
Medical Device Administrative Control System (MDACS)

Combination Products

Technical Reference: TR-010



中華人民共和國
香港特別行政區政府
衛生署

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	1 Apr 2026	<ul style="list-style-type: none"><li data-bbox="572 398 938 432">• First issue of TR-010	TR-010:2026(E)

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1. Introduction

1.1. Background

1.1.1. This document provides reference on combination products and their applicability under the Medical Device Administrative Control System (MDACS) from a technical perspective. In addition, it provides a further explanation on Clause 3.2 of Guidance Notes GN-01 (Guidance Notes for Overview of the Medical Device Administrative Control System).

1.1.2. In the context of MDACS, combination products are generally perceived as products composed of a medical device integrally combined with one or more of the following:

- (a) Pharmaceutical substance; or/ and
- (b) Human blood, blood products, plasma or blood cells of human origin; or/ and
- (c) Transplants, tissues, or cells of human origin, and their derivatives; or/ and
- (d) Transplants, tissues, or cells of animal origin, and their derivatives.

1.1.3. This document has been translated into Chinese. If there is any inconsistency or ambiguity between the English version and the Chinese version, the English version shall prevail.

1.2. Purpose

1.2.1. This document aims to describe different categories of combination products with examples. It also aims to provide references on the eligibility of a combination product to be listed under MDACS. The eligibility for listing of certain combination products shall be evaluated on a case-by-case basis, considering all relevant product characteristics.

2. Scope

- 2.1. This document applies to combination products that fall within the scope of MDACS in accordance with Guidance Notes GN-01 (Overview of the Medical Device Administrative Control System).

3. Definitions and Abbreviations

- 3.1. **Mode of action** is the means by which a product achieves an intended effect or action.
- 3.2. **Primary mode of action (PMOA)** means the single mode of action of a combination product that provides the most important intended action of the combination product. The most important intended action is the mode of action expected to make the greatest contribution to the overall intended effects of the combination product.
- 3.3. 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 Combination Products

- 4.1. The determination of whether a combination product is within the scope of MDACS is based on the PMOA of the combination product.
- 4.2. The below decision tree could be referenced to determine whether a combination product is within the scope of MDACS.

5. Listing of Combination Products under MDACS

5.1. Coverage of combination products within the scope of MDACS

5.1.1. Some products including combination products, notwithstanding that some of them could be identified as medical devices according to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administration Control System), would still not be included into the current scope of MDACS in accordance with Clause 3.2 of Guidance Notes GN-01 (Guidance Notes for Overview of the Medical Device Administrative Control System).

5.1.2. The below table could be referenced to determine whether a combination product is within the scope of MDACS.

Products composed of a medical device integrally combined with one or more of the following	PMOA is attributable to	Within the scope of MDACS
Pharmaceutical substance; or/ and Human blood, blood products, plasma or blood cells of human origin; or/ and Transplants, tissues or cells of human origin, or their derivatives; or/ and Transplants, tissues or cells of animal origin, or their derivatives	Medical devices	✓
	Medical devices with non-viable tissues or cells	✓
	Medical devices with viable tissues or cells	✗
	Pharmaceutical substance	✗
	Human blood, blood products, plasma or blood cells of human	✗
	Transplants, tissues or cells of human origin, or their derivatives	✗
	Transplants, tissues or cells of animal origin, or their derivatives	✗

- 5.1.3. Of all combination products, only those with PMOA attributable to medical devices, as well as having one or more of the specific purpose(s) that is/are intended by the manufacturer in accordance with Clause 2.38 of Guidance Notes GN-00, are considered to be within scope of MDACS.
- 5.1.4. For combination products identified as medical devices, they are classified by different risk classifications (Class I to Class IV as per Technical Reference TR-003 for General Medical Device / Class A to D as per Technical Reference TR-006 for In Vitro Diagnostic Medical Device), depending on the nature of the device and its intended purpose.
- 5.1.5. For examples of combination products **within** the scope of MDACS, please refer to Appendix I. (For reference only)
- 5.1.6. For examples of combination products **out of** the scope of MDACS, please refer to Appendix II. (For reference only)

5.2. Listing Requirement of Combination Products

- 5.2.1. For combination products within the scope of MDACS, please refer to either Guidance Notes GN-02 (Guidance Notes for Listing Class II/III/IV General Medical Devices) for the requirements for the listing of Class II/III/IV general medical devices or Guidance Notes GN-06 (Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Devices) for the requirements for the listing of Class B/C/D in vitro diagnostic medical devices.

