

Medical Device Regulatory Requirements for Taiwan

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Industry Definition

In Taiwan, the definition for medical devices includes the instruments, machines, apparatus, accessories, fittings and spare parts which are used for diagnosing, curing, alleviating, and directly preventing human diseases, or which may affect the structure and function of the human body.

An In Vitro Diagnostic Device (IVD) refers to a diagnostic drug test, apparatus, or system used in diagnosing diseases or other conditions, including the determination of health conditions for the purpose of treating, slowing or preventing disease. In Taiwan, the IVD is used in equipment related to clinical chemistry and toxicology, hematology, pathology, immunology and microbiology. IVDs are regulated as medical devices.

The definition of medical device manufacturer refers to business undertakings that are engaged in manufacturing and assembling medical devices, wholesaling and exporting their own products, and importing raw material for their own use. Manufacturers may concurrently engage in retailing of their own manufactured products.

Introduction to the Taiwan Regulatory System

The Department of Health (DOH) is the local healthcare authority that regulates the importation of medical devices. Under Taiwan's Pharmaceutical Affairs Law, the DOH Bureau of Pharmaceutical Affairs (BOPA) regulates all medical devices. All medical devices are required to obtain pre-market registration from the BOPA before they can be manufactured locally or imported into Taiwan. Since DOH issues licenses only to locally based firms, all foreign suppliers must submit the required documentation and receive the necessary approvals through their Taiwan importers or through a Taiwan registered subsidiary of the U.S. supplier. To market a medical device in Taiwan, the DOH's pre-marketing registration approval must be obtained before the Board of Foreign Trade (BOFT) of the Ministry of Economic Affairs (MOEA) will issue an import license to an agent for a U.S. exporter. New devices will be processed through the Advisory Committee for New Devices.

Other agencies involved with medical device regulatory issues include:

- The National Bureau of Standards (NBS) formulates the design and safety standards for medical equipment.
- The Nuclear Science Council (NSC) inspects X-ray machines and other radiation producing equipment.

- The National Health Administration (NHA) must inspect any product intended for applications for the human body.

Taiwan introduced Good Manufacturing Practice (GMP) requirements in February 1999. Newly established factories, and all new applications for registration and pre-market approval, must comply with GMP. U.S. companies are exempt from many of the requirements thanks to an Exchange of Letters between DOH and USFDA in 1998 (this is explained further below). The agreement allows companies to submit already available USFDA and other quality assurance certificates for their facilities in the United States in lieu of voluminous “Quality System Documentation (QSD)” required of manufacturers in other countries. DOH performs on-site inspections for local manufacturers and reviews Quality System Documentation provided by foreign manufacturers. QSD is based on the 20 GMP requirements found in ISO 13485. All medical devices must meet GMP requirements, which are based on ISO 13485, ISO 9000 and ISO 11137. For more information, visit the following website: <http://doh.gov.tw/ufile/doc>.

The 1998 Exchange of Letters compels USFDA to provide copies of medical device Establishment Inspection Reports (EIRs) of U.S. exporters to Taiwan upon request. As a result, medical devices manufactured in the U.S. are exempt from being required to submit QSD if the following documents are included in their submission to DOH:

- 1) FDA’s Establishment Inspection Report (EIRs);
- 2) Certificate to Foreign Government (CFG); and
- 3) ISO 13485 Certificate (or EN46001 certificate).

Generally, all Class I, II, and III medical devices must meet the GMP requirements. The only exceptions are for Class I products that are measurement devices or do not require sterilization.

Taiwan is currently in the process of harmonizing domestic medical device classifications with the commonly used international classification system. The DOH, following the USFDA’s 21 Code of Federal Regulations (21 CFR 862-892) classification system based on risk category, has categorized medical devices into three separate classes: I, II, and III. All domestically produced and imported medical devices must have their devices classified before they can be imported or manufactured. In-vitro Diagnostic devices (IVDs) for HIV-1/2, HTLV-1/2, Hepatitis B, Anti-A and Anti-B type blood tests were categorized as medical devices in Taiwan in December 2002. IVD devices in these categories must follow the regulatory issues for medical devices as well as the separate IVD regulations.

The DOH has authorized four local accredited organizations to review the GMP/QSD documentation and testing records for all medical devices and IVDs. They are:

- The Industrial Technical Research Institute (ITRI)
- The Metal Industry Research and Development Center
- The Electronics Testing Center, and

- The Pharmaceutical Industry Development Center.

In November 1998, the Center for Measurement Standards/ITRI received FDA approval as one of thirteen “Accredited Persons” for 510(k) review under the FDA Modernization Act. The Office of Medical Device Evaluation (OMDE) is an independent office that is responsible for CMS’ FDA Accredited Person program. The DOH’s Bureau of Food and Drug Analysis (BFDA) is authorized to review Class II and Class III medical devices, and reach a decision on registration approval within 90-120 days, provided that all requested documents are submitted in a timely fashion.

