TR-009:2025-1(E)

Medical Device Administrative Control System (MDACS)

Personalised Medical Devices

Technical Reference: TR-009

中華人民共和國
香港特別行政區政府
衞生署

Department of Health
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision History

Edition Number	Date of Revision	Summary of Revision	Reference Number
0	9 May 2025	• First issue of TR-009	TR-009:2025(E)
1	2 October 2025	• Clause 3.2.3 and 3.2.4 are revised • Clause 3.2.5 is deleted • Clause 4.2 is revised	TR-009:2025-1(E)

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1. Introduction

1.1. Background

1.1.1. This document provides reference on personalised medical devices and their applicability under the Medical Device Administrative Control System from a technical perspective.

1.2. Purpose

1.2.1. This document aims to provide definitions and examples of personalised medical devices and identify and describe different categories of devices that are produced for the use of a particular individual, and also to define some other terms that are relevant to defining these types of devices.

2. Scope

2.1. This document applies to all personalised medical devices.

3. Definitions and Abbreviations

3.1. **Personalised medical device** is a generic term to describe any of the types of medical devices that are intended for a particular individual, which could be either a **custom-made**, **patient-matched**, or **adaptable** medical device.

3.2. **Custom-made Medical Devices** is a medical device that meets the following requirements:

3.2.1. It is intended for the sole use of a particular individual (which could be a patient or healthcare professional);

3.2.2. It is specifically manufactured in accordance with a written request of a healthcare professional, which gives, under their responsibility, specific design characteristics; even though the design may be developed in consultation with a manufacturer;

3.2.3. It is intended to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended; and

3.2.4. It is typically intended for a case where an individual’s specific needs cannot

be met, or cannot be met at the appropriate level of performance, or by an alternative device available on the market.

3.3. **Patient-matched Medical Devices** is a medical device that meets the following requirements:

3.3.1. It is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging;

3.3.2. It is typically produced in a batch through a process that is capable of being validated and reproduced; and

3.3.3. It is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with a healthcare professional;

3.4. **Adaptable Medical Devices** is a medical device that meets the following requirements:

3.4.1. It is mass-produced; and

3.4.2. It is adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomo-physiologic features prior to use.

3.5. Medical devices that are patient-matched, adaptable or mass-produced shall not be considered to be custom-made.

3.6. **Batch** means one or more components or finished devices that are produced using the same lot of raw material, the same method of manufacture, having the same probability of chemical or microbial contamination, and that are intended to have uniform characteristics and quality within specified limits.

3.7. **Mass-produced** medical device means a medical device that is based on standardized dimensions/designs; that is not designed for a particular individual; and that is typically produced in a continuous production run or homogenous batch.

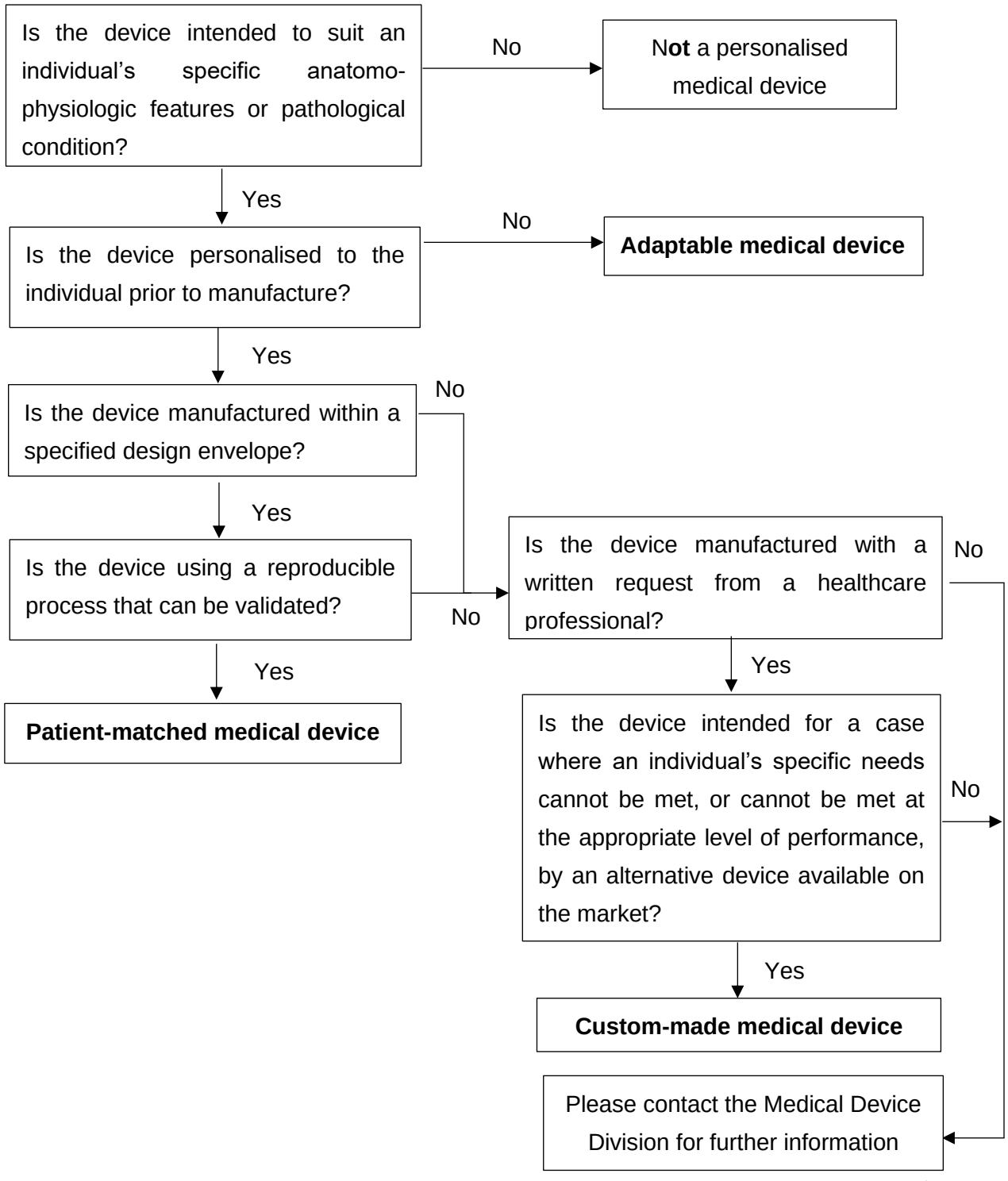
3.8. **Specified design envelope** means minimum and maximum dimensions, mechanical performance limits, and other relevant factors that characterize a medical device for production purposes, which may be based on a standard device template model.

