Enforcement Regulations of the Medical Device Act

[Ministerial Decree Number18 of the Ministry of Health and Welfare, Effective as of September 1, 2010, and Amendment of Other Laws]

Article 1 (Purpose) These Enforcement Regulations are to stipulate the matters delegated by the 「Medical Device Act」 and the Enforcement Decree of the Act, and any necessary matters concerning the enforcement. <Amended on July 27, 2006>

Article 2 (Classification & Designation Etc.) The criteria and procedure for classification and designation of medical devices under Paragraph 2 of Article 3 of the 「Medical Device Act」 (hereinafter referred to as the "Act") shall be as shown in Attached Table 1. <Amended on July 27, 2006>

Article 3 (Application for Manufacturing Business License) ① A person that intends to obtain a manufacturing business license in respect of medical devices pursuant to Paragraph 1 of Article 6 of the Act shall submit an application form as per Attached Form No. 1 (including an application in an electronic form) together with the documents for the following items (including electronic documents) to the Commissioner of the Korea Food and Drug Administration (hereafter the "KFDA Commissioner"). In this case, the KFDA Commissioner shall check the commercial registry certificates (only for a corporation) through the joint use of administrative information under Paragraph 1 of Article 36 of the 「Electronic- Government Act」. <Amended on May 29, 2009 and September 1, 2010 respectively>.

1. A medical certificate from a physician proving that the applicant does not fall under the main body of Item 1, Paragraph 6, Article 6 of the Act, or if the person falls under the proviso of the provision, a medical certificate from a medical specialist capable of proving it, which shall be not more than 6 months old from the issue date (these documents are not required from a corporation); and
2. A medical certificate from a medical specialist proving that the applicant does not fall under Item 3, Paragraph 6, Article 6 of the Act, which shall not be more than 6 months old from the issue date (this document is not required from a corporation)

② If the for business license under Paragraph 1 satisfies the criteria therefor, the KFDA Commissioner shall issue a license as per Attached Form No. 2 to the applicant and describe the following matters in the manufacturing business license register:

1. License number and date of license;
2. Name and the resident registration number of the manufacturer (In case of a corporation, name and the resident registration number of the representative of such corporation); and
3. Name and address of the manufacturing site.

Article 4(Subject of Product Manufacture License and Product Manufacture Notification) ① Medical devices requiring a product manufacture license under Paragraph 2 of Article 6 of the Act shall be as follows:

1. Products of class 2 or 3, or 4 designated under Article 2; and
2. Products whose structure, principle, performance, purpose of use, or instructions for use are not essentially equivalent to those of the products that have already been approved or notified, among the products of class 1 designated under Article 2.

② Medical devices requiring a product manufacture notification under Paragraph 2 of Article 6 of the Act shall be those whose structure, principle, performance, purpose of use, or instructions

for use are not essentially equivalent to those of the products that have already been approved or notified, among the products of class 1 designated under Article 2.

Article 5 (Procedure of product manufacture license and product manufacture notification) ① A person that intends to obtain product manufacture license in respect of medical devices under Paragraph 2 of Article 6 of the Act shall submit an application as per Attached Form No.3 (including an application form in an electronic form) to the KFDA Commissioner, together with the documents for the following items(including electronic documents): <Amended on July 27, 2006 and May 29, 2009 respectively>

1. Technical documents and data concerning safety and efficacy, or results of review of technical documentation etc. under Paragraph 3 of Article 7, which shall not be more than 2 years old from the issue date;
2. In case of entrustment of all manufacturing processes, document proving that the person entrusted is a person capable of being entrusted with all the manufacturing processes under Item 3-A of Attached Table 2; and
3. A copy of an application submitted to the head of the medical device quality management review agency under Item 7-A of the Attached Table 3, or a copy of a quality management compliance certificate.