The DOH also signed an Exchange of Letters with the European Commission on November 4, 2004 and designated six European auditing organizations: TUV Product Service; The National Standards Authority of Ireland (NSAI); G-MED; Medical Device Certification (MDC), British Standards Institute Product Services (BSIPS), and TUV Rheinland Product Safety as participating EU partners. U.S. firms with European facilities can reach these organizations for site inspection. This report may be combined with the auditing report to exempt the firm from required documentation through QSD.

Registration with the Bureau of Pharmaceutical Affairs (BOPA)

A manufacturer who wishes to export medical devices to Taiwan must assign a local agent/distributor who can apply on the manufacturer’s behalf for a product license. The following Quality Systems Documentation (QSD) and the application should be submitted to BOPA:

- A registration form, which:
 - Must have the same address for the applicant as on the Business License and authorization letter
 - Five copies of the outer packages and labeling (2 for examining, 3 for final receiving license)
 - Five copies of the instructions for use in both Chinese and foreign language (2 for examining, 3 for final receiving license), including an original copy of the foreign language instructions
- A letter of authorization, which:
 - States the name of the device, model (type), name and address of the manufacturer and agent
 - Manufacturer information should match what appears on registration form
 - Product name and specifications
 - English and Chinese translation are required if original information is in neither language
 - States that the agent is authorized to register the product
 - Shall be original
 - Shall be valid for one year from date of issue
- A certificate of free sale, which:

- States the name of the device, model (type), name and address of the manufacturer
 - States that the device(s) is/are freely sold in its home market
 - Shall be legalized by the Taipei Economic and Cultural Office (TECRO) representative in the country of origin
 - Shall be original
 - Shall be valid for two years from date of issue
- Seven copies of a leaflet or brochure stating the name, structure, specification usage, and administration of the device, and manufacturer's name and address (8 copies are required for radioactive equipment)
 - Two copies of the quality control record (including testing methods and results)—required for all medical devices
 - Form, structure, dimension, raw materials/ingredients, and quantity, performance and purpose of use, indication or effect
 - A sample of the device (if possible)
 - Two copies of clinical reports for newly developed devices, or for approved medical devices with a new intended purpose, or for special devices (such as implantable appliances, contact lenses, etc.)
 - Two copies of circuit testing records of electrical insulation (only for electrical equipment)
 - Two copies of instructions for operating security (only for electrical equipment)
 - Two copies of automatic measurement adjustment operating records (only for automatic temperature adjusting equipment)
 - Two copies of radiation leakage testing records and certificates (only for radioactive equipment)
 - Labels, instructions, operating manuals and dossiers for use (must be provided in Chinese, as English is not universally understood)
 - Technical results

Abbreviated Registration Available for Class I Devices

As a result of the substantial regulatory revisions adopted during 2004, it can be seen that the DOH is gradually simplifying requirements for the submission of documents, actively seeking to harmonize domestic regulations with international practices on pre-market approval of medical devices, and adopting post-market surveillance to better monitor products after their introduction to the Taiwan market. These changes signify more effective management of the DOH's administrative resources. The Department is able to maintain product-safety review standards without wasting manpower and resources to repeat assessments already completed in developed markets such as the United States and Europe. In addition, the new approach can prevent the occurrence of administrative backlogs that hinder the introduction of new technologies and therefore ultimately compromise patient welfare.

In 2001, the DOH initiated a re-registration process for all medical devices, which was completed on December 20, 2005. Since 44% of the registration workload represented Class I medical devices, DOH decided to implement a fast track registration procedure to simplify the process. Since April 12, 2006, the Class I medical device registration applicant may submit (1) a “Letter of Commitment” (application form in Chinese) and (2) medical devices manufacturer certificate (for local) and medical devices sales certificate to the Bureau of Pharmaceutical Affairs. The applicants can easily obtain the certificate, but the DOH has reserved the authority to check the GMP and other necessary documentation if necessary. If the applicant submitted fraudulent documents, the certificate will be removed.

Fast Track Approval Available for Some Class II Devices

U.S. exporters supplying the USFDA’s CFG and EC (Free Sales Certificate) type-examination certificate for Class II medical devices may be exempt from supplying the following tests and results to DOH:

- Biocompatibility test method and results,
- Functional testing method and results,
- Sterilization method and results, and
- Testing results for the finished product (including lot, model number/product name, date, employee name/number).

Companies producing Class II devices that can provide evidence the product has been marketed in Taiwan for one year are also eligible for fast track approval; however, new Class II and III devices cannot utilize these simplified registration procedures.

In general, requestors should get a response to their registration application and certification of GMP requirements within 90-120 days of submission, provided their application is complete and no other issues are identified.

