Draft Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration

Articles
Chapter 1 General Provisions
Article 1 The present regulations are stipulated in accordance with Article 29 of the Medical Devices Act (hereinafter referred to as "the Act").
Article 2 Terms used in the present regulations shall have the following meanings: 1. The manufacture and free sale certificates of the country of origin: refers to verifying documents issued by the highest health authority or agency of the country where the imported medical device is manufactured to prove that the medical device is manufactured and can be sold freely in the country. 2. A foreign original manufacturer authorization letter: refers to an authorized agent letter issued by a foreign original manufacturer of the imported medical device. 3. In Vitro Diagnostic Device (hereafter referred to as IVD): refers to a medical device such as diagnostic reagents, instruments, software or systems used to collect, prepare, and test specimens from human body in order to diagnose disease, determine the state of health or other conditions. 4. Predicate product: refers to a medical device that has obtained domestic license or listing and meets one of the following conditions: (1) the medical device has the same intended purpose and technical characteristics as another medical device intending to apply for license or listing; (2) the medical device other than the preceding Paragraph has similar intended purpose with another medical device intending to apply for license or listing, but its technical characteristics are different; however, such differences will not affect the product's safety and efficacy.
Chapter 2 Registration and Market Approval of Medical Device and Issuance of License
Article 3 Applicants who intend to apply for license to manufacture medical devices, or registration and market approval for imported medical devices, shall prepare relevant documents and information in accordance with Articles 4 and 5, pay the fees and submit the application to the central competent authority. With the exception of medical devices that are approved for export only, applicants whose application for registration and market approval, as mentioned in the preceding Paragraph, requires testing in accordance with the provisions of the present regulations, shall follow the testing notice, pay the testing fees, and submit said medical devices to the examination process with adequate samples for examination by the designated deadline. Items required for registration and market approval referred to in Paragraph 1 are as follows: 1. Chinese and English product names;

2. Name of the medical device firm;
3. Name and address of the medical device manufacturer;
4. Efficacy, intended use, or indications;
5. Ingredients, materials, structures, specifications or model number of the medical device;
6. Labeling, instructions and packaging.
7. Other items designated for registration, as announced by the central competent authority.

Article 4 Applicants applying for registration and market approval to manufacture or import Class I medical devices shall submit documents and information as specified in Attachment 1.

The central competent authority may waive Items 5 and 6 of Paragraph 3 of the preceding Article for the aforementioned application.

Article 5 To apply for registration and market approval to manufacture or import Class II or Class III medical devices, applicants shall submit documents and information as specified in Attachments 2 and 3.

The central competent authority may waive items 5 and 6 of Paragraph 3 of Article 3 for the aforementioned of the product manufactured for export only.

Article 6 Upon receiving the applications, the central competent authority shall conduct formality examination to examine the documents and information.

In the event that the central competent authority discovers that the application documents and information are not complete, the central competent authority shall notify the applicant who shall make corrections within four months. In the event that the applicant fails to make corrections before the designated deadline, the application shall be rejected.

Article 7 Upon completing the aforementioned examination, the central competent authority shall conduct substantial examination.

In the event that the central competent authority discovers that the application documents and information are incomplete during substantial examination and corrections may be made, the central competent authority shall notify the applicant who shall make corrections within three months. In the event that the applicant fails to make corrections before the designated deadline, the application shall be rejected.

Article 8 If any of the following circumstances applies to the application, the applicant may submit relevant documents and information and apply for priority examination to the central competent authority:

1. For the purpose of preventing, diagnosing, or treating life-threatening diseases or diseases causing severe disability, with no appropriate medication, medical device or appropriate alternative treatment available yet domestically;
2. For the purpose of preventing, diagnosing, or treating rare diseases as specified in Paragraph 1 of Article 3 of The Rare Disease and Orphan Drug Act.
3. The application has received priority support or subsidy from the central competent authority or other agency and has conducted or will conduct clinical trial domestically to verify its