② If it is deemed that the product for which an for product manufacture license under Paragraph 1 has been filed meets the criteria, the KFDA Commissioner shall issue a product manufacture license as per Attached Form No.4 to the applicant and describe the following matters in the product license register:

1. License number and date of license; and
2. Name of the product (product name and model name).

③ A person that intends to file a product manufacture notification in respect of a medical device under Paragraph 2 of Article 6 of the Act shall attach documents (including electronic documents) under Items 2 and 3 of Paragraph 1 to a notification form as per Attached Form No. 5 (including a notification in an electronic form) and submit such documents and notification form to the head of local food and drug administration having jurisdiction over the location of the manufacturing site; provided, however, that such documents and notification form shall be submitted to the KFDA Commissioner if an manufacturing business license and a product manufacture notification are filed simultaneously pursuant to Paragraph 3 of Article 6 of the Act. <Amended on July 27, 2006 and May 29, 2009 respectively>

④ If the KFDA Commissioner or the head of local food and drug administration accepted the product manufacture notification under Paragraph 3, they shall issue a certificate of notification as per Attached Form Number6 to the applicant and describe the following matters in the product notification register.

1. Notification acceptance number and date of acceptance; and
2. Name of product (product name and model name).

⑤ Details concerning (i) the methods for the preparation of attached documents necessary for filing an for manufacturing business license in respect of medical devices under Article 3 and the preparation of attached documents necessary for filing an for product manufacture license and a product manufacture notification under requirements for each of such documents, and (iii) scope of or exemption, etc., shall be specified and published by the KFDA Commissioner.

Article 6 (Standards for Manufacturing Facilities and Quality Management System) The standards

for manufacturing facilities and quality management system which shall be satisfied by a person that intends to obtain a product manufacture license or file a product manufacture notification under Paragraph 4 of Article 6 of the Act shall be as shown in Attached Table 2.

Article 7 (Review of Technical Documents, Etc.) ① A person that intends to obtain a product manufacture license may have a prior review conducted by the KFDA Commissioner with respect to the suitability of technical documents and clinical data to be submitted pursuant to Paragraph 5 of Article 6 of the Act; provided, however, that in the case of products specified by the KFDA Commissioner as medical devices whose structure, principle, performance, purpose of use, and instructions for use are essentially equivalent to those of the products that have already been approved or notified, a simplified review may be conducted by the review agency designated by the KFDA Commissioner (hereafter "Technical Document Review Agency").

② A person that intends to have a review conducted of technical documents, etc. under Paragraph 1 shall submit the following data (including data in an electronic form), together with a review request form as per Attached Form No. 7 (including a review request form in an electronic form) and the products for which such review is desired (only when deemed necessary by the KFDA Commissioner)submit, to the KFDA Commissioner (or the head of the Technical Documentation Review Agency in case of the proviso of Paragraph 1). <Amended on July 27, 2006 and May 29, 2009, respectively>

1. Data on technical documents
   A. Data on purpose of use
   B. Data on physical and chemical characteristics
   C. Data on electrical and mechanical safety
   D. Data on biological safety
   E. Safety data concerning radiation
   F. Data concerning electro-magnetic interference
   G. Data concerning product performance
   H. Data concerning test specifications to confirm performance and safety of the product, the grounds for setting such specifications, and the actually measured values.
2. Data concerning safety and efficacy; provided, however, that such data may be omitted in case of products whose structure, principle, performance, purpose of use, and instructions for use are essentially identical to those of the products that have already been approved.
   A. Data on the origin or discovery and background for development
   B. Data concerning safety
   C. Data concerning clinical s
   D. Data concerning usage status in foreign countries, etc.
   E. Data cross-checked with similar domestic products, as well as data concerning characteristics of the medical device concerned.

③ The KFDA Commissioner or the Head of the Technical Document Review Agency, who was asked to conduct review under Paragraph 2 shall notify the applicant of the result of review in accordance as per Attached Form No.8.

④ Details concerning the methods for preparation of attached documents necessary for review of technical documents, etc., requirements for each data, the procedure and scope of exemption, scope and criteria for review, etc. shall be specified and published by the KFDA Commissioner <Amended on May 29, 2009>.

Article 8 (Application for Conditional Approval, Etc.) ① A person that intends to obtain a

conditional manufacturing business license under Paragraph 1 of Article 7 of the Act shall submit the following documents(including electronic documents), together with an application form (including an application in an electronic form) as per Attached Form Number1, to the KFDA Commissioner. In this case, the KFDA Commissioner shall check the commercial registry certificates (only for a corporation), a certified copy of land register or a certified copy of building register through the joint use of administrative information under Paragraph 1 of Article 36 of the 「Electronic-Government Act」. <Revised on July 27, 2006 and May 29, 2009 and September 1, 2010 respectively>

