Overview of Hong Kong Medical Device Listing Process

Scope of MDACS and Device Classification

The Department of Health implements the **voluntary Medical Device Administrative Control System (MDACS)**, which includes a listing system for medical devices covering **General Medical Devices (GMD)** and **In Vitro Diagnostic Medical Devices (IVDMD)**, classified by risk. Class I GMD and Class A IVDMD are the lowest risk.

	❌ Outside MDACS listing scope	✔️ Eligible for listing under MDACS
GMD	Class I	Class II, III and IV
IVDMD	Class A	Class B, C and D

Eligibility to Apply

☑ The applicant must be a local manufacturer or a **Local Responsible Person (LRP)** designated by the manufacturer.

☑ The LRP must be a legal person incorporated in Hong Kong, or a natural or legal person with with business registration in Hong Kong.

Application Procedures

Preparation

1. Prepare the required documents for application
2. For first-time applications, open an account on the **Medical Device Information System** (**MDIS**)

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Applications must be submitted electronically via MDIS

Pathway 1 : Undergo conformity assessment by a **Conformity Assessment Body** (**CAB**) to obtain a Conformity Assessment Certificate

or

Pathway 2 : Submit **marketing approval documents** from recognised regulatory jurisdictions (including China, United States, European Union, Canada, Japan, Australia, South Korea, and Singapore)

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Review by the Medical Device Division, Department of Health

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Provide supplementary information on MDIS (if applicable)

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Listing approved

🕒 Typical review time: **12 weeks** (counted from submission of all required information)
📅 Certificate validity: **5 years**
💰 Fee: **Free of charge**

⚠️ During the review, the Medical Device Division may request supplementary information. If the information remains insufficient by the specified deadline, the application will be closed.

Required Documents for Application

Mainly include:

☑ Manufacturer's Letter for Designating a Local Responsible Person

☑ Applicant's valid Hong Kong Business Registration Certificate

☑ CAB Conformity Assessment Certificate (applicable to Pathway 1 only)

☑ Marketing approval documents from recognised regulatory jurisdictions (applicable to Pathway 2 only)

☑ ISO 13485 certificate or equivalent evidence

☑ Essential Principles Conformity Checklist or Essential Principles Declaration of Conformity

☑ Clinical Evaluation Report (GMD) or Performance Evaluation Report (IVDMD)

☑ Device labelling such as instructions for use, manuals, labels and special listing information

☑ Relevant licence in Hong Kong (e.g. Radiation Ordinance (Cap. 303))

☑ Other technical documentation

Renewals and Changes

☑ **Renewal application:** Submit at least 12 weeks to 1 year before expiry.

⚠️ Renewal applications submitted less than 12 weeks before expiry will not be processed.

☑ **Change application:** Major changes require prior approval; minor changes require notification.

Post-market Surveillance

The Local Responsible Person must fulfil the following responsibilities:

☑ Handle complaints

☑ Report adverse events

☑ Manage product recalls

☑ Keep records for inspection by the Medical Device Division

Contact and Enquiries

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This summary covers the key information of MDACS for reference only. For specific requirements, please refer to guidance documents issued by the Medical Device Division.

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醫療器械科 Medical Device Division MD 衞生署 Department of Health