safety and efficacy or the medical device is responding to public health emergencies or urgent medical demand;
Article 9 In the event that any of the following circumstances matches the application upon substantial examination, the application shall not be approved: 1. The applicant has not paid the prescribed application fee; 2. The attached documents and information are incomplete, or are inconsistent with the contents of the application; 3. The applicant has failed to submit samples for testing according to the regulations, or the samples submitted for testing do not meet requirements; 4. The medical device under application is more hazardous than beneficial to human health; 5. Other circumstances that are inconsistent with laws, regulations or administrative directives.
Article 10 The central competent authority shall inform the applicant the result of the examination; If a license is granted after registration and market approval, the applicant shall, within three months after the arrival date of the notice, pay the fees for the license, and provide labels, instructions or packaging according to the approved content to the central competent authority to obtain the license. If the applicant fails to follow the preceding paragraph, or fails to obtain the license before the deadline, the central competent authority may revoke the license.
Article 11 The preliminary determination made by the central competent authority is that the product has the efficacy stated in the application; does not present any major risk; and meets one of the following circumstances, the central competent authority may ask the applicant to provide their plan to conduct safety monitoring or post-market surveillance before issuing a license with shorter validity. 1. For the purpose of preventing, diagnosing, or treating life-threatening diseases or diseases causing severe disability, with no appropriate medication, medical device or alternative treatment available yet domestically; 2. The necessity of responding to public health emergencies or urgent medical demand; 3. The product is innovative or novel, and has significant clinical benefits, and are used to improve or assist medical diagnosis and treatment. If the applicant fails to conduct safety monitoring or post-market surveillance plan according to the preceding paragraph, the central competent authority may revoke the license.
Chapter 3 Changer, and re-issuance or replacement of license.
Article 12 If any of the following circumstances applies to the content of the license, labels, instructions or packaging, the applicant shall prepare documents and information listed in Attachment 4, pay the fees and submit the application to the central competent authority. 1. Change of Chinese product name 2. Change of English product name 3. Change of the original instructions, label, or packaging.

4. Change of ingredients, materials, structures, specifications or model number. 5. Change of efficacy, intended use or indication. 6. Change of the name of the manufacturer; 7. Change of address of the manufacturer or country of origin; 8. Change of the license holder; 9. Change of the name of the license holder; To apply for replacement or re-issuance of damaged or lost licenses, or approved documents of labels, instructions or packaging, the documents and information listed in Attachment 4 shall be submitted and relevant fees paid. Application for re-issuance or replacement of license, as mentioned in the preceding Paragraph, the applicant shall, within three months after the arrival date of the notice, pay the fees for the license to the central competent authority to obtain the license. If the applicant fails to obtain the license before the deadline, the central competent authority may revoke the license. For applications referred to in Items 1 and 2, the central competent authority shall annotate changed registration items and changed date on the original license, then return the license with the stamp.
Article 13 Under any of the following circumstances, manufacturers may, of their own accord, change labels, instructions or packaging, and the relevant changes shall be documented accordingly: 1. No changes in the originally approved text: （1） Only changing the material, shape, graphic design or colors of labels, instructions or outer box and the graphic design shall not be offensive, indecent or misleading; （2） Resizing the approved graphic design or text to fit a different size of packaging, or repositioning the approved graphic design or text; （3） Changing the fonts of the approved text. However, the font size of English text may not be larger than that of Chinese text; （4） Adding printings on outer boxes or using new outer boxes to replace the labels. The design of text and graphs shall be identical to those approved; 2. Changing the text without affecting the quality or safety of the medical device: （1） Only adding or changing bar-codes, recycling marks, “GMP” before the medical device manufacturer’s name, CE marks, the suggested retail price, customer service telephone line, the manufacturer's telephone number, fax number and contact; copyright registration number or company trademark approved by Taiwan Intellectual Property Office, CNS mark or trademark registration number. （2） Adding or changing the distributor’s name or address. The font size of the distributor’s name may not be larger than that of the medical device manufacturer's (license holder's) name. （3） Adding or changing the medical device firm's name, the manufacturer’s name or address as approved by the central competent authority;

（4） Adding, deleting or changing the name of the medical device firm adding to the changed Chinese and English product name, as approved by the central competent authority;

Article 14 To apply for changes to Class I medical devices, Article 4 shall be applied mutatis mutandis for preparation of the required documents and information.

Article 15 To apply for changes to medical device manufactured exclusively for export, Article 5 shall be applied mutatis mutandis for preparation of the required documents and information.