1. Documents which can prove ownership of the site or a copy of lease agreement (in case that it can be confirmed from a certified copy of land register, such confirmation shall substitute for such documents), if a building is constructed to set up manufacturing facilities;
2. Documents which can prove ownership of the building or a copy of lease agreement (in case that it can be confirmed from a certified copy of building register, such confirmation shall substitute for such documents), if manufacturing facilities are established in an existing building; and
3. Documents specified in each item of Paragraph 1 of Article 3

② A person that intends to obtain a conditional product manufacture license under Paragraph 1 of Article 7 of the Act shall submit an application as per Attached Form No.3 (including an application form in an electronic form) accompanied by the documents (including electronic documents) under Item 1 of Paragraph 1 of Article 5, and a person that intends to file a conditional product manufacture notification shall submit a notification form (including a notification in an electronic form) as per Attached Form No. 5, to the KFDA Commissioner or head of local food and drug administration having jurisdiction over the manufacturing site; provided, however, that they shall be submitted to the KFDA Commissioner if an for conditional manufacturing business license and a conditional product manufacture notification are filed simultaneously. <Revised on May 29, 2009>

③ If The KFDA Commissioner or the head of local food and drug administration grants a conditional manufacturing business license or a conditional product manufacture license or accepts a conditional product manufacture notification, they shall describe the matters specified in Paragraph 2 of Article 3, Paragraph 2 of Article 5 or Paragraph 4 of Article 5, as well as conditions of such license or notification, in the manufacturing business license register, the product manufacture license register, or the product manufacture notification register, and shall issue a conditional manufacturing business license as per Attached Form No. 9, a conditional product manufacture license as per Attached Form No. 10, or a conditional product manufacture notification as per Attached Form No. 11.

Article 9 (Report and Verification of Performance of Conditions) ① If a person that was granted a conditional license or filed a conditional notification under Article 8 performed the conditions of such license or notification, the fact shall be reported to the KFDA Commissioner or the head of local food and drug administration having jurisdiction over the manufacturer site. <Amended on May 29, 2009>

② If the KFDA Commissioner or the head of local food and drug administration was notified of the performance of the conditions pursuant to Paragraph 1, they shall verify whether the conditions have been performed, within 20 days from the date of notification, and then change the provisional manufacturing business license, the provisional product manufacture license, or the provisional product manufacture notification under Paragraph 3 of Article 8 into the manufacturing business license under Paragraph 2 of Article 3, the product manufacture license

under Paragraph 2 of Article 5, or the product manufacture notification under Paragraph 4, which shall be issued.

Article 10 (Application for Re-examination Etc.) ① If the KFDA Commissioner orders, when granting a product manufacture license, re-examination pursuant to Paragraph 1 of Article 8 of the Act, the KFDA Commissioner shall mention a period for such re-examination.

② A person that applies for re-examination under Paragraph 2 of Article 8 of the Act shall submit the application as per Attached Form No. 12 (including an application form in an electronic form) within the period of application for re-examination under Paragraph 1, to the KFDA Commissioner, together with the following attached documents (including data in electronic form); <Amended on July 27, 2006>

1. Data concerning investigation of product safety and efficacy after the sale of the products in Korea;
2. Domestic and foreign data concerning any side effects and safety; and
3. Data concerning domestic and foreign sales status and product approvals abroad.

③ If the KFDA Commissioner receives an application for re-examination under Paragraph 2, he or she shall carry out re-examination of the product through review by the Medical Device Committee (hereafter "Medical Device Committee") under Paragraph 1 of Article 5 of the Act within 6 months from the date of application, and notify the result to the applicant in accordance as per Attached Form No. 13.

④ The manufacturer, which has been notified of the result of re-examination under Paragraph 3, shall take an action according to the result of re-examination within 30 days from the date of notice.

⑤ Detailed methods for preparation of attached documents, requirements for each data, scope of exemption, scope and criteria for review, etc., to the extent that they are required for application for re-examination, shall be specified and published by the KFDA Commissioner.

