MdME

LEGAL UPDATE

Implementing rules for the supervision and administration of medical devices

Administrative Regulation No. 11/2026

Administrative Regulation no. 11/2026 (published on 18 May 2026) (the "Regulation") sets out the implementing rules for Law no. 12/2025 (the "Law") on the supervision and administration of medical devices in Macau.

While the Law establishes the core legal framework, the Regulation provides the operational and procedural detail necessary for its implementation. This includes, in particular, provisions on the establishment of a dedicated expert committee, specific labelling and package leaflet requirements, applicable regulatory obligations for medical devices, licensing requirements for relevant entities, and the operational rules governing business establishments.

As a starting point, it is useful to recall how medical devices are classified under the Law, as this classification underpins several of the obligations introduced by the Regulation (please refer to our separate **legal alert on the Law** for further detail). Medical devices are categorized according to risk: Class I (low), Class IIa (medium-low), Class IIb (medium-high), and Class III (high).

The Regulation will enter into force on 1 July 2026 (alongside Law no. 12/2025). In the sections below, we highlight the key points of the Regulation and what they may mean for your operations in Macau.

I. Creation of Committee of Experts and Advisors for the Assessment of Medical Devices

The Regulation establishes a Committee of Experts and Advisors for the Assessment of Medical Devices. The Committee comprises an odd number of members (with a minimum of 11), appointed for terms of up to three years, which may be renewed. At the request of the Pharmaceutical Administration Bureau ("**ISAF**"), the Committee is tasked with providing technical opinions on applications for the registration of medical devices.

II. Regulations on the denomination, labels, and leaflet of medical devices

The Regulation imposes several requirements on the denomination, labelling, and accompanying leaflets of medical devices.

Pursuant to the Regulation, the **denomination of the medical device** should not:

- Be misleading as to the quality, efficacy or safety of the medical device;
- Be offensive to public morals or good costumes;
- Use expressions that may compare the device with others;
- Infringe industrial property rights; or
- Use concepts that are not scientifically or clinically substantiated.

Furthermore, the Regulation sets out a detailed list of labelling requirements aimed at ensuring the proper identification, traceability, regulatory transparency, and safe use of medical devices. It also establishes key principles governing the content of labels and package leaflets, by prohibiting any misleading content (such as suggesting that diagnosis or treatment can be obtained without medical consultation), exaggerated claims (such as implying that failure to use the device may result in harm to health), and inappropriate material (such as by including content that is contrary to public morality or good customs).

Medical devices of classes I and II (which includes sub-classes IIa and IIb) do not require a package leaflet where, in its absence, they can be used safely in accordance with their intended purpose.

For ease of reference, the Regulation notes that the technical specifications relating to denomination, labelling, and package leaflet content may be further detailed through technical instructions issued by ISAF.

III. Procedures for medical device registration and listing

The Law establishes a system of prior administrative control for the circulation of medical devices, based on two main distinct mechanisms: registration (*registo*) and listing (*inscrição*). It also provides for a special procedure, applicable to certain categories of devices.

The Regulation further specifies the procedural requirements, as shown below:

	REGISTRATION (*REGISTO*)	LISTING (*INSCRIÇÃO*)
Scope	Class IIb and Class III medical devices	Class I and Class IIa medical devices
Procedure stages	Registration comprises the following phases. **1.** Pre-procedural consultation **2.** Review **3.** Inspection **4.** Decision	Listing comprises the following phases. **1.** Pre-procedural consultation **2.** Formal review, focusing on the completeness of the filing materials and the applicant's legal standing to submit the application. **3.** Notification
Application requirements	An application must be filed with ISAF using the prescribed form and must include key information on the applicant and the device, and a comprehensive set of supporting documents. These documents cover the applicant's eligibility (including identification, criminal record, tax compliance, and authority to apply) and the device's characteristics, safety, quality, and performance (including technical specifications, risk analysis, testing, and clinical data). Additional materials may also be required, such as labelling and leaflet	An application must be submitted to ISAF using the prescribed form and include the same core information on the applicant and the medical device as required for registration (such as identification details, device description, classification, and intended use). The supporting documentation is more streamlined but still covers key aspects of the applicant's eligibility and the device's compliance. Compared to the registration regime, the listing process involves a lighter documentation burden, while

