufacturer should establish protocols to protect a patient's identity information in the imaging data and subsequent design files. The manufacturer should establish controls to protect the integrity of the imaging data and the design files, especially when such data is stored and shared in cyberspace. Furthermore, the manufacturer should establish controls to ensure that the critical information on the device design is not lost or corrupted during file format conversions.

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Annex 2 for GN17 List of Configurations –

Template for **Patient-matched medical devices**: a range of parameters within the design envelope

Name as per Device Label	Identifier	Brief description of item
<Name per label> (<to specify parameter's range>, <if the number of device in a pack is a variable, to specify>)	<Common identifier on label, as applicable> (<length, breadth, thickness and/ or relevant parameters within the specified design envelope>)	<Additive manufacturing method>
MAGIC mesh (length: 20- 100mm, breadth: 10- 100mm , thickness: 1 – 5mm) (pack of 1, 2 or 3)	<u>Z150</u> (length, breadth, thickness)	Powder bed fusion (Selective laser sintering)
MAGIC Strip (length: 20- 100mm, breadth: 10- 100mm , thickness: 1 – 5mm)	<u>Z250</u> (length, breadth, thickness)	Powder bed fusion (Selective laser sintering)

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Dealer's Licensing & Post-market Obligations

- To engage in the manufacture, import and/or wholesale of medical devices in Singapore, the appropriate dealer's licences will need to be obtained from HSA. The submission requirements and process will follow as per [GN-02](#): Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices.
- Dealers of medical devices are obliged to perform post-market duties, including but not limited to reporting of adverse events, defects and recall to HSA and ensuring appropriate investigation is conducted so as to ensure the continued safe use of the devices. Healthcare professionals and users of 3D-printed medical devices may also report any [adverse events](#) related to the use of a medical device or device failure related issues to HSA on a voluntary basis.
- For licensed importers of custom-made devices, importers to additionally submit a list of all custom-made medical devices they are currently importing to the Medical Device Branch via hsa_md_sa@hsa.gov.sg with the email subject "List of custom-made MDs". Refer to [this link](#) for more information.

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- This is the current regulatory position based on a risk-based regulatory approach and current knowledge of foreseeable risks associated with 3D-printed devices manufactured via additive manufacturing (AM).
- Please note that 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.
- Where deemed necessary and based on new scientific information, HSA may require additional technical documents during product registration of 3D-printed devices and/or post-market surveillance and investigations in the interest of patient health and safety.

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[IMDRF 2018 Final Document](#) – **Definitions for Personalised Medical Devices**

[IMDRF 2020 Final Document](#) - **Personalized Medical Devices – Regulatory Pathways**

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