Article 11 (Method and Procedure of Re-evaluation Etc.) ① When re-evaluation of a medical device is intended under Article 9 of the Act, the KFDA Commissioner shall decide on the products subject to re-evaluation through review by the Medical Device Committee, and publish the followings:

1. Products subject to re-evaluation;
2. Period of application for re-evaluation; and
3. Content of submitted documents for re-evaluation

② The manufacturer of a medical device subject to re-evaluation shall submit an application for re-evaluation of medical device as per Attached Form No. Number14 (including an application in an electronic form) to the KFDA Commissioner, together with the attached documents under Item 3 of Paragraph 1 (including documents in an electronic form). <Amended on July 27, 2006>

③ If The KFDA Commissioner receives an application for re-evaluation under Paragraph 2, he or she shall perform re-evaluation of the product and publish the results of such re-evaluation after making available, for inspection by the draft of the re-evaluation results for one (1) month or more to enable such submit its opinion (if any).

④ Detailed methods for preparation of documents to be submitted under , requirements for each

of such documents, scope of exemption, scope and criteria for re-evaluation, etc. shall be specified and published by the KFDA Commissioner.

Article 12 (Approval of clinical trial Plan, Etc.) ① A person that intends to obtain approval of clinical trial plan pursuant to Paragraph 1 of Article 10 of the Act shall submit an application for approval of clinical trial plan (including an application in an electronic form) as per Attached Form No. 15 to the KFDA Commissioner, and a person that intends to obtain approval of amended clinical trial plan shall submit an application for approval of amended clinical trial plan (including an application in an electronic form) as per Attached Form No. 16 Form to the KFDA Commissioner, together with, in each case, the approval letter for clinical trial plan and the documents mentioned in the following items (including documents in an electronic form); provided, however, that in case of an application for approval of amended clinical trial plan, part or all of the documents mentioned in Items 2 though 4 of this Paragraph may not be submitted as specified and published by the KFDA Commissioner. <Amended on July 27, 2006>

1. Clinical trial plan or amended clinical trial plan;
2. Documents demonstrating that the medical device for clinical trial is manufactured in the facilities which comply with the facility standards for manufacturing sites under Attached Table 2;
3. Technical documents, etc. under Paragraph 2 of Article 7; and
4. Approval letter issued by institutions conducting clinical investigation (“clinical trial institution).

② Matters that are required to be included in the clinical trial plan under Item 1 of Paragraph 1 shall be as follows:

1. Title of a clinical trial;
2. Name and location of the clinical trial institution;
3. Names and titles of the principal investigator, investigators, and co-researchers of a clinical trial;
4. Name and title of the person in charge of managing medical devices for clinical trial;
5. Name and address of the person requesting the clinical trial;
6. Purpose and background of a clinical trial;
7. Purpose of use of the medical device for clinical trial (including the intended diseases or indications);
8. Selection criteria and exclusion criteria for subjects, the number of subjects and the grounds therefor;
9. Period of a clinical trial;
10. Method of a clinical trial(including use quantity, instructions for use, period of use, and combined therapy);
11. items that shall be observed, items that shall be tested in clinical laboratory, and method of observation ;
12. Expected adverse side effects and cautions for use;
13. Criteria for discontinuation and elimination;
14. Performance evaluation criteria, evaluation method, and analytical method(by statistical method);
15. Criteria and method for safety evaluation including adverse side effects, and reporting method;
16. Consent form from the subjects;
17. Agreement for compensation for victims;
18. Matters concerning medical treatment of subjects after a clinical trial;
19. Measures for safety protection of subjects; and

20. Other necessary matters to safely and scientifically conduct a clinical trial

③ If KFDA Commissioner examines an for approval of a clinical trial plan submitted pursuant to Paragraph 1 and determines that the is appropriate, the KFDA Commissioner shall issue an approval letter for clinical trial plan as per Attached Form No.17 to the applicant, and if the KFDA Commissioner approves the amended clinical trial plan, details of such amendment shall be described in the amendment and disposition portion of the written approval letter.

④ Detailed methods for preparation of submitted documents, scope of exempted data, requirements, criteria, and procedures, etc. at the time of applying for approval of clinical trial plan or for approval of amended clinical trial plan under Paragraphs 1 through 3 shall be specified and published by the KFDA Commissioner.