Chapter 4 License Extension

Article 16 To apply for license extension, applicants shall file the application with the following documents and information and pay the fees to the central competent authority within six months prior to the expiration date:

1. Original license;
2. The manufacture and free sale certificate of the country of origin, unless the medical device is manufactured domestically;
3. The foreign original manufacturer authorization letter, unless the medical device is manufactured domestically;
4. Documents verifying that the medical device manufacturer has conformed with the medical device quality management system regulations;
5. If the license issued in accordance with the provisions of Paragraph 1 of Article 11, the post-approval study reports shall be submitted;
6. Other documents and information designated by the central competent authority.

Article 17 To apply for extension of license of Class I medical devices, Article 4 shall be applied mutatis mutandis for preparation of the required documents and information.

Article 18 If the license holder fails to file for extension before the expiration date in accordance with the provisions of Article 16, the license holder shall re-apply for registration and market approval for re-issuance of the license in accordance with Articles 4 and 5.

However, in the case of Class II and Class III medical devices, and the re-application is submitted within six months after the expiration date of the original license, the applicant shall prepare the following documents and information, without being subjected to the restrictions set forth in Article 5:

1. The medical device business permit;
2. The original license;
3. The original copy of the approved labels and form for attaching instruction of use stamped with tally impression of the central competent authority.
4. Drafts of the labels and instructions and both shall be attached on the forms for attaching labels and instructions.
5. The manufacture and free sale certificate of the country of origin, unless the medical device is manufactured domestically;
6. The foreign original manufacturer authorization letter, unless the medical device is

manufactured domestically;

7. Documents verifying that the medical device manufacturer has conformed with the medical device quality management system regulations;

8. Other documents and information designated by the central competent authority.

Once the application referred to in Paragraph 1 is approved, the new license will be given a new number.

Chapter 5 Listing and Annual Declaration

Article 19 To apply for listing of medical device manufacturing or imported medical devices, the applicant shall file the application on the medical device listing system (hereinafter referred to as "the System") established by the central competent authority and pay the fees to obtain the listing number:

1 Chinese and English product names;

2. Name of the medical device firm;

3. Name and address of the manufacturer;

4. Name and number of the medical device classification;

5. Sterile conditions of the medical device;

6. Circumstances explaining that the medical device manufacturer has conformed with the medical device quality management system regulations;

7. Other documents and information designated by the central competent authority.

Article 20 With the exception of changes mentioned in Paragraph 4 of the preceding Article, all other changes to the listing shall be made on the system and relevant fees shall be paid.

Changes to the name of the medical device firm mentioned in Paragraph 2 of the preceding Article shall be limited to those that do not involve transfer of rights.

The name and number of medical device classification mentioned in Paragraph 4 of the preceding Article shall not apply for changes of listing.

Article 21 Those who have been listed for one full year shall conduct annual declaration on the listing system, confirm the following items and pay the fees annually in October:

1. Chinese and English product names;

2. Name of the medical device firm;

3. Name and address of the manufacturer;

4. Name and number of the medical device classification;

5. Circumstances explaining that the medical device manufacturer has conformed with the medical device quality management system regulations;

6. Sterile conditions of the medical device;

7. Other documents and information designated by the central competent authority.

Article 22 Those who have been listed according to Paragraph 4 of Article 25 of the Act by the central competent authority shall follow the provisions of the preceding Article after the expiration date of the original license. The same applies to who have been listed by the central

competent authority for less than one year.
Chapter 6 Supplementary Provisions
Article 23 If the documents and information submitted with an application filed in accordance with this regulation are not in traditional Chinese or English, a traditional Chinese or English translation shall be additionally provided.
Article 24 If the application involves contract manufacturer, approval certificate obtained in accordance with medical device contract manufacturing operation guidelines.
Article 25 The product name of a medical device shall comply with the following regulations: 1. A product name shall not use the trademark or name of another medical device firm, unless the trademark has been awarded or authorization has been obtained. 2. A product name shall not be the same as or be similar with medical devices made by other firms, or cause confusion with medical devices made by other firms. 3. A product name shall not involve any false or exaggerated statement, or leading people in improper association with medical device and/or efficacy or causing confusion. 4. The Chinese product name shall not contain any character in any other language or in numbers, unless phrases used contain meaning directly related, or English trademarks contains special meaning and approved by the central health competent authority. 5. The Chinese and English names of medical devices exclusively for export shall not be the same as those of domestically manufactured medical devices. The precedence of medical device names that are identical or similar shall be determined on the basis of the precedence of trademarks, company names, or other identifiable names.
Article 26 This regulation shall be implemented on the date of promulgation of the Act.

