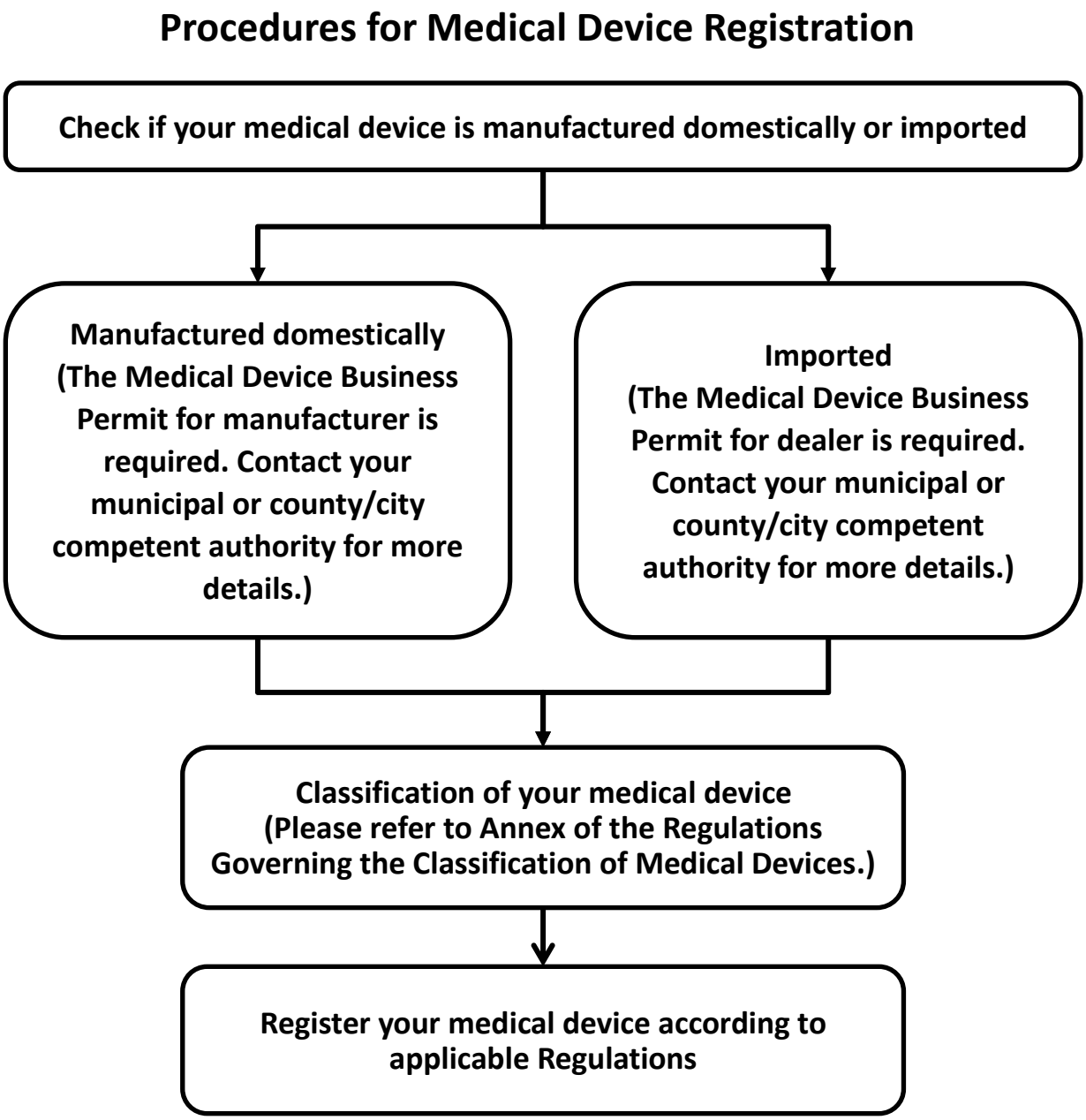
Frequently Asked Questions Regarding Registration of Medical Devices

Q1: Is there a hotline when I have questions related to laws and regulations of medical devices?

A: If you have questions about medical devices regulations, please contact the Medical Device Regulatory Consultation & Assistance Center by calling +886-2- 8170-6008 for assistance. You can also visit the webpage of the Center (https://6008.cde.org.tw) or leave a voicemail. The technical specialists will get back to you as soon as possible. The Center was set up by the Center for Drug Evaluation (CDE) and is sponsored by Taiwan Food and Drug Administration.

Q2: How to apply for medical device registration in Taiwan?

A: Please see the following graph for the application procedures.



Q3: How to apply for medical device licenses?

A: To apply for a medical device license, first you need to know the classification of your medical device. You also need to find out if there is any predicate device. The classification of medical devices are determined in accordance with the Regulations Governing the Classification of Medical Devices promulgated by the Ministry of Health and Welfare and the Annex of the Regulations offers more detailed information.

