QD-722-3-57 V1

Overview of Macau Regulation

2026-06



ISO 13485 CERTIFIED

bsi. ISO 13485 Medical Devices Quality Management

MD 653109

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OVERVIEW

- Macau medical device classification: I, IIa, IIb, III
- Macau medical devices are mainly regulated through two methods
  - Device Registration (for device class IIb and III)
    - Applicants shall hold the Operating License to import, export, or wholesale medical devices or Drug License/Chinese Medicine License
    - Listing will be approved by reference market approval approach
    - Deadline for registration: 30/06/2028
  - Listing (for device class I and IIa)
    - Similar to self-declare approach
    - Deadline for listing: 30/06/2029

OVERVIEW

Definition of Medical Device

- an instrument, apparatus, equipment, reagent for in vitro diagnosis and calibrator, material, and any other similar or related article, intended to be used, directly or indirectly, in the human body, including the necessary computer software, whose effects are achieved mainly by physical means and not by pharmacological, immunological or metabolic means, or, even if such means are involved, they serve only a supportive role, and whose purposes are the following:
  - Diagnosis, prevention, monitoring, treatment or alleviation of diseases
  - Diagnosis, monitoring, treatment, alleviation or functional compensation of injuries
  - Analysis, substitution, regulation or support of physiological structures or physiological processes
  - Support or maintenance of life
  - Control of conception
  - Provision of information for medical or diagnostic purposes by examining samples from the human body

MEDICAL DEVICE CLASSIFICATION



Basis for classification

- Intended purpose
- Structural characteristics
- Mode of use

Authority requirements

The classification catalogues for each class are approved and published by the Secretary for Social Affairs and Culture; detailed classification rules are set out in ISAF technical instructions.

If not listed in the catalogue

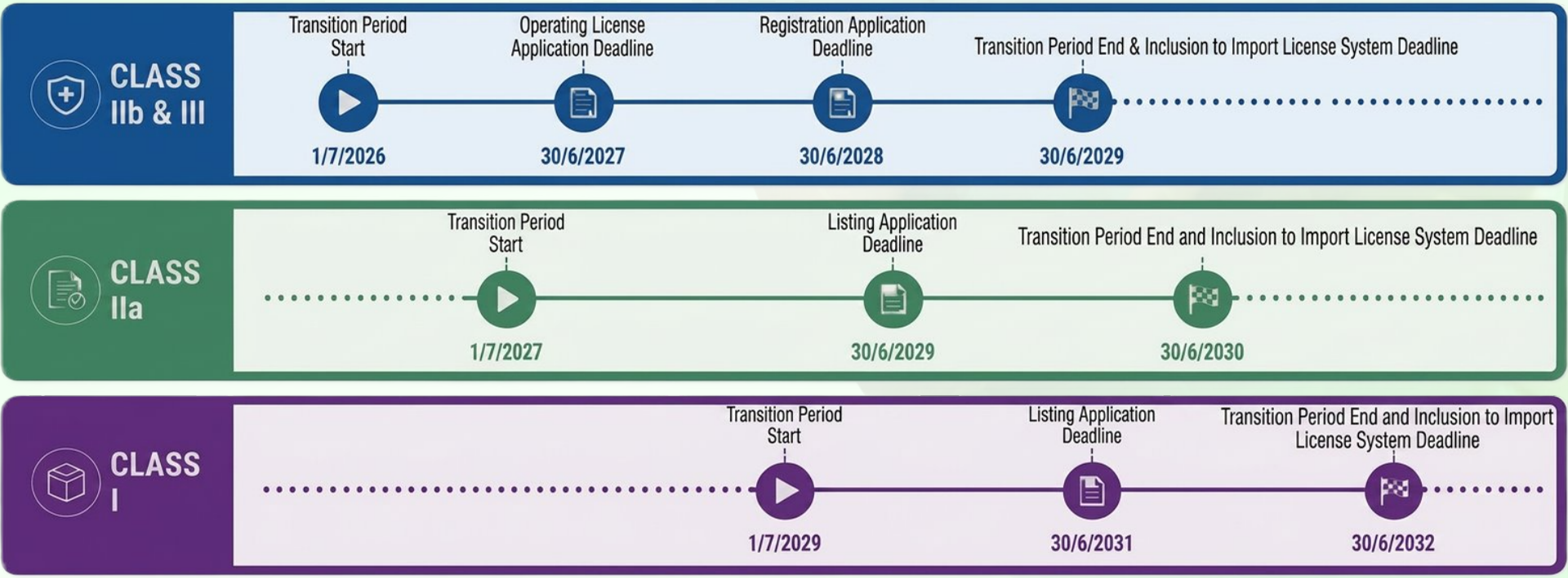
The applicant may estimate the product class according to the classification rules and apply to ISAF for class confirmation.