3.9. Please refer to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) for the definitions and abbreviations of the terms that appear in this document.

4. Determination of Personalised Medical Devices

Personalised medical devices are categorised into custom-made, patient-matched, or adaptable medical device, as defined above.

4.1. The below decision tree could be referenced to determine the type of personalised medical device. Examples for each type of personalised medical device are provided in Appendix I.



4.2. Some other distinguishing features contrasting custom-made and patient-matched, adaptable medical devices.

	Custom-made medical devices	Patient-matched medical devices	Adaptable medical devices
Sole use of a particular individual	✓	X	X
Manufactured under the **responsibility** of a healthcare professional	✓	X	X
Manufactured under the **responsibility** of a manufacturer	X	✓	✓
Adapted, adjusted, assembled or shaped **at the point of care prior to use**	X	X	✓

5. Listing of Personalised Medical Devices under MDACS

5.1. Classification of personalised medical devices

5.1.1. As with all General Medical Devices, personalised medical devices are classified into different risk classification (Class I to Class IV) as per Technical Reference TR-003 (Classification of General Medical Devices) depending on the nature of the device and its intended purpose.

5.2. Listing requirement of personalised medical devices

5.2.1. For personalised medical device within the scope of MDACS stipulated in Guidance Notes GN-01, please refer to Guidance Notes GN-02 for the requirements for the listing of Class II/III/IV general medical devices.

5.3. Changes to personalised medical devices

5.3.1. LRP shall inform the Medical Device Division of applicable changes to

personalised medical devices in accordance with the Guidance Notes GN-10 (Guidance Notes for Changes of Listed Medical Devices).

6. Enquiries

Enquiries concerning this document and MDACS should be directed to:
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Department of Health,
Telephone number: 3107 8484
Facsimile number: 3157 1286
Email address: mdd@dh.gov.hk
Website: www.mdd.gov.hk

7. References

7.1. International Medical Device Regulators Forum. Personalised Medical Devices – Regulatory Pathways. IMDRF/PMD WG/N58 FINAL: 2023 (Edition 2) https://www.imdrf.org/documents/personalised-medical-devices-regulatory-pathways. accessed on 2 February 2025.

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7.3. Global Harmonization Working Party (formerly Asian Harmonization Working Party). Handbook for Approval of Patient-matched Medical Devices Using 3D Printers. https://www.ahwp.info/sites/default/files/Final_Guidance_Handbook_for_approval_of_patient-matched_MD_using_3D%20Printers.pdf. Accessed on 3 Feb 2025.

7.4. National Medical Products Administration. 定制式医疗器械监督管理规定（试行）. https://www.gov.cn/gongbao/content/2019/content_5442291.htm. Accessed on 3 Feb 2025.

7.5. Therapeutic Goods Administration (TGA). Understanding personalised medical devices rules (including 3D-printed devices). https://www.tga.gov.au/resources/guidance/understanding-personalised-medical-devices-rules-including-3d-printed-devices. Accessed on 9 Apr 2025.

7.6. Medical Device Coordination Group (MDCG) of European Commission. MDCG 2021-3. https://health.ec.europa.eu/system/files/2021-03/mdcg_2021-3_en_0.pdf

7.7. Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.

7.8. Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.

7.9. Department of Health. Guidance Notes for Listing Class II/III/IV General Medical Devices. Guidance Notes GN-02.

8. Appendix I Examples of Personalised Medical Devices

	Examples	Design Characteristics of the Device
Custom-made Medical Devices	Dental crown	Based on a particular patient's individual condition
	Artificial cervical disc replacement	Based on the individual's specific anatomo-physiological features and pathological condition
	An acetabular cup implant	Based on DICOM compliant scan images, manufactured by a 3D printing implant manufacturer
Patient-matched medical devices	Mandibular implants	Produced by a 3D printing manufacturer, from a template model and DICOM files
	Externally worn orthosis to support, prevent or assist body functions	Based on external 3D scan images of the patient and manufactured within validated parameters
	Plates used to fix a broken bone	Based on a template model and DICOM files/ images of the patient, manufactured by 3D printing
	Made to order contact lenses	By clearly specified dimensions, produced on request typically in batches with validated or verified production processes using standardised tools and materials
Adaptable medical devices	Polymer surgical implants for cranial reconstruction	Can be thermoformed during the surgical procedure, for heating and shaping the implant to suit a patient's particular anatomy.
	Spectacle frames and optical glasses (assembled together to form spectacles)	Adapted, adjusted, assembled or shaped at the point of care, traditionally by a healthcare professional to suit an individual patient's specific anatomo-physiologic features prior to use
	Patient fitted wheelchairs	