Attachment 1: Documents and information required to apply for the manufacture and import Class I medical devices:

Item	Application Category	Manufacture	Import
1	Application form for Class I medical device registration and market approval	○	○
2	A photocopy of medical device business permit	○	○
3	Documents verifying that medical device manufacturers in conformity with medical device quality management system regulations	△	△
4	Instructions from the original manufacturer	△	△
5	Pre-clinical testing and the test specifications and methods, and the test reports	△	△
6	Other documents and information designated by the central competent authority	△	△

Explanation:

I. ○: Documents of the item should be submitted. △：Depending on the case. ╳: Documents of the item is not required.

II. A photocopy of medical device business permit:

(I) The Medical device manufacturer shall submit a photocopy of medical device manufacturer permit, and the medical device Importer shall submit a photocopy of the medical device dealer permit with the business item including the "Import".

(II) For a domestically commissioned manufacture, the medical device business permit of both the commissioner and the commissioned manufacturer should be submitted.

III. Documents verifying that medical device manufacturers in conformity with medical device quality management system regulations: The documents mentioned herein refer to the copy of the documents issued by the central competent authority to prove that the medical device manufacturer conforms to the Medical Devices Quality Management Systems Regulations. However, product items announced by the central competent authority shall not be required to obtain a manufacturing license, this document may be exempted.

IV. Instructions from the original manufacturer: shall including the instruction for use, function, working principle, and composition (or ingredients) of the medical device, and the contents of which shall be sufficient to identify the medical product as meeting the identification of the Class I classification.

V. Pre-clinical testing and the test specifications and methods, and the test reports: The properties/specifications of the products are stipulated in the identification of the Class I classification or in accordance with the announcement pursuant to Article 30 of the Law of the Central Competent Authority.

VI. The central competent authority may, depending on the circumstances of the case, request relevant documents and information be submitted:

(I) If the product name also bears trademark, the product shall be accompanied by the relevant information for trademark registration. If the product name also bears the name or trademark of another manufacturer, the applicant shall attach a letter of consent from the company which its name or trademark has been added.

(II) In line with the restricted import commodities and the Consolidated List of Commodities Subject to Export Restriction and Commodities Assisted by Customs for Export Examination announced by the Bureau of Foreign Trade under the Ministry of Economic Affairs, for imported medical devices with China as the origin, importer of such medical devices shall first obtain a certificate of export approval from the Bureau of Foreign Trade under the Ministry of Economic Affairs before applying for inspection and registration with the central competent authority.

Attachment 2: Documents and information required to apply for the manufacture and import Class II and Class III medical devices:

	Application category / Documents to be submitted	Class II Medical Devices		Class III Medical Devices		Same product with different product names		For export only
		Manufacture	Import	Manufacture	Import	Manufacture	Import	Manufacture
1	Application form for medical device registration and market approval	○	○	○	○	○	○	○
2	Two (2) copies of draft labels and instructions.	○	○	○	○	○	○	×
3	A photocopy of the medical device business permit	○	○	○	○	○	○	○
4	The original copy of the manufacture and free sale certificate of the country of origin.	×	△	×	△	×	○	×
5	The original copy of foreign original manufacturer authorization letter.	×	○	×	○	×	○	×
6	Documents verifying that the medical device manufacturer has conformed with medical device quality management system regulations.	○	○	○	○	×	×	○
7	Pre-clinical testing and the test specifications and methods, the original test records, and the test reports of	△	△	○	○	×	×	×

	the quality control conducted by the original manufacturer.							
8	Relevant documents concerning product structure, materials, specifications, functions, intended uses, and drawings, etc.	○	○	○	○	×	×	×
9	Clinical evidence	△	△	△	△	×	×	×
10	Radiation safety information for equipment generating ionizing radiation	△	△	△	△	×	×	×
11	Basic specifications and summary of technical documentation (STED) for the safety and efficacy of medical device	×	△	○	○	×	×	×
12	The original manufacturer's letter explaining that the product is the same product with different product names.	×	×	×	×	○	○	×
13	A photocopy of the approved labels and instructions stamped with tally impression of the central competent authority.	×	×	×	×	○	○	×
14	A photocopy of the original	×	×	×	×	○	○	×

	approved medical device license							
15	Other documents and information designated by the central competent authority.	△	△	△	△	△	△	△
16	Samples for testing	╳	╳	△	△	╳	╳	╳

Description:

I. ○: Documents of the item should be submitted. △: Depending on the case. ╳: Documents of the item is not required

II. Draft labels and instructions:
   1. Chinese instruction leaflet catalog, instructions, packaging, labeling, and draft color pictures of the physical appearance of product to be attached on the labels and outer box instruction.
   2. For those who imports medical devices, the original labels, packaging, instructions and draft detailed Chinese instructions.

