

# How to apply for Medical Device License in Taiwan

According to 『Pharmaceutical Affairs Act (PAA) 』, all medical devices regardless their classification shall apply for “Medical Device License” before they are placed on Taiwan market.

## 1. Manufacturers of medical devices/Dealers of medical devices

As required by Article 14, 15, 16 and 17 of 『Guidelines for Registration of Medical Devices 』, submitter of product premarket review application shall provide a copy of its “Medical Device Manufacturer License” or “Medical Device Distributor License”.

The term “Manufacturers of Medical Devices” is defined in Article 18 of PAA as a company manufacturing, assembly medical device, or distribution and export of its devices, or import of the materials used by medical devices. Local manufacturer shall apply for factory license to local industry authority and pharmaceutical manufacturer license for medical device to local health authorities.

## 2. Identify the classification of your medical device

Manufacturer or distributor shall identify the intended use of its medical device to verify the product is eligible for medical device regulations. According to its intended use, medical device can be classified into three Classes.

Article 13 of PAA defines medical device as any instruments, machines, apparatus, and their accessories, fittings and parts which are used in diagnosing, curing, alleviating, or directly preventing the diseases of human beings, or which may affect the body structure or functions of human beings.

Department of Health, Executive Yuan published 『Regulations Governing Management of Medical Devices 』 to classify medical devices into Class I (low risk), Class II (moderate risk), Class III (high risk) and new medical device (no equivalent device approved by DOH).

In addition to classification, DOH categorized medical devices according to device use. The category of medical devices is listed as bellow :

No	Name	Items
A	Clinical chemistry and clinical toxicology devices	225

B	Hematology and pathology devices	99
C	Immunology and microbiology devices	171
D	Anesthesiology devices	131
E	Cardiovascular devices	134
F	Dental devices	120
G	Ear, nose, and throat devices	53
H	Gastroenterology-urology devices	60
I	General and plastic surgery devices	69
J	General hospital and personal use devices	81
K	Neurological devices	100
L	Obstetrical and gynecological devices	83
M	Ophthalmic devices	97
N	Orthopedic devices	85
O	Physical medicine devices	67
P	Radiology devices	68
	Unclassified	24

If manufacturer or distributor has problems in classifying its medical devices, it could apply for “Request for Medical Device Classification and Regulation”.

The regulatory requirements for Class I, II, III and new medical devices are summarized as below :

Class	I	II	III	New
Good Manufacturing Practice	No (except for those are sterile or with measuring function)	Required	Required	Required
Medical Device License	Required	Required/technical review	Required/technical review	Required/technical review
Clinical Data	Not required	Not required	Required for IVD and DOH designated medical devices	Required

### 3. Class I Medical Device License

Submission for Class I device includes :

- Application Form
- A copy of Pharmaceutical Medical Device Manufacturer/Distributor License

#### **4. Class II/III Medical Device License**

##### 4-1 Medical Device Good Manufacturing Practice (GMP)

There are four types of inspection to medical device manufacturers including :

- inspection on new establishment, move, expending, reopening or increase of new product
- follow-up inspection
- regional routine inspection
- other special inspection

The facility of medical device manufacturer shall comply with the requirements of Chapter II of 『Pharmaceutical Factory Establishment Standards』 and be inspected by local industry and health authorities. Quality management system of manufacturers shall be inspected by DOH and its designated auditing organizations in accordance with Medical Device GMP as defined in Volume IV of 『Pharmaceutical Factory Establishment Standards』 .

Inspection to foreign manufacturers is conducted through Quality System Documentation review. Foreign manufacturer or its initial importer may apply for on-site inspection.

Domestic and foreign manufacturers may apply for GMP inspection in accordance with Good Manufacturing Practice, ISO 13485 : 2003 or CNS 15013.

