

Medical Device Registration in Taiwan Overview and General Requirements

Over the past several years Taiwan's regulatory environment for medical device registration has undergone several revisions. In Taiwan the definition for medical devices includes the instruments, equipment, apparatus, accessories and spare parts which are used for diagnosing, curing, alleviating and directly preventing human diseases, or changing the structure and function of the human body. The Department of Health (DOH) is the local healthcare authority that regulates the importation of medical devices. US exporters, or in this case their designated agents, must obtain the DOH's pre-marketing registration approval before they will receive an import license from the Ministry of Economic Affairs' (MOEA) Board of Foreign Trade (BOFT).

Good Manufacturing Practice (GMP) requirements were introduced in February 1999. Newly established factories, and all new applications for pre-market approval, have to comply with GMP. U.S. companies are exempt from many of the requirements thanks to a special agreement reached in 1998. They are often allowed to submit already available U.S. FDA and other quality assurance certificates in lieu of voluminous "Quality System Documentation" for their facilities in the U.S.

The DOH announced a new medical device reclassification on June 30, 2000. Manufacturers of foreign or locally made medical devices must have their devices classified before they can be imported or manufactured. 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 (CFR), has classified medical devices into three classes: I, II, III.

In-Vitro Diagnostic (IVD) devices for HIV-1/2, HTLV-I/II, hepatitis B, Anti-A, and Anti-B type blood test were classified as medical devices in December 2002. IVD products 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 devices and IVD's. 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. The DOH's Bureau of Food & Drug Analysis (BFDA) is authorized to review Class II and III medical devices. In general, the number of days for GMP and registration approval is 90-120 days, if there are no delays due to the submission of incomplete documents or other issues.

Regulatory Agency

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 US supplier. Other agencies are involved with regulatory issues. 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 to the human body.

Regulatory Framework

Taiwan's Department of Health (DOH) regulates the importation of medical equipment. 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.

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), has classified medical devices into three classes: I, II, III. This uses the classification system/risk categorization system.

US Exporters will register their products through the Pre-market Application or through the GMP/QSD. Taiwan's healthcare authority has required GMP compliance for all new applications for registration and market approval since Feb. 10, 1999. All medical devices need to meet GMP requirements, which are based on ISO 13485, ISO 9000 and ISO 11137.

New devices will be processed through the Advisory Committee for New Devices.

Device Classification

Class I:

The device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present the potential for unreasonable risk of illness or injury.

Class II:

The device is purported or represented to be for use in supporting or sustaining human life.

Class III:

The device is life-supporting or sustaining or for a use which is of substantial importance in preventing impairment of human health. Or, the device may present the potential for unreasonable risk of illness or injury.

The DOH has classified medical devices into 16 categories, as follows:

- Clinical chemistry and clinical toxicology devices
- Hematology and pathology devices
- Immunology and microbiology devices
- Anesthesiology devices
- Cardiovascular devices

Dental devices
 Ear, Nose, and Throat devices
 Gastroenterology-Urology devices
 General and Plastic Surgery devices
 General hospital and personal use devices
 Neurological devices
 Obstetrical and Gynecological devices
 Ophthalmic devices
 Orthopedic devices
 Physical medicine devices
 Radiology devices

For more detailed information on the reclassified categories of medical devices, please visit the following website: <http://medical.cms.itri.org.tw/measure> . Taiwan classifications are generally consistent with those of the USFDA.

In some cases, the importer/distributor will need to submit a written request to the DOH to determine whether the product is a medical device, to which classification it belongs, or if a new classification must be created. The DOH may take up to 30 days to reach its decision.

Standards Compliance

Taiwan is currently in the process of harmonizing domestic medical device classifications with the commonly used international classification system. In addition, all medical devices will now need to meet the Good Manufacturing Practice Requirements. The GMP is based on ISO 13485.