III. A photocopy of the medical device business permit
   1. Those who manufacture medical devices should attach a photocopy of the firm's license as a medical device manufacturer. Those who import medical devices should attach a photocopy of the license as a medical device dealer showing that the operating items include "importing medical devices".
   2. For domestic contract manufacturing, both the hiring firm and the contract manufacturer's medical device business permit shall be submitted.

IV. Manufacture and free sale certificate of the country of origin:
   1. This document should record the following items:
      （1） The name, the specifications and model of the medical device
      （2） The manufacturer’s name, address, the circumstances of manufacture, and the certification of approval for domestic sale in that country.
   2. This document may be replaced by document issued by other authorities or other documents in accordance with the following provisions:
      （1） If the medical device is not regulated by the highest health authority in the country of the manufacturer, said document may be issued by the local health agency or an organization approved by Taiwan's central health competent authority.
      （2） If the medical device is commissioned to be manufactured, said document may be issued by the highest health authority in the country where the hiring firm or the contract manufacturer is located.
      （3） If the medical device is commissioned to be manufactured, and it is not sold in the country where the contract manufacturer is located, said document may be

replaced by a free sales certificate issued by the highest health authority in the country where the hiring firm is located, and a certificate of manufacture issued by the country where the contract manufacturer is located.

（4） Said document may be replaced by a manufacture certificate issued by the country of the manufacturer, and a free sale certificate issued by the highest health authority of the United States or EU member states.

（5） If the medical device is a completely new device with no predicate product, the on-site inspection reports provided by the central competent authority after conducting on-site inspection of foreign medical device manufacturer and medical device clinical trials reports carried out domestically shall be submitted. Manufacture and free sale certificate of the country of origin is not required.

3. This document shall remain valid for two years after the date of issuance, and shall be notarized by Taiwan's embassy or consulate, representative office, other official office, or overseas organization in that country authorized by the Ministry of Foreign Affairs (hereafter referred to as the overseas representative organization of Taiwan). A Chinese or English translation shall be attached when the verifying documents are not in English, and the translation shall also be notarized. However, certificates issued by the highest health authority of a country who has signed technical cooperation agreement for pre-market review of medical devices with Taiwan or certificates recognized by the central competent authority are exempt from notarization.

V. Foreign original factory authorization letter:

1. This document should record the following items:

1、 The original manufacturer authorizes agents in Taiwan to apply for registration and market approval, and agrees to work with agents in Taiwan to comply with relevant medical devices management regulations.

2、 Specify the name and address of the medical device manufacturer commissioned or authorized to register and the name, specification and model of the medical device.

2. This document may be replaced by other documents in accordance with the following provisions:

（1） Authorized agent letter issued by a foreign original manufacturer of the imported medical devices to authorize the agent in Taiwan to apply for registration and market approval. The content shall indicate the name and address of the manufacturer and the name and address of the commissioned or authorized medical device firm as well as the name, specification and model of the medical devices.

（2） An authorization letter issued by the original manufacturer of the imported medical device to its foreign agent, and another authorization letter issued by the foreign agent that authorizes the importer in Taiwan to register, that shall

explicitly state the name and address of the commissioned or authorized medical device firm, and the name, specifications, and model of the medical device.

3. This document shall be valid within one year from its issuance date. If the document is not written in English, a Chinese or an English version of translation of the document shall be submitted as well.

VI. Documents verifying that the medical device manufacturer has conformed with medical device quality management system regulations.

1. This document refers to a photocopy of the certification document issued by the central competent authority stating that the medical device manufacturer has conformed with the medical device quality management system regulations.
2. For firms that were originally regulated as pharmaceutical firms, the document may be replaced by photocopies of certification documents showing that the firm has conformed with the Pharmaceutical Good Manufacturing Practice Regulations within three years from the date of proclamation of listing change.