MEDICAL DEVICE REGULATION TIMELINE

MACAU MEDICAL DEVICE TRANSITION SCHEDULE

Key Milestones by Device Classification



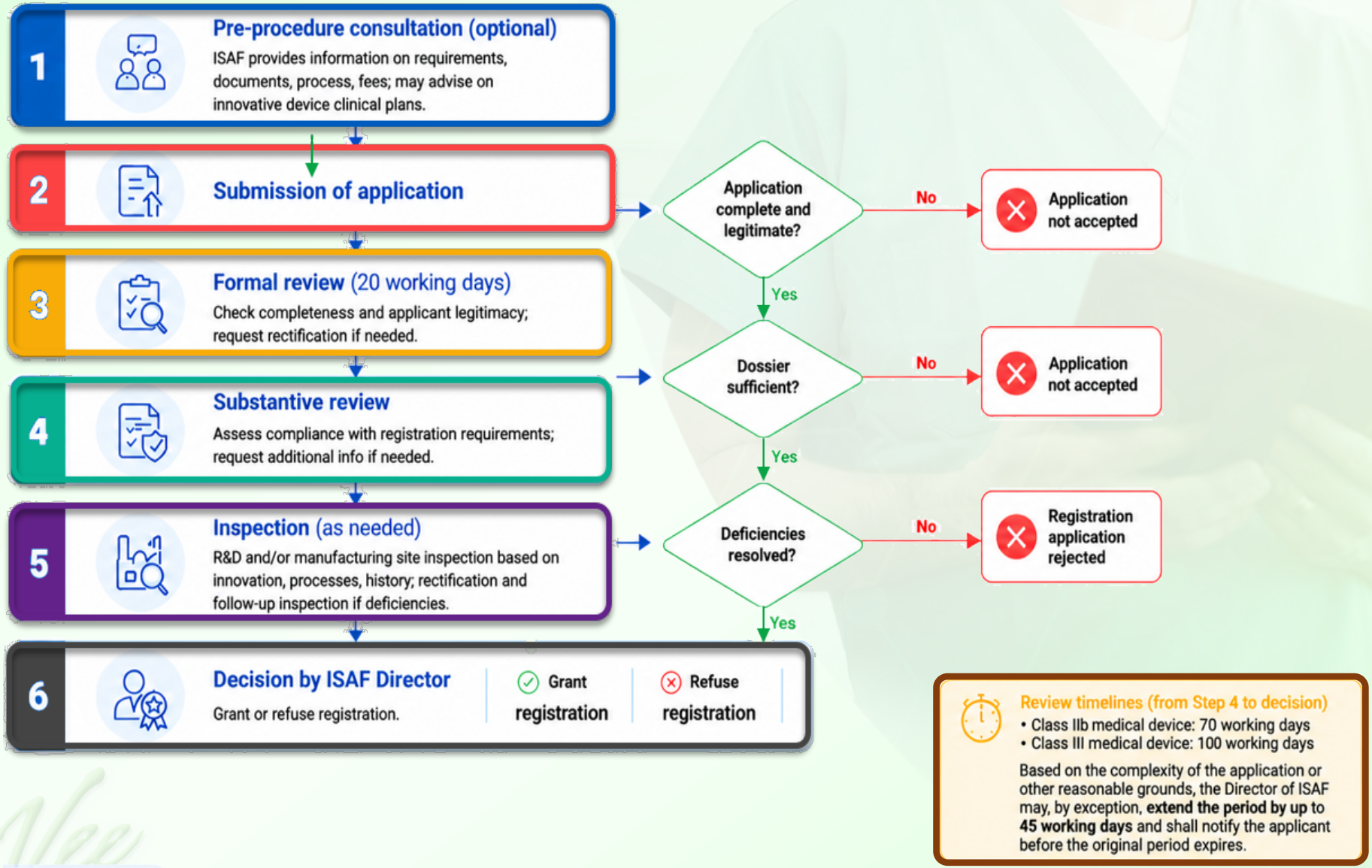


Note: Dates are in day/month/year format.

MEDICAL DEVICE REGISTRATION

- Medical Device Registration
  - Applicable to Class IIb and III medical device
  - The process by which the authority, in response to an application submitted by an applicant in accordance with legal procedures and requirements, reviews the safety, effectiveness, and quality controllability of a medical device and issues a registration certificate to the applicant.
- Once registration of the medical device is approved, the Pharmaceutical Administration Bureau (ISAF) issues a registration certificate
- Device registration in Macau is based on the reference market approval approach (e.g., EU MDR, US 510k etc.)
- Custom-made medical devices do not require listing or registration
- Registration certificate is valid for 5 years and could be renewed upon expiry

REGISTRATION PROCESS



Review timelines (from Step 4 to decision)

- Class IIb medical device: 70 working days
- Class III medical device: 100 working days

Based on the complexity of the application or other reasonable grounds, the Director of ISAF may, by exception, **extend the period by up** to **45 working days** and shall notify the applicant before the original period expires.

