Operations Procedure for Applying for Medical Device Certificates

Manufacture or importation of medical devices may be permitted since registration is applied for with the competent central health authority and the medical device certificate is issued.

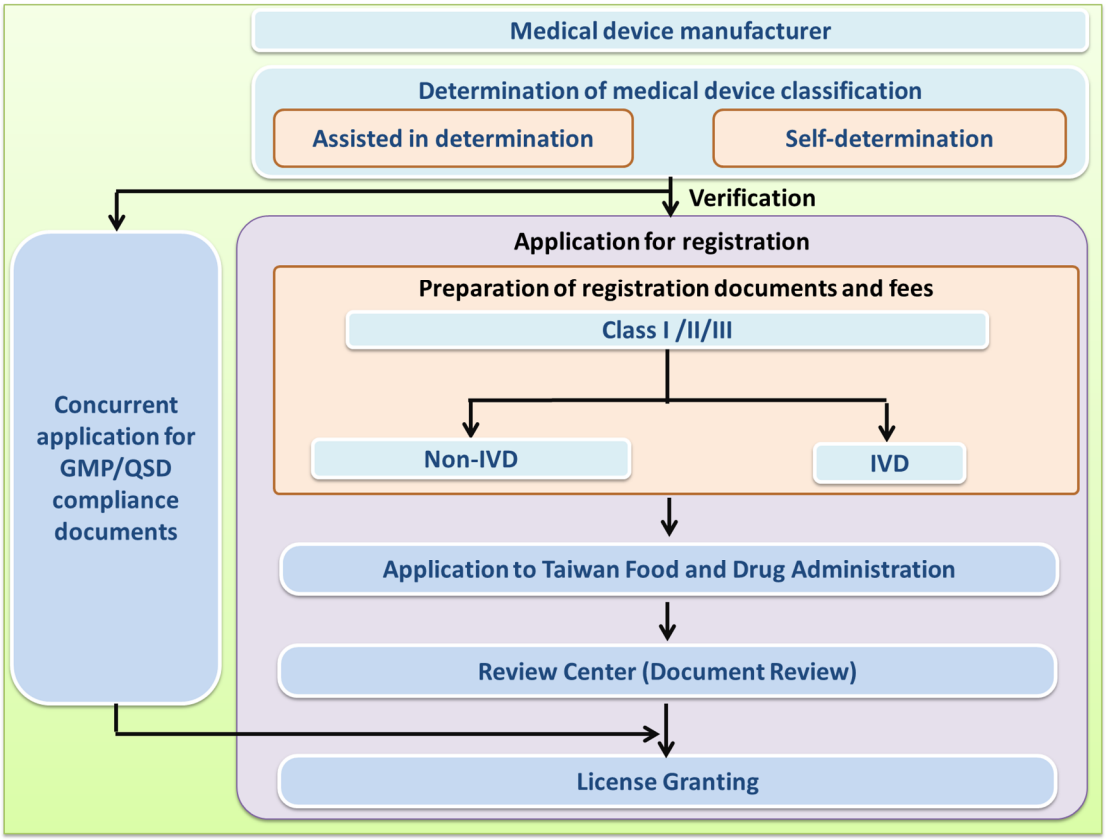
Medical devices shall be imported by the holder of the certificate or the authorized company.

The competent central health authority defines the application requirements, review procedures, approval criteria, and the others which should be followed for certificate registration, change, transfer, extension, renewal, and re-issuance.

Explanation of the certificate registration application flowchart:

Before applying for registration, manufacturers must determine the classification of their products. Medical devices can be divided into non-in-vitro diagnostic devices and in-vitro diagnostic devices (IVDs). In addition, they may also be divided into Class I and Class II/III according to their risk level. Once the classification is determined, application documents and fees are required to apply to the Taiwan Food and Drug Administration for the registration.

Meanwhile, manufacturers may apply for the documents verifying that the factories are in conformity with the GMP for medical devices.


Medical device manufacturer
Determination of medical device classification
Assisted in determination
Self-determination
Verification
Application for registration
Preparation of registration documents and fees
Class I /II/III
Non-IVD
IVD
Application to Taiwan Food and Drug Administration
Review Center (Document Review)
License Granting
Concurrent application for GMP/QSD compliance documents