VII. Pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer:

1. This document shall include information on safety and functional testing to ensure the claimed efficacy, structure, material, design and quality of the product.
2. If predicate products have been approved by the central competent authority to be listed as Class II medical devices, the document can be replaced by one of the following documents:
   （1） Market approval documents issued by the government of a country who has signed technical cooperation agreement for pre-market review of medical devices with Taiwan and basic specifications and summary of technical documentation for the safety and efficacy of medical device.
   （2） An affidavit of pre-clinical testing document showing that the medical devices are product items announced by the central competent authority and predicate products produced by the manufacturer in the same classification and category have been approved for sale by the central competent authority.
3. For Class II medical devices listed in Attachment 3, if the same manufacturer has predicate products of the same product that has been approved for sale by the central competent authority, and the license is still valid, said document may be replaced by Class II medical device product comparison and pre-clinical testing conformity affidavit.
4. If the central competent authority has announced that the medical device requires testing, two (2) copies of this document shall be attached.
5. The commissioned laboratory responsible for biocompatibility, electrical safety, and electromagnetic compatibility (EMC) tests shall conform with any of the following:
   1、 Conforms with the provisions of ISO/ IEC 17025.

2、Conforms with the provisions of Good Laboratory Practice for Nonclinical Laboratory Studies (GLP).

VIII. The structure, materials, specifications, performance, usage, drawings and other related information of the product: For instrument products, the operation manual and maintenance manual that cover this item can be replaced.

IX. Clinical evidence:

1. This document includes academic theoretical basis, relevant research reports and information, clinical evaluation reports or clinical trial reports.
2. The central competent authority shall determine or announce whether or not the medical device applying for registration and market approval requires clinical trials in Taiwan in light of the medical device product item, the case, and the materials submitted by the applicant.
3. For medical devices with predicate products that have been approved by the central competent authority sale, unless it is necessary to verify the safety and effectiveness of the medical device with clinical evidence, this document may be exempted.
4. For Class II medical devices without predicate products, unless otherwise specified, the clinical trial report may be replaced with supporting data that meets all the following conditions:
   （1） There is no ethnic difference in the expected efficacy of this product.
   （2） There is no report of undesirable effect related to the claimed intended use or indications of such products in foreign countries and the products have not been required to be removed.
   （3） Pre-clinical data (including trial) can be used to verify that the difference between the product and products that have been approved to be sold domestically will not affect said product's safety and effectiveness; or provide market approval certification document showing that the product can be sold in the United States and the European Union and the applied indications do not exceed the scope approved by both the United States and the European Union.

X. Radiation safety information for equipment generating ionizing radiation: Medical devices generating ionizing radiation shall submit this document.

XI. Basic specifications and summary of technical documentation for the safety and efficacy of medical device:

1. The format of this document shall be handled in accordance with the announcement of the central competent authority.
2. If Class II medical device applied for is in the description VII.2.(1) situation, this document shall be attached.

XII. An explanatory letter from the original manufacturer explaining that the product is the same product with different names: The letter shall explain the product for which a new application has been made and the originally-approved product are identical, and noting the license number of the originally-approved medical device license.

XIII. Other documents and information designated by the central competent authority.

1. For medical devices using bovine or ovine/hircine tissues, an explanation of animal raw material source control procedures and proof of raw material source from the original manufacturer shall be submitted in order to verify that the processes associated with the medical device and the ultimate finished product do not use any bovine or ovine/hircine product from the bovine spongiform encephalopathy (BSE) epidemic areas announced by the Council of Agriculture, Executive Yuan, and have not been contaminated by BSE pathogens. However, for the applications conforming to the announcement from the central health competent authority regarding the exemption from submitting the documentation in the preceding paragraph after considering the international regulatory guidelines for controlling bovine or ovine/hircine tissues in accordance with the risk of contamination of the tissues by BSE pathogen, this provision shall not apply.
2. If the product name bears the trademark, the applicant shall attach relevant materials related to trademark registration. If the product name bears the names or trademarks of another medical device firm, a consent letter issued by the medical device firm shall be attached.
3. To comply with the consolidated list of commodities subject to import restriction and commodities assisted by customs for import examination announced by the Bureau of International Trade of the Ministry of Economic Affairs, medical devices imported from China shall first obtain permit for import from the Bureau of International Trade of the Ministry of Economic Affairs before submitting to the central competent authority registration and market approval.
4. For medical devices made for export only, the instructions, function, working principle, product composition (or ingredients) of the medical device should be attached, and the content should be sufficient to determine that the product meets the identification of the application item.