Import Labeling

Class II and III medical devices require submission of three copies of the product’s packaging and labeling on a “Labeling Attachment Form.” In addition, labeling and packaging must have the product name, license number, name and address of the manufacturer printed in Chinese, while clearly distinguishing the manufacturing date and/or expiration date (this can, but does not have to be, printed in Chinese). Finally, the Chinese product name cannot be in a smaller print than the foreign product name.

Import Packaging

Besides the requirement for English and Chinese translation if the original literature is in neither language, the packaging must have instructions translated into Chinese, and the manufacturing and/or expiration date of the product must be easily identifiable.

Import Documentation

All medical device classes require submission of:

- The original and one copy of the registration form
- Instructions and operating manual translated into Chinese for the device
- The original authorization letter from the manufacturer to the local agent
- A photocopy of the business license (all referred to above under “Registration with BOPA”); and
- A copy of the “License Attachment Form”

The following requirements differ between Class I and Class II/III medical devices:

Class I

- Supporting literature which demonstrates Good Manufacturing Practice (GMP) compliance (only if GMP compliance is required)
- Literature which shows that the device’s structure, materials, specifications, performance and indications meet Class I device requirements

Class II/III

- Three copies of the product’s packaging and labeling (accompanying a “Labeling Attachment Form”)
- Affidavit Form
- Original copy of Manufacturing and Marketing Approval, including identical manufacturer and product information as found on the registration form—this is issued by the government of the country of origin and authorized by the Taiwan Embassy or equivalent agency (valid for two years)
- Pre-clinical trial, including Quality Control (QC) testing specifications, methods, records and reports—two copies each of three different batches (Class III usually need testing after review of QC information and document examination)
- Two copies of device’s structure, materials, specifications, performance, indications and appearance, etc.—operation and maintenance manuals can be used to meet this requirement for medical instruments
- GMP certification of the manufacturer
- Two copies of relevant research reports and supporting literature
- Safety testing reports (for devices using ionizing radioactive materials)—two copies for each of three different batches

Import in-vitro diagnostic devices follow many of the same requirements (registration letter, business license, affidavit form, authorization letter, manufacturing and marketing approval) as Class II and III products do, but they also must meet additional provisions:

Safety and Effectiveness Information

- Technical File—product structure, components, materials, performance and uses, etc., including:
 - Features and principle of the procedure
 - Functional features including accuracy, sensitivity, reliability, etc.
 - Effective evaluation
- Manufacturing methods and packaging
- Validation of analytic methods or process procedure and data analysis
- One copy of the GMP/QSD certificate
- Production Process Control or Batch Manufacturing Record
- Testing results for the finished product (including lot, model number/product name, date, employee name/number)

Contacts

There are two major approaches by which U.S. medical suppliers can sell products in Taiwan; either through local agents or through the establishment of a branch office. As business practices and sales channels for expensive medical equipment differ between the U.S. and Taiwan, a critical step for most exporters is finding a qualified local agent to market their products. The agent can also gather and provide market information; introduce new technology and equipment to local medical service providers, and train end-users to operate the equipment properly. If local agents have technical staff, they can efficiently provide after-sales assistance to customers.

U.S. firms wishing to learn more about regulatory issues related to medical devices in Taiwan are encouraged to contact the following agencies and individuals for additional information:

The Department of Health (DOH), Executive Yuan
 Bureau of Pharmaceutical Affairs (BOPA)
 11th Floor, No. 100 Ai Kuo E. Road
 Zhongjheng District
 Taipei 10092, Taiwan
 Tel: 886-2-2321-0151
 FAX: 886-2-2397-1548

2nd Division (Medical Devices):
 Contact: Ms. Shiow-Jane Lin, Chief
 E-Mail: pajane@doh.gov.tw
 Or
 In Vitro Diagnostic Device Team
 Contact: Ms. Chien –Wen Hsu
 E-Mail: pahsu@doh.gov.tw

American Institute in Taiwan

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You can contact the following persons of AIT's Commercial Section for more information:

Gregory Harris, Commercial Officer
Commercial Section
American Institute in Taiwan
333 Keelung Road, Room 3207, Sec.1, Taipei, Taiwan
Tel: 886-2-2720-1550 ext. 385
FAX: 886-2-2757-7162
E-Mail: Gregory.Harris@mail.doc.gov

Angeli Chou, Specialist
Commercial Section
American Institute in Taiwan
333 Keelung Road, Room 3207, Sec.1, Taipei, Taiwan
Tel: 886-2-2720-1550 ext. 310
FAX: 886-2-2757-7162
E-Mail: Angeli.Chou@mail.doc.gov

AIT's Commercial Section is also on the World Wide Web at the following address:
<http://www.ait.org.tw>.