As for predicate devices, please visit the Medical Products, Medical Devices, and Cosmetic Certificates Inquiry System (https://info.fda.gov.tw/MLMS/H0001.aspx) to check if there are predicate devices. Please refer to the promulgated Process to Determine Predicates of Medical Device and Instructions of Written Inquiry.

Please provide information on one or two predicate devices, including their approved labels and instructions for use, or make a comparison table with predicate devices.

To apply for medical device license of Class II or Class III medical devices (including IVD products), please deliver the following

documents by mail or deliver in person to the receiving counter of the Food and Drug Administration, Ministry of Health and Welfare:

1. Application Form for Domestic/Imported Medical Devices;
2. Two drafts of labels, instructions for use and packaging of the medical device;
3. A copy of the medical device business permit;
4. Relevant administrative/technical documentation, and test reports.

For more detailed information, refer to the Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration (https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030128).

For details of the documents you should prepare, please download the Information and References for Documents to Be Prepared for Registration (Chinese version).

For IVD products, please refer to the Guidelines for Registration of In Vitro Diagnostic Medical Device.

Please make sure that you have filled in all the information required and use the Data Sheet and Checklist for Domestic/Imported Class II

and III Medical Devices to double check and tick the box to confirm that all documents required have been enclosed.

Q4: What should I do if I want to apply for a Medical Device license extension?

A: Please prepare the documents listed in the following table. You can also use the Checklist for Extension of Medical Devices to double check**.**

No.	Documents to be enclosed	Manufactured domestically	Imported
		Class 2 and Class 3	Class 2 and Class 3
1	Application Form for Extension of Medical Device Licenses	V	V
2	Original Licenses	V	V
3	Original copy of the manufacture and free sale certificate of the country of origin		V
4	Original copy of the foreign original manufacturer authorization letter		V
5	Document verifying that the medical device manufacturer conforms to the Medical Device Quality Management System Regulations	V	V

Note 1: For medical devices manufactured by outsourced manufacturers, the original copy of the Contract for Outsourced Manufacture including both manufacturer's name and address, and name of the product should also be enclosed.

Note 2: Subject to change. Please check the latest announcements of the Ministry of Health and Welfare before submitting your application.

Note 3: One application for one certificate.

Q5: What should I do if I want to change any registration particulars of an approved medical device?

A: You will need to prepare documents to apply for changing, re-issuance, or replacement of medical device license. You can refer to Appendix 4 of Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration (https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030128).

Q6: What do you mean by "Manufacture and Free Sale Certificate of the Country of Origin"?

A: A manufacture and free sale certificate of the country of origin is also known as Certificate to Foreign Government, Certificate of Free sale or

Free Sale Certificate. It is a certified document issued by the highest health authority or agency of the country where the medical device is manufactured, proving that the medical device is manufactured and sold freely in that country. This document shall provide the following particulars:

1. Name and specifications and/or model number of the medical device.
2. Manufacturer’s name, address, manufacturing status, and actual status for domestic sale as approved in that country.

Under the following circumstances, this document may be replaced by a document issued by other authorities or another document:

1. If the medical device is not regulated by the highest health authority in manufacturer’s country, this document may be issued by the local health agency or an organization approved by the central competent authority of the Republic of China (Taiwan).
2. If the medical device is commissioned to be manufactured, this document may be issued by the highest health authority in the country where the contract party or the contract manufacturer is located.

3. If the medical device involves contract manufacturing and it is not sold in the country where the contract manufacturer is located, this document may be replaced by a free sale certificate issued by the highest health authority in the country where the contract party is located, and a manufacture certificate issued by the government of the country where the contract manufacturer is located.
4. This document may be replaced by a manufacture certificate issued by the government of manufacturer’s country and a free sale certificate issued by the highest health authority of the United States of America or of a European Union Member State.
5. If the medical device is a product that is first in the world with no predicate, a report from the central competent authority after conducting an on-site inspection of the foreign medical device manufacturer and a report of medical device clinical trials carried out in the Republic of China (Taiwan) shall be submitted for the exemption from submitting the manufacture and free sale certificate of the country of origin.

   This document shall remain valid for two years from the date of issuance, and shall be notarized by Republic of China’s (Taiwan’s)

overseas embassy or consulate, representative office, other official office stationed in the region, or overseas organization authorized by the Ministry of Foreign Affairs (hereafter referred to as the ROC overseas representative office). If the certification document is not issued in English, a Chinese or English translation shall be submitted at the same time and the translation shall be notarized. However, those issued by the highest health authority of a country that has established technical cooperation agreement with the Republic of China (Taiwan) for the premarket review of medical devices or those recognized by the central competent authority are exempt from notarization.

Q7: What should I do if it is impossible to obtain the Manufacture and Free Sale Certificate issued by the competent health authority because the product is not considered to be a medical device in the country of origin?

A: If the medical device is not regulated by the highest health authority in manufacturer's country, this document may be issued by the local health agency or an organization approved by the central competent authority of the Republic of China (Taiwan).