Article 13 (Standards for Clinical Trials, Etc.) ① The standards for clinical trials under Paragraph 7 of Article 10 of the Act shall be as follows:

1. The clinical trial shall be conducted in a safe and scientific manner the clinical trial plan;
2. The clinical trial shall be conducted in a clinical trial institution designated by the KFDA Commissioner;
3. The principal investigator shall be selected among those who have expertise, ethical qualities, and sufficient experience for conducting clinical trial for the relevant medical device;
4. Details of the clinical trial and compensation for damage to the health which may be suffered by the subject during the clinical trial, and the procedure for such compensation, shall be explained to the subject, and a consent form shall be obtained from the subject in the manner specified by the KFDA Commissioner; provided, however, that if consent cannot be obtained due to insufficiency of the subject's ability to understand such explanation or express opinion, consent from a person with parental right over the subject or from the guardian of the subject shall be obtained;
5. Safety measures for the subject shall be taken;
6. The medical device for clinical trial shall not be used for any purposes other than clinical trials, with the exception of use for patients with serious life-threatening diseases such as cancer in terminal stage, etc., except in cases specified by the KFDA Commissioner;
7. A clinical trial shall be initiated within two (2) years from the date when an approval of clinical trial plan or an approval of amended clinical trial plan is obtained;
8. Prior to conducting clinical trial, the investigator's Brochure shall be provided to the clinical investigator in the manner specified by the KFDA Commissioner;
9. When new data or information related to safety and performance of a medical device for clinical trial is obtained, it shall be notified to the investigator without delay, and shall be examined as to whether it would be reflected or not;
10. The medical device for clinical trial for a clinical trial shall be properly manufactured under the standards for manufacturing and quality management of medical devices under Attached Table 3; and
11. Other matters specified by the KFDA Commissioner for proper operation of a clinical trial shall be observed;

② A person who conducts a clinical trial shall submit a report as per Attached Form No. 18 (including a report in an electronic form) on the progress of the clinical trial to the KFDA Commissioner by the end of February every year, and when the clinical trial is terminated, shall submit a report as per Attached Form No. 19 Form (including a report in an electronic form) to the KFDA Commissioner within 20 days from the date of termination. <Amended on July 27, 2006>

③ A person who terminated a clinical trial shall keep the clinical trial plan and records and data concerning operation of the clinical trial for ten (10) years from the date of termination.

④ Detailed standards for the conduct of clinical trials under Paragraph 1 and detailed matters on the criteria for designation of clinical trial shall be specified and published by the KFDA Commissioner.

Article 14 (Application for Amended License, Etc.) ① If there is any change in the granted manufacturing business license, the Paragraph 1 of Article 11 of the Act, submit an for obtaining an amended license (including an application in an electronic form) as per Attached Form No. 20 to the KFDA Commissioner, within 30 days from the date when such amendment occurred, together with the manufacturing business license and the documents set forth in the following items (including documents in an electronic form): <Amended on July 27, 2006>

1. Deleted <July 3, 2006>
2. Change of location: A copy of itemized statement for facilities in the relevant and a copy of entrustment agreement (only to the extent that part of the manufacturing process or testing has been entrusted).

② The KFDA Commissioner who received an application under Paragraph 1 shall check the business registration certificate or the commercial registry certificates (only for a corporation) through the joint use of administrative information under Paragraph 1 of Article 36 of the 「Electronic-Government Act」; provided, however, that if the applicant does not agree that the business registration certificate is checked, such government official shall cause the document to be attached. <Newly added on July 3, 2006 and May 29, 2009 and September 1, 2010 respectively>

③ If there is any change in the granted product manufacture license or a change in the filed product manufacture notification, the Paragraph 1 of Article 11 of the Act, submit an for obtaining an amended license as per Attached Form No. 21 (including an application in an electronic form) or a notification form as per Attached Form No. 5 (including an application in an electronic form), together with the (existing) product manufacture license or the (existing) notification acceptance letter and documents confirming the change (including electronic documents), to (i) (in the case of the for obtaining an amended license) the KFDA Commissioner and (ii) (in the case of an amended notification) the head of local food and drug administration having jurisdiction over the manufacturing site. In this case, if there is any major change that may influence safety or efficacy of the product such as design, material, chemical components, energy source, manufacturing process, etc. of the medical device, technical documents etc. under Item 1, Paragraph 1, Article 5 shall be additionally submitted as attachment. <Amended on July 3, 2006 and May 29, 2009 respectively>