XIV. Samples for testing: The applicant shall, in accordance with the testing notice, pay the testing fee by the designated deadline, and submit said medical devices to the examination process with adequate samples for examination.

Attachment 3: Applicable classifications of Class II Medical Devices Comparison and Preclinical Test Data Conformity Statement

	Item Code	Name
1	A.1020	Acid phosphatase (total or prostatic) test system
2	A.1025	Adrenocorticotropic hormone (ACTH) test system
3	A.1035	Albumin test system
4	A.1050	Alkaline phosphatase or isoenzymes test system
5	A.1070	Amylase test system
6	A.1110	Bilirubin (total or direct) test system
7	A.1150	Calibrator
8	A.1345	Glucose test system
9	A.1660	Quality control material (assayed and un-assayed)
10	C.5510	Immunoglobulins A, G, M, D, and E immunological test system
11	D.5630	Nebulizer
12	E.1130	Noninvasive blood pressure measurement system
13	E.2340	Electrocardiograph
14	E.2700	Oximeter
15	F.3200	Resin tooth bonding agent
16	F.3590	Preformed plastic denture tooth
17	F.3660	Impression material
18	F.4850	Ultrasonic scaler
19	F.6070	Ultraviolet activator for polymerization
20	F.6660	Porcelain powder for clinical use
21	H.5470	Ureteral dilator
22	I.0006	Medical protective clothing
23	I.4370	Surgical drape and drape accessories
24	I.4495	Stainless steel suture
25	I.4580	Surgical lamp
26	J.2800	Sterilization process indicator
27	J.2910	Clinical electronic thermometer
28	J.5440	Intravascular administration set
29	J.5570	Hypodermic single lumen needle
30	J.5860	Piston syringe
31	J.6850	Sterilization wrap
32	M.5918	Rigid gas permeable contact lens care products
33	M.5928	Soft (hydrophilic) contact lens care products
34	O.5500	Infrared lamp

Attachment 4: Documents and information required to apply for change, transfer, and re-issuance or replacement of licenses

Item to be changed / Item		Change of Chinese product name	Change of English product name	Change of the original instructions, labels, and packaging	Change of the ingredients, materials, structures, specifications or model number;	Change of efficacy, intended use, or indications;	Change of the name of the manufacturer;	Change of the address of the manufacturer or country of origin	Change of the license holder	Change of the name of the license holder	Re-issuance or replacement of a lost or damaged license
1	Application form for change in medical device license	○	○	○	○	○	○	○	○ Note 8	○	○
2	Application form for medical device registration and market approval	╳	╳	╳	╳	╳	╳	╳	╳	╳	△ Note 12
3	Original copy of the license.	○	○	○	○	○	○	○	○	○	△ Note 13
4	Original copy of the approved labels and instructions stamped with tally impression of the central competent authority.	╳	╳	○	△ Note 2	○	╳	╳	╳	╳	△ Note 14
5	Two (2) copies of draft labels and instructions.	╳	╳	○	△ Note 3	○	╳	╳	╳	╳	△ Note 15
6	A photocopy of medical device business permit.	╳	╳	╳	╳	╳	△ Note 5	△ Note 5	○ Note 9	○ Note 11	╳
7	The original copy of the manufacture and free sale certificate of the country of origin.	╳	△ Note 1	╳	△ Note 4	△ Note 4	△ Note 4	△ Note 6	╳	╳	╳

8	The original copy of foreign original manufacturer authorization letter.	╳	╳	╳	△ Note 4	△ Note 4	△ Note 4	△ Note 4	△ Note 10	╳	╳
9	Documents verifying that the medical device manufacturer has conformed with medical device quality management system guidelines.	╳	╳	╳	╳	╳	○	○	╳	╳	╳
10	Pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer.	╳	╳	╳	△ Note 3	○	╳	△ Note 7	╳	╳	╳
11	Relevant documents concerning product structure, materials, specifications, functions, intended uses, and drawings, etc.	╳	╳	╳	△Note 3	△	╳	△ Note 7	╳	╳	╳
12	Clinical evidence	╳	╳	╳	△ Note 3	△	╳	╳	╳	╳	╳
13	Radiation safety information for equipment generating ionizing radiation	╳	╳	╳	╳ Note 3	╳	╳	╳	╳	╳	╳