REGISTRATION GOVERNMENT FEE

	Item	Amount (MOP)
1.	Medical device registration	500
2.	Renewal of medical device registration	200
3.	Re-issuance of registration certificate	200
4.	Change of registration information (the fee is charged per item of information to be amended; for related linked amendments, each piece of information involved is counted as a separate item)	100

REGISTRATION DOCUMENTS

Required Information for Macau Medical Device Registration			
1)	Applicant's name (individual or legal entity) and address	11)	Medical device requirements
2)	Applicant Information - Individual: ID document and proof of address. - Company: Business registration certificate + IDs of managers and board members. - Association/Foundation: Registration certificate + governance structure + IDs of key officials.	12)	Summary of test
		13)	Clinical evaluation data
3)	Criminal Record Certificate - Company: Criminal records of managers and board members. - Association/Foundation: Criminal records of key officials.	14)	Non-clinical evaluation data
4)	Certificate issued by the Financial Services Bureau confirming that the applicant has no debts under tax enforcement.	15)	Instructions for use (IFU) specimens and label
5)	Device name and place of manufacture	16)	QMS certification
6)	Device description (model/specification, intended use, class, performance, main structural composition etc.)	17)	Market approval for device manufactured outside of Macau (except for regions exempted)
7)	Accessories or products intended to be used together with the device	18)	Evaluation report from a credible third-party technical assessment body for innovative device
8)	Statement or evidence that the applicant is legitimately entitled to submit the application	19)	Patent protection documentation for the device (if not patented, a declaration is required)
10)	Essential principles checklist		

Reference Market Approval exemption (regions exempted by Chief Executive will be published in the Official Gazette – to be confirmed)

CLINICAL EVALUATION REQUIREMENTS

1. Clinical evaluation required



- Clinical evaluation is required for medical devices, except where a specific exemption applies.
- Clinical evaluation aims to demonstrate that the device is safe and effective for its intended use.

2. When clinical evaluation may be waived



- The mechanism of action is well understood, the design is fixed and the manufacturing process is mature.
- The normal intended use is unchanged and similar devices have been used clinically for many years.
- No serious adieuse device events have been recorded for the same type of device.
- Or, safety and effectiveness can be demonstrated through non-clinical evaluation alone.

3. How clinical evaluation is performed



- Primarily through analysis and assessment of clinical documentation and clinical data from the same type of device.
- If existing clinical documentation and clinical data are insufficient to confirm safety and effectiveness, a clinical investigation must be conducted.

4. Clinical investigation and detailed rules



- Any clinical investigation of medical devices in Macau requires prior authorisation from ISAF.
- ISAF will issue technical instructions defining detailed requirements for clinical evaluation and clinical investigations.
- The same instructions will specify which medical devices are exempt from clinical evaluation.

LABELING REQUIREMENTS

Required Information on Medical Device Labels

Item	Required label content
1	Name
2	Model or specification
3	Expiry date; if no expiry date, indicate manufacturing date and, if applicable, period of use
4	Batch number or serial number
5	Name of the manufacturer, or name of the registration holder or listing person.
6	Country or place of origin
7	Performance, main structural components, main ingredients or scope of application
8	Approval certificate number, if any, in the place of origin or any country or region where the product has been approved for marketing
9	Contraindications, precautions, and other content requiring warnings or alerts, if any
10	Installation and use instructions or diagrams, if any
11	Maintenance and servicing methods, and any special conditions and methods for transport and storage, if any
12	Special instructions for safe use, if applicable
13	Possible adverse events of the medical device, or components or excipients that may cause side effects, if applicable

1) The name shall include the generic name of the medical device or the product name.
2) Labelling and IFU contents shall be consistent with contents submitted for registration or listing.
3) Information shall be in either Chinese, Portuguese or English.

If items 5–13 cannot be included on the label, this information **must be provided in the instructions for use.**

REGISTRATION CERTIFICATE

澳門特別行政區政府
GOVERNO DA REGIÃO ADMINISTRATIVA ESPECIAL DE MACAU

藥物監督管理局
INSTITUTO PARA A SUPERVISÃO E ADMINISTRAÇÃO FARMACÊUTICA

醫療器械註冊證明書
CERTIFICADO DE REGISTO DO DISPOSITIVO MÉDICO

茲證明下列醫療器械已在澳門特別行政區註冊，有關資料如下：
CERTIFICO que o dispositivo médico abaixo identificado se encontra registado na Região Administrativa Especial de Macau, com as seguintes informações:

名稱：
Denominação:

註冊編號：
N.º do registo:

類別：
Classe:

型號或規格：
Modelo ou especificação:

註冊持有人：
Titular do registo:

附註：
Averbamentos:

首次簽發日期：
Data da 1.ª emissão:

本次簽發日期：
Data da última emissão:

二維碼
Código bidimensional

藥物監督管理局局長
O Presidente do ISAF

（簽署及蓋上鋼印）
(Assinatura e selo branco)

按照第12/2025號法律《醫療器械監督管理制度》的規定發出
Emitido ao abrigo da Lei n.º 12/2025 (Regime de supervisão e administração de dispositivos médicos)

澳門特別行政區政府
GOVERNO DA REGIÃO ADMINISTRATIVA ESPECIAL DE MACAU

藥物監督管理局
INSTITUTO PARA A SUPERVISÃO E ADMINISTRAÇÃO FARMACÊUTICA

醫療器械註冊證明書附件
ANEXO DO CERTIFICADO DE REGISTO DO DISPOSITIVO MÉDICO

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附註：
Averbamentos:

REGISTRATION CERTIFICATE RE-ISSUANCE

- If the registration certificate is lost or damaged, an application for re-issuance may be made.
- The re-issued registration certificate shall bear the wording “Re-issued”.
- The holder of the registration certificate shall, on the date of obtaining the re-issued registration certificate, return the damaged registration certificate to the ISAF

REGISTRATION SUSPENSION, CANCELLATION and CHANGES

1. Suspension of Registration

- Registration is suspended if the registration holder fails to comply with ISAF orders on labelling or instructions.
- Suspension may apply if evidence shows the risk to a specific group outweighs the device's effectiveness.
- Suspension may apply if safety issues are identified in approved quality specifications.
- Suspension may apply if registration information changes without legal procedures.
- For conditionally approved devices, suspension may apply if conditions are unmet within ISAF deadlines.
- The registration holder must correct deficiencies within ISAF's period before suspension is lifted.

2. Cancellation and Lapse

- Registration may be cancelled at the registration holder's request.
- Cancelled if the suspension period expires without reinstatement.
- Cancelled if the holder fails to apply for registration changes under the law.
- Cancelled after a court decision confirming patent infringement, on request of the patent holder.
- Cancelled if obtained through false statements or unlawful means.
- Cancelled if quality issues may endanger public health.
- Lapses when renewal is not requested or approved before validity ends.

3. Effect of Suspension, Cancellation and Lapse

- The registration holder must withdraw affected devices once notified of suspension or cancellation.
- For lapse, withdrawal is required once validity expires.
- Devices with suspended, cancelled, or lapsed registration may not circulate in Macau.

4. Changes to Registration

Notifications or requests to change registration information must be submitted using the form provided by ISAF, which contains the following information:

- Name of the registration certificate holder
- Registration number
- Proposed changes and reasons

- The registration holder must notify ISAF in writing 20 working days before label or IFU changes.
- Prior notice required for administrative registration updates.
- Prior notice for improvements that do not change function post-market.
- Prior notice for non-quality related changes.
- Other changes need prior ISAF approval.
- Device names cannot change; a new registration application is needed instead.