④ If a change under Paragraph 3 is a minor one specified and published by the KFDA Commissioner, such as a change in appearance, packing material, packing unit, etc. of the product, a document describing such change (including an electronic document) shall, notwithstanding Paragraph 3 above, be submitted to the KFDA Commissioner or the head of local food and drug administration having jurisdiction over the manufacturing site. In this case, an amended license under Article 11 of the Act shall be deemed to have been obtained or an amended notification under Article 11 of the Act shall be deemed to have been filed. <Newly added on July 27, 2006 and April 2, 2007 and May 29, 2009 respectively>

⑤ If a person to whom the manufacturing facilities, manufacturing method, etc. have been transferred by spin-off or merger intends to obtain an amended product manufacture license or file an amended product manufacture notification pursuant to Paragraph 3, such person shall submit the relevant transfer agreement on manufacturing facilities, manufacturing method, etc. for the product as an attached document to the KFDA Commissioner. In this case, the conditions equivalent to those attached to the product manufacture license of the transferor may be attached with respect to the amended product manufacture license (of the transferee). <Amended on July 3, 2006, July 27, 2006>

⑥ If the KFDA Commissioner has given a the directions to amend the license or notification according to the result of re-evaluation of medical devices under Paragraph 3 of Article 11 and the manufacturer amended the license or notification subsequently, an amended license under Article 11 of the Act shall be deemed to have been obtained or an amended notification under Article 11 of the Act shall be deemed to have been filed. <Amended on July 3, 2006 and July 27, 2006 respectively>

⑦ In the event that the KFDA Commissioner grants an amended license or accepts an amended notification pursuant to Paragraphs 1 through 6, details of such amendment shall be described in the relevant register and the relevant license or notification acceptance letter. <Amended on July 3, 2006, July 27, 2006>

Article 15 (Observances of Manufacturer, Etc.) ① Matters that are required to be observed by the medical device manufacturer pursuant to Paragraph 1 of Article 12 of the Act shall be as follows:

1. The manufacturer shall hygienically control the manufacturing facilities and thoroughly check the health condition of employees to ensure that there are no health or sanitation risks;
2. The manufacturer shall not place anything that may cause risk in the working place, and make sure that harmful substance to public health is not released or leaked from the working place;
3. If the medical device sold impairs safety and efficacy or their quality is poor, the manufacturer shall take a corrective action such as recall etc., and report the result to the KFDA Commissioner; provided, however, that the records shall be kept for more than two (2) years;
4. In case of a sterile product, a new container shall be used;
5. If new data or information(including the cases of adverse side effects by use of the medical device) for the approved or notified products is known to the manufacturer, the manufacturer shall report it in the manner specified by the KFDA Commissioner and take necessary safety measures; and
6. The manufacturer shall observe the standards for manufacturing and quality management of medical devices under Attached Table 3, and sell the medical devices which have been proven to meet these standards.

② Pursuant to Paragraph 2 of Article 12 of the Act, the manufacturer shall report the amount of production and export of the previous year to the KFDA Commissioner by April 15 every year in the manner specified and published by the KFDA Commissioner.

Article 16 (Notification of Closure of Business, Etc.) ① If the manufacturer is to notify a closure or suspension of business under Article 13 of the Act, the manufacturer shall submit a notification as per Attached Form No. 2 (including document in an electronic form), together with the documents for the following items, to the KFDA Commissioner, and the manufacturer

desiring to file a notification of resumption of business shall submit a notification as per Attached Form No. 22 (including a notification in an electronic form) to the KFDA Commissioner. <Amended on July 27, 2006>

1. In case of closure of business: the manufacturing business license, all product manufacture licenses, and all product manufacture notification acceptance letters; and
2. In case of suspension of business: the manufacturing business license.

② If the KFDA Commissioner receives notification for closure of business under Paragraph 1, the KFDA Commissioner shall describe the details in the manufacturing business license register, and if the KFDA Commissioner receives a notification of closure or resumption of business, the KFDA Commissioner shall describe the details in the manufacturing business license register and the manufacturing business license.