5.3. Changes to Combination Products

- 5.3.1. LRP shall submit application to the Medical Device Division on applicable changes to combination products in accordance with the Guidance Notes GN-10 (Guidance Notes for Changes of Listed Medical Devices).

5.4. Post Market Monitoring

5.4.1. LRP shall report all reportable adverse events and safety alerts for combination products within the scope of MDACS to the Medical Device Division in accordance with Guidance Notes GN-03 (Guidance Notes for Adverse Event Reporting by Local Responsible Persons) and Code of Practice COP-01 (Code of Practice for Local Responsible Persons).

6. Enquiries

6.1 Enquiries concerning this document and MDACS should be directed to:

Medical Device Division,

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. National Medical Products Administration (NMPA). 国家药监局关于发布以医疗器械作用为主的药械组合产品等2项注册审查指导原则的通告(2022年第3号)
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- 7.4. Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.
- 7.5. Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.
- 7.6. Department of Health. Guidance Notes for Listing Class II/III/IV General Medical Devices. Guidance Notes GN-02.
- 7.7. Department of Health. Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Devices. Guidance Notes GN-06.
- 7.8. Department of Health. Guidance Notes for Changes of Listed Medical Devices. Guidance Notes GN-10.
- 7.9. Department of Health. Classification of General Medical Devices. Technical Reference TR-003.
- 7.10. Department of Health. Classification of In Vitro Diagnostic Medical Devices (IVDMDs) Technical Reference TR-006.
- 7.11. Department of Health. Code of Practice Local Responsible Persons. Code of Practice COP-01.

Examples of Combination Products Within the Scope of MDACS (For reference only)

Products composed of a medical device integrally combined with	PMOA is attributable to	Examples of combination products
Pharmaceutical substance	Medical devices (General Medical Device)	<ul style="list-style-type: none"> • Drug-coated devices (e.g., catheters and leads) • Wound dressings and barriers with antimicrobial or medicinal agents • Contraceptive devices with medicinal components
	Medical devices (In Vitro Diagnostic Medical Device)	<ul style="list-style-type: none"> • Calibrators with pharmaceutical substance • Breath-based diagnostic test for microbial infection
Human blood, blood products, plasma or blood cells of human origin	Medical devices (General Medical Device)	<ul style="list-style-type: none"> • Human blood-derived products for tissue repair
	Medical devices (In Vitro Diagnostic Medical Device)	<ul style="list-style-type: none"> • Faecal occult blood diagnostic test kit with human haemoglobin • Erythrocyte sedimentation rate (ESR) controls

Products composed of a medical device integrally combined with	PMOA is attributable to	Examples of combination products
Transplants, tissues or cells of human origin, or their derivatives	Medical devices with <u>non-viable</u> tissues or cells (General Medical Device)	<ul style="list-style-type: none"> • Devices incorporating <u>non-viable</u> human derivatives (e.g., surgical sealants containing human serum albumin or thrombin (non-cellular substance))
	Medical devices with <u>non-viable</u> tissues or cells (In Vitro Diagnostic Medical Device)	<ul style="list-style-type: none"> • IVDs containing human-derived <u>non-viable</u> components
Transplants, tissues or cells of animal origin, or their derivatives	Medical devices with <u>non-viable</u> tissues or cells (General Medical Device)	<ul style="list-style-type: none"> • Devices incorporating <u>non-viable</u> animal derivatives (e.g., porcine heart valves and porcine xenograft dressings)
	Medical devices with <u>non-viable</u> tissues or cells (In Vitro Diagnostic Medical Device)	<ul style="list-style-type: none"> • IVD reagents incorporating <u>non-viable</u> animal tissues (e.g., brain trauma immunoassay controls and calibrators containing bovine protein)

Examples of Combination Products Out of the Scope of MDACS (For reference only)

PMOA is attributable to	Examples of combination products
Pharmaceutical substance	<ul style="list-style-type: none"> • Irrigation solutions containing pharmaceutical substance • Syringes prefilled with pharmaceutical substance
Human blood, blood products, plasma or blood cells of human origin	<ul style="list-style-type: none"> • Blood-derived biologicals and associated devices (e.g., platelet-rich plasma with injection kit to treat injuries and inflammation)
Medical devices with <u>viable</u> tissues or cells	<ul style="list-style-type: none"> • Maggot dressings for maggot debridement therapy • Leaches for leach therapy
Transplants, tissues or cells of human origin, or their derivatives	<ul style="list-style-type: none"> • Wound care products incorporating recombinant human collagen/ carboxylated chitosan
Transplants, tissues or cells of animal origin, or their derivatives	<ul style="list-style-type: none"> • Porcine xenokidney transplant with containers