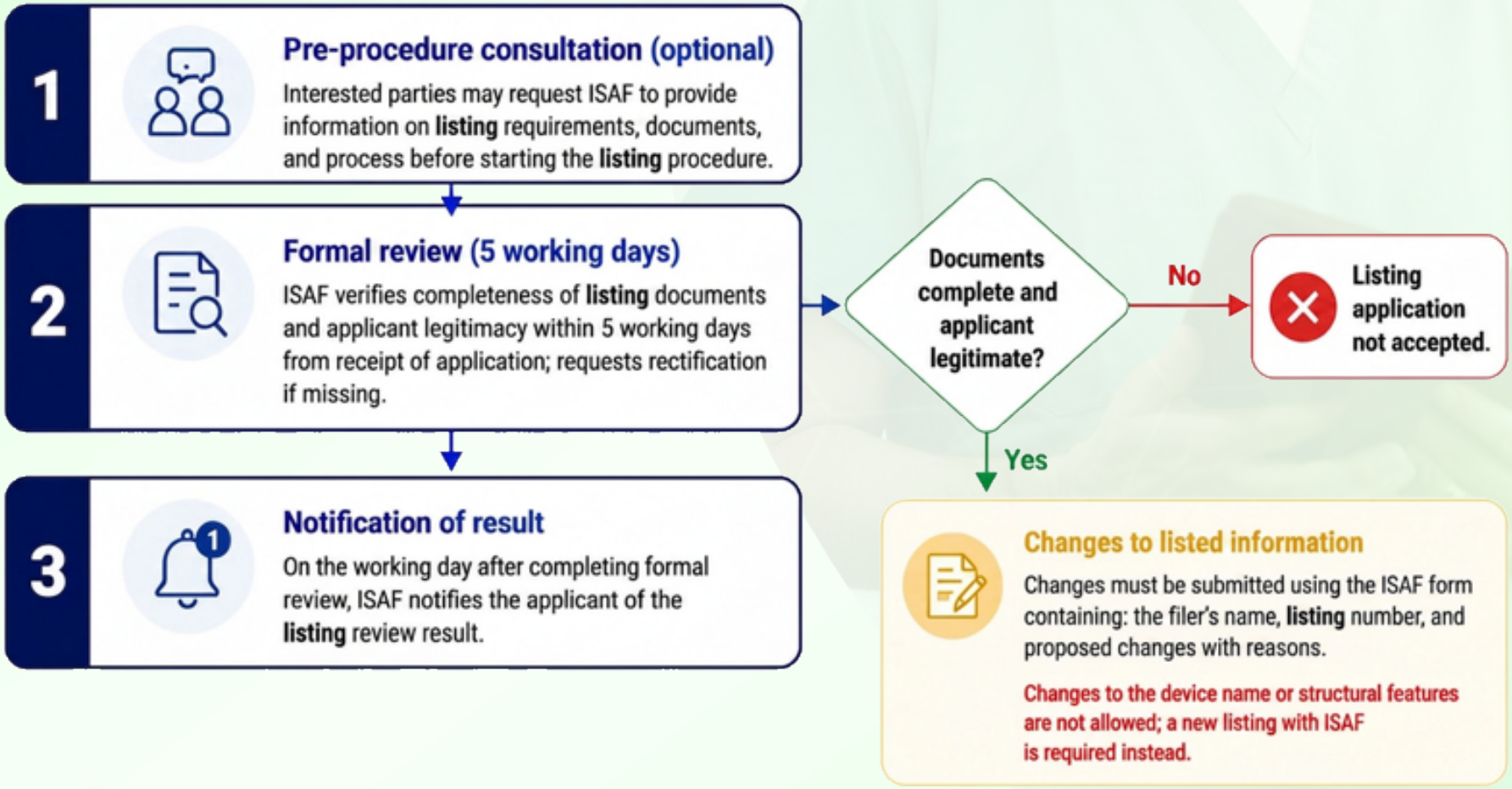
REGISTRATION RENEWAL

- The registration certificate holder must apply for renewal between 90 days and 180 days before the registration expired
- Renewal application must be submitted by the form provided by ISAF, which contains the following information:
  - A declaration which include:
    - The registration certificate holder still legitimately meets with the requirements of Law No. 12/2025 Medical Device Regulation
    - The device maintains compliance with Law No. 12/2025 Medical Device Regulation
    - The device label and IFU align with the versions approved by the ISAF
  - Adverse event report
  - Market approval for foreign-manufactured device (except for regions exempted by Chief Executive dispatch published in the Official Gazette – to be confirmed)

MEDICAL DEVICE LISTING

- Medical Device listing
  - Applicable to Class I and IIa medical device
  - Submitting information about medical devices to the authority in accordance with legal procedures and requirements for its listing and future reference.
- No Certificate will be issued
- After confirming that all submitted documents for listing and future reference are complete, the ISAF will notify the applicant that the listing process has been completed

LISTING PROCESS



LISTING DOCUMENTS

Required Information for Macau Medical Device Listing

No)	Listing dossier item
1	Completed application form provided by ISAF, including the applicant's name or entity name and domicile/address.
2	Medical device name and place of manufacture.
3	Medical device summary, including model/specification, class, performance, principal structure/components, mechanism of action, intended purpose, and scope of application.
4	Accessories of the medical device, or products intended to be used together with it, if any.
5	Applicant information.
6	Criminal record certificate.
7	Certificate issued by the Financial Services Bureau confirming that the applicant has no debt under enforced tax collection procedures.
8	Risk analysis data for the medical device, if any.
9	Statement or documentary proof that the applicant is legitimately entitled to submit the application.
10	Medical device technical requirements.
11	Label specimen and instructions for use specimen, if any.
12	For a device manufactured outside the Macau SAR, market authorization/marketing approval document issued by the competent authority or authorized body of the country/region of origin or of the country/region where the device is approved for marketing, unless the device is manufactured in a region exempted by Chief Executive order published in the Official Gazette, the region to be confirmed.
13	Documentary proof that the medical device is protected by patent; if it is not patent-protected, a corresponding declaration.

LISTING CANCELLATION



Notification of listing

ISAF notifies the applicant once completeness of the submitted information is confirmed and the file is archived for possible verification.