##### 4-2 Premarket Review of Class II and Class III devices

Class II and Class II premarket submissions are reviewed by Bureau of Food and Drug Analysis (BFDA). As required by Article 15 and 17 of 『Guidelines for Registration of Medical Devices』 , submissions shall include the following information :

- 1) Application form ;
- 2) Three copies of Chinese labeling, instruction for use, packaging inserts ;
- 3) A copy of Pharmaceutical License for Medical Device Manufacturer/Distributor ;
- 4) Truth and Accuracy Statement ;

- 5) For import medical device, Free Sale Certificate issued by the health authority of the country of original and authorization letter issued by original manufacturer are required ;
- 6) Two copies of preclinical test, quality control procedure and test reports ;
- 7) Two copies of product structure, material, specifications, intended use and drawings. Operation manual and maintenance manual of instrumentation which include the above-mentioned information may be provided alternatively ;
- 8) A copy of GMP/QSD Compliance Letter ;
- 9) Radioactive safety information, if applicable.

For Class II medical devices, approval documents issued by both the US and EU health authorities/Notified Bodies may be provided as alternative to the information of preclinical test, quality control procedure and test reports.

If the production of medical device involves subcontracting, manufacturer shall comply with the requirements of 『 Guidelines for Pharmaceutical products subcontracting for production and testing 』 .

It is recommended to refer to DOH published “Medical Device Recognized Standards” for safety and effectiveness evaluation.

#### 4-3 Technical review of Class II IVD

Class II IVD submission shall be submitted to DOH. The information contained in the submission is the same as Class II/III medical device. However, the safety and performance of IVD is reviewed according to the requirements of 『 IVD Premarket Review Guidance 』 .

#### 4-4 Technical Review of Class III IVD

In addition to section 4-3, Class III IVD including Hepatitis B/C/D Virus, HIV, HTLV and blood typing kits shall be tested by BFDA before the Medical Device License is granted.

#### 4-5 Technical Review of New Medical Devices

If a medical device is not substantially equivalent to any of DOH approved medical devices, the new device is regulated a “New Medical Device”. As a general rule, new medical devices are those with new principle, new structure, new material

or new effectiveness. New IVD are those with new principles, new method or new testing.

- 1) Application form ;
- 2) Three copies of Chinese labeling, instruction for use, packaging inserts ;
- 3) A copy of Pharmaceutical License for Medical Device Manufacturer/ Distributor ;
- 4) Truth and Accuracy Statement ;
- 5) For import medical device, Free Sale Certificate issued by the health authority of the country of original and authorization letter issued by original manufacturer are required ;
- 6) Two copies of product structure, material, specifications, intended use and drawings. Operation manual and maintenance manual of instrumentation which include the above-mentioned information may be provided alternatively ;
- 7) Two copies of preclinical test, quality control procedure and test reports ;
- 8) A copy of GMP/QSD Compliance Letter ;
- 9) Literature review and related study reports ;
- 10) Clinical investigation reports ;
- 11) Radioactive safety information, if applicable.

## **5. Approval and maintenance of Medical Device License**

### 5-1 Issuance of Medical Device License

According to 『Guidelines for Registration of Medical Devices』, the application will not be approved if there is one of the following situations :

- Review fee is not paid, information is insufficient or inconsistent ;
- Required premarket testing is not complete or the testing fails ;
- Packaging, labeling or instruction for use is not consistent with that DOH approved ;
- Medical device may have risks to human health, safety, quality or effectiveness ;
- The submission does not comply with DOH published orders or guidance.

A medical device is adulterated and misbranded if the device

1. may cause risks to human health or errors in diagnosis ;
2. contains toxic or poisonous substances ;

3. expires ;
4. quality, quantity or strength is not consistent with DOH approved specifications.

The license holder shall apply for renewal of Medical Device License before five-year effective period expires.

5-2 During the effective period, the Medical Device License may be extended, revised, adding specifications, adding effectiveness and change names of manufacturer or distributor.

<b>Maintain and Change your License</b>	<b>Guidelines for Registration of Medical Devices</b>
Change, Transfer, and Re-issuance of Permit License	Article 20~33
Extension of a Permit License	Article 34~35
the drafting and publication of medical device instructions, labels, and packaging	Article 36
The product name of a medical device	Article 37

**Reference and recommended readings :**

- 『Pharmaceutical Affairs Act 』 (amended on May 30, 2006)
- 『Guidelines for Registration of Medical Devices 』 (amended on April 12, 2006)
- 『Regulations Governing Management of Medical Devices 』 (amended on July 22, 2005)

**Figure 1. Medical Device License application Flowchart for Manufacturers of medical devices/Dealers of medical devices**