Following the recommendation from the Global Harmonization Task Force (GHTF), the medical devices pre-market evaluation includes: Basic Safety Standards, Group Safety Standards, and Product Safety Standards. The Department of Health announced 15 International Standards that will be used evaluate medical devices on June 28, 2004. DOH adopted these standards to ensure the safety of medical devices electrical, biological, and sterilization procedures and for technical reference.

DOH Series	Standard Series	Standard Description
DOH-00001	IEC 60601-1, 1998 Amendment 1, 1991 Amendment 2, 1995	Medical Electrical Equipment – Part 1: General Requirement for Safety and Amendment 1, Amendment 2
DOH-00002	IEC 60601-1-1: 2000	Medical Electrical Equipment – Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
DOH-00003	IEC 60601-1-2: 2001	Medical Electrical Equipment – Part 1, General Requirements for Safety; electromagnetic Compatibility –

		Requirements and Tests
DOH-00004	IEC 60601-1-3: 1994	Medical Electrical Equipment – Part 1: General Requirements for Safety: General Requirements for Radiation Protection in Diagnostic X-ray Equipment
DOH-00005	IEC 60601-1-4: 2000	Medical Electrical Equipment – Part 1: General Requirements for Safety; 4 Collateral Standard: Programmable Electrical Medical Systems
DOH-00006	ISO 11134: 1994	Sterilization of Health Care Products – Requirements for Validation and Routine Control-Industrial Moist Heat Sterilization
DOH-00007	ISO 11135: 1994	Medical Devices _ Validation and Routine Control of Ethylene Oxide Sterilization
DOH-00008	ISO 11137: 1995, Amendment 1: 2001	Sterilization of Health Care Products _ Requirements for Validation and Routine Control-Radiation Sterilization and Amendment 1
DOH-00009	ISO 10993-1: 2003	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
DOH-00010	ISO 10993-5: 1999	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
DOH-00011	ISO 10993-6: 1994	Biological Evaluation of Medical Devices – Part 6: Test for Local Effects After Implantation
DOH-00012	ISO 10993-7: 1995	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
DOH-00013	ISO 10993-10: 2002	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization – Maximization Sensitization Test
DOH-00014	ISO 10993-11: 1993	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
DOH-00015	ISO 10993-12: 2002	Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials

Sources: The Department of Health

GMP Requirements

Good Manufacturing Practice (GMP) requirements were introduced in February 1999 and full compliance became mandatory on February 10, 2004.

The Department of Health performs on-site inspections for local manufacturers and reviews quality system documentation provided by foreign manufacturers. Quality System Documentation (QSD) is based on the 20 requirements of the GMP (ISO13485). For more information, please visit the following website: <http://doh.gov.tw/ufile/doc>

The DOH and USFDA signed an Exchange of Letters on January 9, 1998 in which the USFDA agreed to provide copies of medical device Establishment Inspection Reports (EIR's) of US Exporters to Taiwan upon request. As a result, medical devices manufactured in the U.S. are exempt from being required to submit quality system documentation if the following documents are included in their submission to DOH:

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

Generally, all Class I, II, and III medical devices must meet the GMP requirements. The only exemption is for Class I devices which do not require sterilization.

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. US firms with facilities in Europe can reach these organizations for site inspection. This report may be combined with the auditing report to exempt the firm from required QSD documentation.

Clinical Investigations

Hospitals seeking to conduct a clinical investigation with an unapproved medical device should submit a clinical trial proposal to the DOH. After approval by the DOH, the hospitals will be able to import the devices directly or they may assign a local agent to implement the import procedures.