Effects of cancellation of listing

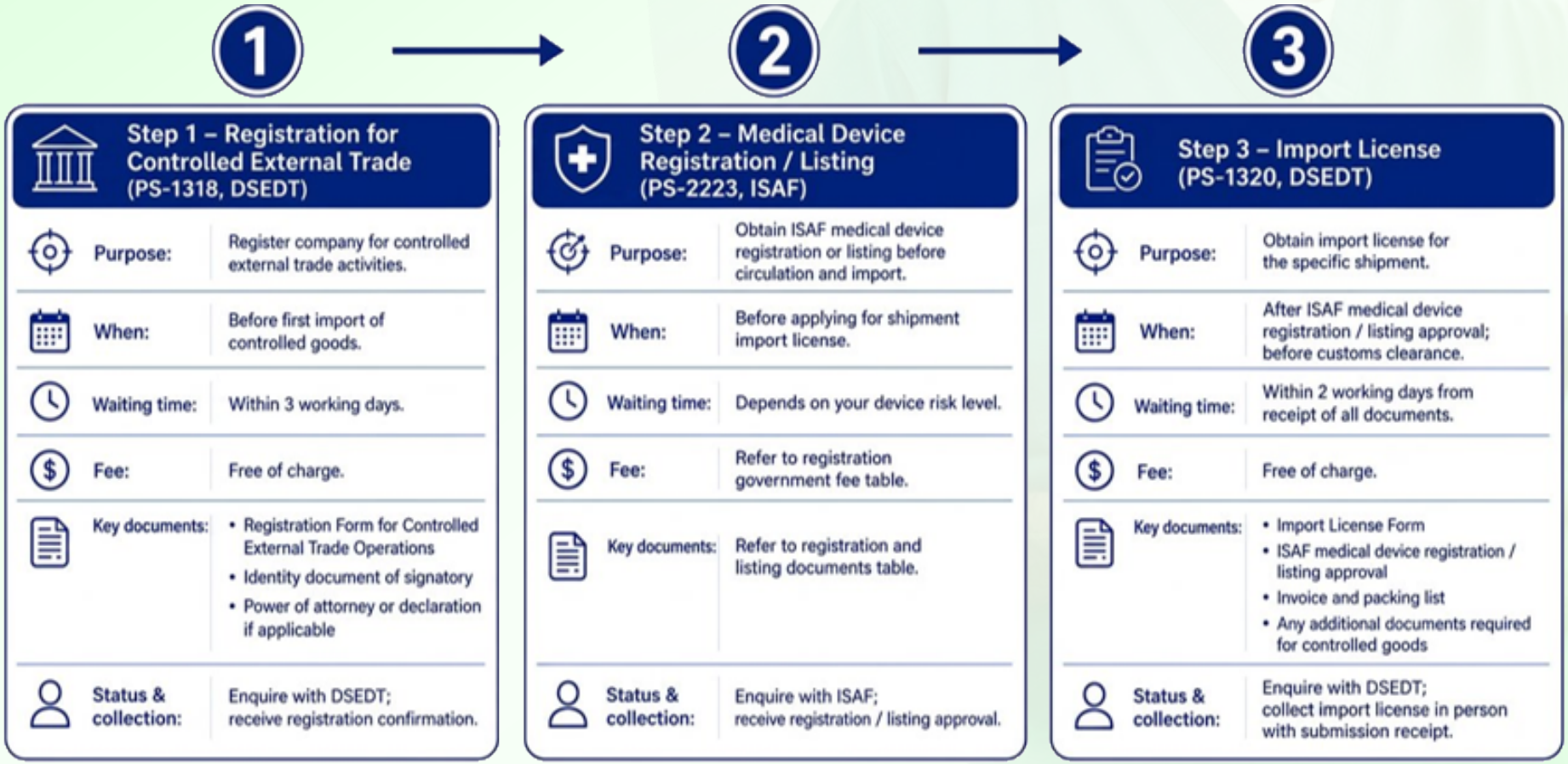
If the listing is cancelled, the devices must be withdrawn from the market from the date of receipt of ISAF's notification and may no longer circulate in Macau.



Alteration of listing

Certain listing changes must be notified to ISAF in writing at least 5 working days in advance. Change of name or structural characteristics is prohibited, except through a new listing.

MEDICAL DEVICE IMPORT PROCESS



Not sure whether the product is a medical device or a medical hygiene product? Apply to ISAF for Product Classification (PS-1574).

All forms (PS-xxxx) are available on the respective department websites. Requirements may be updated; please refer to the latest guidance.

