MdME

LEGAL UPDATE

Macau's Regime for Supervision & Administration of Medical Devices

Law no. 12/2025, of 28 July

A new law has been published on 28 July 2025, introducing a new legal framework governing the registration, listing, and business activities related to medical devices in Macau (Law no. 12/2025 or the "Law"). Aimed at safeguarding public health, ensuring the quality and safety of medical devices, and fostering innovation in the sector, the Law establishes a new legal framework where none previously existed.

The law defines **"medical device"** broadly to include instruments, apparatuses, reagents, software, and other related items used for medical purposes.

Keep reading to understand the main changes to the medical devices legal framework.

I. Classification of Medical Devices

The Law introduces an innovative classification system for medical devices in Macau, pursuant to which medical devices are primarily classified according to their risk level, with Class I being medical devices of low risk, Class II being medical devices of

medium risk (sub-classified as medium-low [Class IIa] and medium-high risk [Class IIb]), and Class III being medical devices of high risk.

Prior controls applicable to medical devices depend on its classification.

II. Mandatory registration (*registo*) and listing (*inscrição*)

The circulation of medical devices now requires either registration or listing: registration is mandatory for Class IIb and Class III devices, while Class I and Class IIa devices must be listed. The registration shall remain valid for 5 years (renewable for successive periods of the same duration), while the listing shall remain valid unless cancelled upon request of the applicant or under circumstances provided in the Law.

In addition to the foregoing, if the medical device was manufactured from abroad, it must also be registered or granted sale permission in the jurisdiction of origin, except otherwise provided by the Chief Executive.

III. Licensing of Commercial Activities

The Law distinguishes two main types of business licenses related to medical devices:

1. **Manufacturing License** – required for medical device manufacturing activities. Valid for 3 years (renewable for equal periods).
2. **Operation License** –required for the import, export, wholesale, and retail of medical devices. Class III medical devices may not be distributed in retail channels. Upon its issuance, the operation license is valid until 31 December of the following year, renewable annually.

Entities who have obtained a license for the import, export and wholesale of medication, or entities who have obtained a license for the import, export and wholesale of traditional Chinese medicine, are not required to obtain the operation license for the import, export and wholesale of Class IIb and III medical devices.

Changes to the license (including change of name or address of the establishment, layout / configuration of premises, installation and/or equipment, categories of

medical devices authorized for manufacture or operation, or the ownership or legal control of the license), require the Pharmaceutical Administration Bureau (ISAF)'s prior authorization.

Furthermore, licenses may be suspended or cancelled by ISAF on several grounds (including through applicant's request, application of ancillary penalties, non-fulfilment of license requirements, etc.). In the event of suspension, cancellation and expiry of license, the license holder shall immediately cease all business activities related to medical devices (with existing stock of medical devices being surrendered to ISAF or transferred to other licensed establishments).

IV. Supervision and Penalties

ISAF is the competent authority for supervising and implementing preventive and control measures pursuant to the Law.

Non-compliance with the Law may lead to the application of a fine between MOP 1,000 MOP 700,000. The following ancillary penalties may also be applicable: forfeiture of objects involved in the offence to the territory of Macau; prohibition from engaging in business activities related to medical devices; prohibition from applying for the registration or listing of medical devices; disqualification from participating in public tender procedures; temporary closure of the establishment.

Furthermore, the Law also defines several criminal offences, including the crime of counterfeit medical devices (related to the import, export, sale, manufacture, transport, storage or exhibition of counterfeit medical devices), which is punishable by imprisonment between 1 and 8 years.

V. Entry into force and transitional provisions

The Law will enter into effect on 1 July 2026.

Entities engaged in commercial activities related to medical devices, as well as medical devices already on the Macau market prior to the entry into force of the Law (i.e., 1 July 2026), are still required to comply with the licensing, registration and listing requirements pursuant to the Law. Additional time has been granted to these entities to facilitate compliance:

For the manufacturing license:

MEDICAL DEVICES MANUFACTURED	DEADLINE FOR OBTAINING THE MANUFACTURING LICENSE
Class III/IIb	1 July 2027
Class IIa	1 July 2028
Class I	1 July 2027

For the operation license:

COMMERCIAL ACTIVITIES RELATED TO MEDICAL DEVICES	DEADLINE FOR OBTAINING THE MANUFACTURING LICENSE
Import, export, wholesale and retail of medical devices of Class IIb	1 July 2027
Import, export, wholesale of medical devices of Class III	

Medical devices already in circulation benefit from transitional periods based on their respective classifications. If the applicable registration or listing requirements are not met within the prescribed deadlines, the devices may no longer be circulated in Macau once the transitional period expires.

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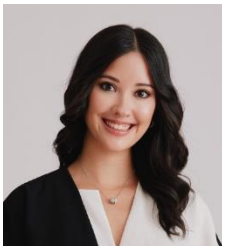

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