Registration Requirements

A medical device manufacturer who wishes to export medical devices to Taiwan must assign a local agent/distributor in Taiwan who can apply, on the manufacturer's behalf, for a product license. The following documents (Quality System Documentation) and the application should be submitted to the Bureau of Pharmaceutical Affairs (BOPA):

- ③ A letter of authorization which:
 - States the name of the device, model (type), name and address of the manufacturer and agent
 - States that the agent is authorized to register the product
 - Shall be original
 - Shall be valid for one year from the date of issue

- ③ A certificate of free sale
 - States the name of the product, model (type) and 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 your area
 - Shall be original
 - Shall be valid for two years from the issued date

- ③ A leaflet/brochure (7 copies)
- ③ Two copies of the quality control record (including testing methods and results) - required for all medical devices.
- ③ Form, structure, dimension, raw materials/ingredients, and quantity, performance, and purpose
- ③ A sample of the device (if feasible)
- ③ Clinical reports (2 copies) for newly developed devices or for approved medical devices with a new intended purpose or some special devices: such as implantable appliances, contact lenses etc.
- ③ Circuit testing records of electrical installation (only for electrical equipment) (2 copies)
- ③ Instructions for operating security (only for electrical equipment) (2 copies)
- ③ Operating records of automatic measurement adjustment (only for automatic temperature adjusting equipment) (2 copies)
- ③ Testing records and certificate of radiation leakage (only for radioactive equipment) (2 copies)
- ③ Labels and instructions for use (Labels, instructions and dossiers must be provided in Chinese. English is not universally understood.)
- ③ Technical results

Local Clinical Trials

Local clinical trials are required for rigid gas permeable contact lens (Class II, III), Soft (hydrophilic) contact lens (Class II, III), and other categories specified by the central competent health authority (DOH's Medical Reviewing Board's requirement).

Simplified Path

US exporters supplying the USFDA's CFG (Certificate to Foreign Government) and the EC (Free Sales Certificate) type-examination certificate for Class II medical devices may be exempt from supplying 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 and number. The simplified path is also permissible for Class II devices that have been on the market for one year (grandfathered items). New Class II and Class III devices cannot utilize the simplified registration procedures

In Vitro Diagnostic Medical Device

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 treatment, slowing, or the prevention of diseases. This type of product is used in the collection, preparation, and testing of the human body.

In Taiwan, the IVD is used in

- (1) Equipment used in clinical chemistry and clinical toxicology;
- (2) Equipment used in hematology and pathology; and
- (3) Equipment used in immunology and microbiology.

The IVD Registration Requirements listed below are in addition to medical device registration requirements:

Information required in the determination of safety and effectiveness of IVD's

- USFDA's Certificate to Foreign Government
- Instruction for Use/Catalog/Label
- Quality System Documentation
- Description/Specification/Material
- Functional testing method and results
- Sterilization method and results
- Testing results for the finished product, which should include lot, model no./product name, date, employee name/number
- Sample testing

Key Contacts

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

The Department of Health

Bureau of Pharmaceutical Affairs
No. 100 Ai Kuo E. Raod, Taipei, 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
5th Division (IVD Devices)
Contact: Dr. Horng-I Yeh, Chief
e-mail: pahiyeh@dohr6.doh.gov.tw

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AIT's Commercial Section can be contacted at Tel: 886-2-2720-1550, Fax: 2757-7162. AIT's Commercial Section is also on the World Wide Web at the following address: <http://www.ait.org.tw>.

If this report has alerted you to a commercial opportunity in Taiwan, and you subsequently pursue it with successful results, please let us know. We track U.S. successes and want to know how our market reports and services are being used. The American Institute in Taiwan is a private non-profit corporation established to carry out relation between the people of the United States, and the people of Taiwan. AIT's Commercial Section includes the mission of helping the U.S. firms export their goods and services to Taiwan.

You can contact the following for more information.

Gregory Harris, Commercial Officer
Commercial Section
American Institute in Taiwan
Rm. 3207, 333 Keelung Road, 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
Rm. 3207, 333 Keelung Road, Sec. 1, Taipei, Taiwan
Tel: 886-2-2720-1550 ext/ 310
Fax: 886-2-2757-7162
E-mail: Angeli.Chou@mail.doc.gov

Registration Flow Chart