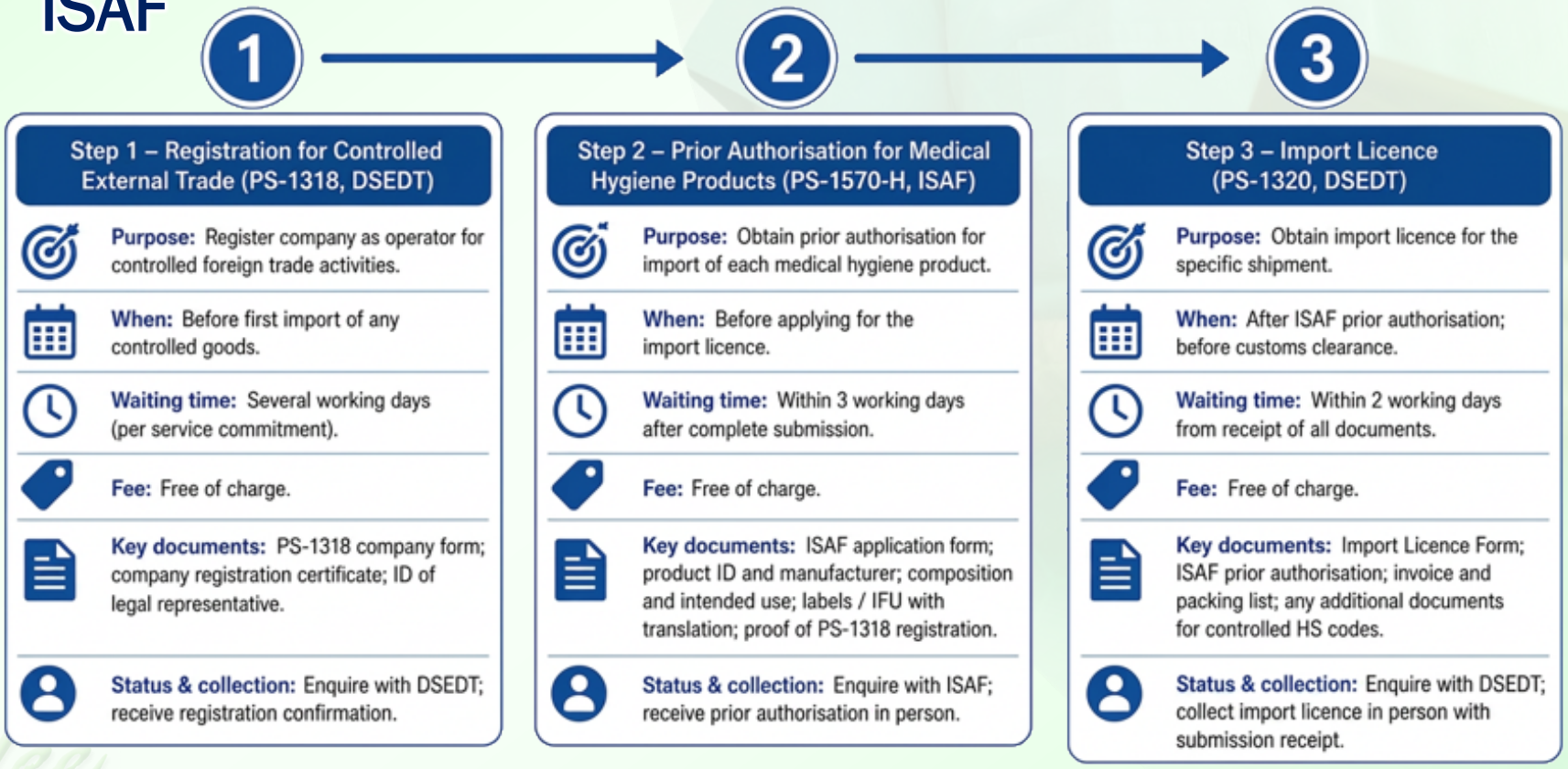
MEDICAL HYGIENE PRODUCTS

- Defintion
  - Medical hygiene products fall under the Pharmaceutical Administration Bureau (ISAF)
- Below are the Medical hygiene products
  - The list is subject to updates
  - Product categories depend on the exporting country' s customs identification

HS code(s)	Description	Notes
Chapter 30	Medicaments (excluding glands and organs for organo-therapeutic uses, blood, human blood and animal blood)	Pharmaceutical products
3102, 3105	Phosphatic or chemical nitrogenous fertilisers; compound fertilisers containing nitrogen, phosphorus and potassium; other fertilisers in small packings	Non-medical – fertilisers
3201	Extracts of vegetable materials obtained by enzymatic treatment; tannins and derivatives	Chemical / plant extracts
3202	Synthetic organic and inorganic colouring matter; prepared colouring materials	Colouring agents
3203	Colouring preparations based on synthetic organic colouring matter; vegetable or animal colouring preparations	Colouring preparations
3204	Synthetic organic colouring matter; optical brightening agents and luminophores	Optical brighteners
3301; 3305.10.10; 3305.20.10; 3305.30.10; 3305.90.30	Essential oils, resinoids, olecresins, fats and oils containing essential oils, and specified hair preparations	Perfumery / cosmetic base
3808	Insecticides, rodenticides, fungicides, herbicides, plant-growth regulators, disinfectants and similar products	Biocides / disinfectants
3822	Diagnostic or laboratory reagents, including those *in* diagnostic kits, excluding heading 30.06	*In vitro* diagnostic reagents
9018.39.11	Catheters for the administration of topical medicinal products	Medical device
9021.90.11	Vascular stents for the administration or perfusion of medicinal products	Medical device