14	Original manufacturer's covering letter that explains the change	×	○	○	∆Note 3	○	○	○	×	×	×
15	A comparison table of the change and the original approved content.	×	×	○	∆Note 3	○	×	×	×	×	×
16	Assignment contract jointly issued by the assignor and the assignee.	×	×	×	×	×	×	×	○	×	×
17	An affidavit from the medical device firm receiving agency rights (assignee) affirming responsible for the transferred medical device.	×	×	×	×	×	×	×	○	×	×
18	One affidavit from the medical device firm after name change affirming responsible for every item on the changed license.	×	×	×	×	×	×	×	×	○	×
19	One affidavit that claims no assignment of rights involved in this application for change in name of the medical device firm.	×	×	×	×	×	×	×	×	○	×

20	Other documents and information designated by the central competent authority.	△	△	△	△	△	△	△	△	△	△ Note 16
21	Samples for testing	╳	╳	╳	△	╳	╳	△	╳	╳	╳

Description:

I. ○: Documents of the item should be submitted. △: Depending on the case. ╳: Documents of the item is not required

II. See description of Attachment 2 for regulations with regards to draft labels and instructions, photocopy of medical device business permit, the manufacture and free sale certificate of the country of origin, foreign original manufacturer authorization letter, documents verifying that the medical device manufacturer has conformed with medical device quality management system guidelines, pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer, relevant documents concerning product structure, materials, specifications, functions, intended uses, and drawings, etc., clinical evidence, radiation safety information for equipment generating ionizing radiation, other documents designated by the central competent authority, and relevant regulations regarding samples for testing.

Note:

1. The manufacture and free sale certificate of the country of origin shall indicate the changed product and the already approved product are in fact the same, unless the medical device is manufactured domestically.
2. This does not apply if the change of specification does not involve the originally approved instructions, labels or packaging.
3. This does not apply if the change involves deletion of specifications.
4. This does not apply for medical device manufactured domestically. This does not apply if the change involves deletion of specifications.
5. Domestic medical device firm shall attache a photocopy of the new firm's license as a medical device manufacturer. This does not apply if the firm only imports medical devices.
6. This does not apply for medical devices manufactured domestically. If change of the manufacturing factory address was due to house-numbering system change, this document may be exempted, but a certificate issued by government shall be submitted; in the case of imported medical devices, the certificate shall be notarized by R.O.C (Taiwan) foreign affairs office.
7. If necessary, the central competent authority may order submission of technical documentation such as relevant documents concerning product structure, materials, specifications, performance, intended use, drawing and others, and documents of pre-clinical testing, and the test results of quality control of the original manufacturer. If the application for change involves a Class III IVD, this information shall be attached. If the central competent authority has announced that the medical device requires testing, two (2) copies of this information shall be attached. The applicant shall, in accordance with the testing notice, pay the testing fee by the designated deadline, and submit said medical devices to the examination process with adequate samples for examination.
8. Application for change of license holder shall be applied by the transferor and the transferee jointly.
9. A photocopy of the transferee's license as a medical device dealer.
10. The foreign original manufacturer authorization letter shall explain in detail about termination of the rights of the transferor, and bestowing of such rights to the transferee, and shall state the product name and the names and addresses of assignor and assignee. This does not apply for medical device manufactured domestically.
11. Photocopy of the transferee's license as a medical device dealer after the name change.
12. This information shall be attached when applying for re-issuance or replacement of a lost or damaged medical device license. This does not apply when applying for re-issuance or replacement of lost or damaged instructions, labels and packaging.
13. This does not apply when applying for re-issuance of a lost license.
14. This information shall be attached when applying for re-issuance or replacement of lost or damaged instructions, labels and packaging. This does not apply when applying for re-issuance or replacement of a lost or damaged license, instructions, labels and packaging.
15. This information shall be attached when applying for re-issuance or replacement of lost or damaged instructions, labels and packaging. This does not apply when applying for re-issuance of a lost or damaged license.
16. When applying for re-issuance of a lost license, an affidavit stating that the original license indeed being lost must be attached. When applying for re-issuance or replacement of lost or

damaged instructions, labels and packaging, an affidavit stating that the original instructions, labels and packaging indeed being lost must be attached.