	templates, proof of manufacturing compliance, evidence of authorization in the country of origin (for imported devices), and, where applicable, specific documentation for innovative devices or patent status.	still ensuring a minimum level of regulatory oversight.
Timeline	• **Class IIb devices**: decision within 70 business days • **Class III devices**: decision within 100 business days from receipt of the application and all materials necessary for assessment. The abovementioned periods may be extended by up to 45 business days where justified by the complexity of the application or on other reasonable grounds.	**5 business days** from the date of receipt of the application for the formal review. ISAF must notify the applicant of the result on the business day immediately following the completion of the formal review.
Renewal Period	The registration holder must submit the renewal application for the medical device registration within the period of 90 to 180 days prior to its expiry date.	N.A. (as the listing remains valid until it is cancelled)
Replacement	Replacement of the registration certificate may be requested in the event of loss or damage	N.A.
Amendment of information	Any notification or application to amend registration information must be submitted using the prescribed form provided by the ISAF, at least **20 business days** prior to the amendment.	Any notification or application to amend the listing information must be submitted using the prescribed form provided by the ISAF, at least **5 business days** prior to the amendment.

As noted above, the registration and listing regimes to not apply to certain categories of medical devices (such as those used in public health emergencies, for research or clinical trials, as samples for regulatory purposes, for exhibition, for public sector use in shortage situations, or for specific patients on clinical justification). These devices are instead subject to a separate authorization procedure with ISAF.

IV. Procedures for a Medical Device Business License

The Law distinguishes between two main types of business licences for medical devices: (i) a manufacturing licence and (ii) an operation licence, but does not set out the corresponding licensing procedures.

To address this gap, the Regulation sets out the key procedural stages for the referred licenses:

	MANUFACTURING LICENSE	OPERATION LICENSE
Scope	Applicable to entities carrying out the manufacture of medical devices	Applicable to entities carrying out import, export, wholesale, or retail of medical devices.
Pre-procedural consultation	Before initiating the application process, the interested party may request consultation services from ISAF regarding the applicable requirements, necessary documentation, procedures, and fees for the licensing application.	
Review of the application	ISAF forwards the application to the Environmental Protection Bureau (DSPA) on the business day immediately following receipt of the application, for the issuance of a binding opinion within **30 business days**. Once all required documents and the DSPA opinion have been obtained, ISAF must prepare its report and issue a decision within 30 business days, notifying the applicant of either the approval (including any conditions) or a reasoned refusal.	ISAF forwards the application to the relevant authorities for their opinions, on the business day immediately following receipt of the application. Statutory timelines apply for the issuance of opinions (generally 30 or 15 business days, depending on the authority). ISAF must also issue its own opinion and may convene a technical meeting where necessary. After receiving all opinions, ISAF must decide on project approval within **5 business days**, notify the applicant of the

		outcome (including any conditions).
Inspection	To be requested by applicant **within 1 year** of project approval (extendable by 1 year)	To be requested by the applicant **within 6 months** of project approval (extendable by 6 months)
Decision	ISAF must decide on the granting of the license within **20 business days** after the final inspection result and receipt of all necessary documents.	ISAF must decide on the granting of the license within **5 business days** after the final inspection result and receipt of all necessary documents.
Renewal Period	Between 90 and 180 days before the expiry of the licence	During December of each year
Modification and transfer of license	Modification of the elements of the license (such as the name or address of the establishment, the layout, facilities or equipment, and, for manufacturing licenses, the scope of manufacturing activities) is allowed, subject to prior approval by ISAF. The license may be transferred to a new holder, provided that ISAF verifies that the proposed transferee meets all applicable requirements.	

V. Operational rules for the establishment

The Regulation establishes detailed operational requirements for medical device establishments, focusing on proper identification, storage, and handling of devices, as well as the segregation of non-compliant products. It imposes robust record-keeping obligations, particularly for manufacturing activities, to ensure full traceability across the device lifecycle, while applying proportionate documentation requirements to distribution and retail of higher-risk devices. It also requires the appointment of a technical director in each establishment, responsible for ensuring regulatory compliance, product quality and safety, and proper operational management.

VI. Conclusion

Although the Law and the Regulation are scheduled to enter into force on 1 July 2026, the catalogue classifying medical devices into the relevant risk classes has not yet been published. This catalogue, to be issued by the Secretary for Social Affairs and Culture

by way of dispatch, will be critical in clarifying the practical scope and application of the procedures outlined above.

We will continue to monitor these developments and provide further updates as additional guidance becomes available.

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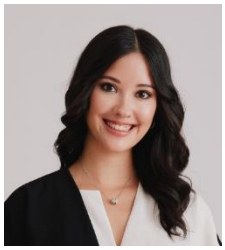

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