MEDICAL HYGIENE PRODUCTS IMPORT PROCESS

- Medical Hygiene Products' Imports and exports inspections are fall under Macau's Economic and Technological Development Bureau (DSEDT) and ISAF



OPERATING LICENSE

- Only with an operating license may an entity:
  - Import and wholesale Class IIb and Class III medical devices.
  - Retail Class IIb medical devices (Class III retail is prohibited; only supply to medical institutions and research units).
- Import, wholesale and retail of Class I and IIa devices do not require an operating license
- Retail premises for Class IIb medical devices must have a technical supervisor.
- The technical supervisor requirements are:
  - Must not be under any period of additional penalty, supplementary punishment, security measure that prohibits engaging in medical device business activities
    - Hold a higher diploma or above in a field related to medical devices or;
    - Have at least 3 years of relevant work experience
- The operating license is valid from the date of issue until 31 December of the following year and may thereafter be renewed annually.

OPERATING LICENSE FEE

Item	Amount (MOP)
1. Issue of license	2,000
2. Renewal of license	300
3. Re-issue of license	300
4. Changes to license	
4.1 Change of premises name	300
4.2 Change of premises address and inspection	600
4.3 Change of premises layout, facilities or equipment and inspection	600
4.4 Change of license holder	300
4.5 Appointment of new manager, member of management body or key officer	300
5. Issue of contract manufacturing authorization	500
6. Renewal of contract manufacturing authorization	200

OPERATING LICENSE EXEMPTION

- Holders of a license for the
  - import, export, and wholesale of medicines under Decree-Law No. 58/90/M (Drug License), or;
  - import, export, and wholesale of Chinese medicines under Law No. 11/2021 (Chinese Medicine License),

  are exempted from obtaining a separate operating license for import, export, and wholesale of Class IIb and Class III medical devices

- Exempted operators shall still comply with the provisions of Law No. 12/2025 Medical Device Regulation and its supplementary regulations regarding the operation rules of premises

LICENSE SUSPENSION, CANCELLATION and CHANGES

1 License Changes Requiring Approval

- Name or address changes
- Modifications to layout or equipment
- Changes to approved devices
- New licence holder info for legal entities
- New managers or key officers need approval

2 Suspension Conditions

- Reasons for license suspension
- Limitation on duration
- Required corrective actions
- Conditions to lift the suspension

3 License Cancellation Circumstances

- Holder's request for cancellation
- Operations during suspension
- Failure to correct issues
- Non-renewal of license
- Not starting business within a year
- Loss of industrial license or holder's death

4 Obligations Upon Suspension or Cancellation

- Immediate cessation of activities
- Proper handling or transfer of stock within a time frame
- Provide evidence of stock transfer
- Ensure appropriate storage during suspension

RESPONSIBILITIES OF REGISTRATION/LISTING HOLDER

- Guarantee that the medical device meets the specifications and quality requirements relating to its listing and filing.
- Establish a quality management system appropriate to the medical device and maintain its effective operation.
- Define a post-market investigation and risk-control plan and ensure its effective implementation.
- Establish and implement a traceability and product recall process, and communicate product recalls to ISAF in a timely manner.
- Have and maintain the resources necessary to comply with these obligations.

POST-MARKET VIGILANCE OBLIGATION

Key obligations – serious adverse events and post-market evaluation

- ☑ Notify ISAF within **24 hours** after becoming aware of serious adverse events regarding medical devices.
- ☑ Submit a detailed report within the timeframe specified by ISAF, if requested.
- ☑ Conduct post-market evaluations as needed when scientific research alters safety or efficacy understanding.
- ☑ Conduct post-market evaluations when monitoring indicates potential issues with medical devices.

VEECARE BACKGROUND

- ISO 13485–certified medical device regulatory consultancy
- Offices and regulatory teams in Taipei and Hong Kong — local Greater China presence
- Extensive submission experience with good understanding on regulatory requirements
- Leading local license holder / Authorized Representative in Taiwan and HK — over 100 licenses in each market (current clients include Huawei, Apple, Penumbra, IBA, Masimo, etc.)
- End-to-end services: registration strategy, dossier prep, submissions, and post-market support

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MD 653109

MD 醫療器械科 Medical Device Division

FDA 食品藥物管理署 Food and Drug Administration

澳門特別行政區衛生局 Serviços de Saúde



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