Article 17 (Application for Import Business License Etc.) ① A person that intends to obtain import business license pursuant to Paragraph 1 of Article 14 of the Act shall submit an application as per Attached Form No. 1 (including an application in an electronic form) to the KFDA Commissioner, together with the documents described in Paragraph 1 of Article 3 (including electronic documents) <Amended on May 29, 2009>

② The KFDA Commissioner who received an application pursuant to Paragraph 1 shall check the commercial registry certificates (only for corporations) through the joint use of administrative information under to Paragraph 1 of Article 36 of the 「Electronic Government Act」. <Newly added on July 3, 2006 and May 29, 2009 and September 1, 2010 respectively>

③ With respect to the procedure, etc. for obtaining an import business license, the provisions of Paragraph 2 of Article 3 shall apply *mutatis mutandis*.In this case, “Manufacturing” shall be regarded as “Import”, and “Manufacturer” as “Importer”. <Amend ed on July 3, 2006 and May 29, 2009 respectively>

Article 18 (Application for Product Import License, Etc.) ① A person who intends to obtain product import license pursuant to Paragraph 2 of Article 14 of the Act shall submit an application as per Attached Form No. 3 (including an application in an electronic form) together with the documents for the following items (including electronic documents) to the KFDA Commissioner. <Amended on July 27, 2006 and May 29, 2009 respectively>

1. Documents under Item 1, Paragraph 1, Article 5; provided, however, that such documents may be omitted if it is demonstrated, in the manner specified by the KFDA Commissioner, that the product to be imported is the same product of the same manufacturer that has already been approved (meaning that the country of production, the manufacturer, and the manufacturing site are the same);
2. Documents in which the government of the country of production, an institution authorized by the government of the country of production or an institution recognized by the KFDA Commissioner recognizes that the quality management of the manufacturing site that manufactures the product (i) is equivalent to or higher than the standards for manufacturing and quality management for medical devices under Attached Table 3 or (ii) meets the international standards; provided that such shall not be less than two (2) years old from the issue date, and that when they have a valid term, such term shall not have expired.
3. A copy of an application submitted to the head of the Medical Device Quality Management Review Agency pursuant to Item 11-A of Attached Table 5, or a copy of quality management compliance certificate for import under Item 11-C of Attached Table 5.
4. Deleted <May 29, 2009>

② If a person who intends to file a product import notification in respect of a medical device pursuant to Paragraph 2 of Article 14 of the Act, such person shall submit a notification as per Attached Form No. 5 (including a notification in an electronic form) together with the documents under Item 2 and Item 3 of Paragraph 1 (including electronic documents) to the head of local food and drug administration having jurisdiction over the location of the importer; provided, however, that if an application for import business license and a product import notification are filed simultaneously pursuant to Paragraph 3 of Article 14 of the Act, they shall be submitted to the KFDA Commissioner. <Amended on July 27, 2006 and May 29, 2009 respectively>

③ Regarding subjects and procedures for product import license or product import notification under Paragraphs 1 and 2, the provisions of Article 4 or Paragraphs 2, 4 and 5 of Article 5 shall apply *mutatis mutandis.* In this case,"Manufacturing"shall be regarded as "Import".

Article 19 (Standards for Quality Inspection Facilities and Quality Management System) The standards for quality inspection facilities and quality management system which shall be satisfied by a person who intends to obtain a product import license or file a product import notification pursuant to Paragraph 4 of Article 14 of the Act shall be as described in Attached Table 4.

Article 20 (Observances by Importers, Etc.) ① Matters that are required to be observed by the medical device importer pursuant to Paragraph 5 of Article 14 of the Act shall be as follows: <Amended on July 27, 2006 and December 31, 2008 and May 29, 2009 respectively>

1. The importer shall hygienically control the place of business to ensure that there shall be not health or sanitation risks;
2. If the medical devices sold impair safety and efficacy or the quality is poor, the importer shall take a corrective action such as recall etc., and report the result to the KFDA Commissioner; provided, however, that the records shall be kept for more than two (2) years;
3. If new data or information(including the cases of adverse side effects by use of the medical device) for the approved or notified product is known to the importer, the manufacturer shall report it in the manner specified by the KFDA Commissioner and take necessary safety measures; and
4. The importer shall observe the standards for import and quality management of medical devices under Attached Table 5, and sell the imported medical devices which have been proven to meet such standards;
5. The methods for import and export of medical devices as published by the Minister of Knowledge Economy pursuant to Article 12 of the 「Foreign Trade Act」, and the regulations for control of imported medical devices as provided by the KFDA Commissioner shall be observed; and
6. If secondhand medical devices are imported, a test certificate issued by the testing agency shall be attached thereto before selling such medical devices.

② Pursuant to Paragraph 5 of Article 14 of the Act, the importer shall report the amount of import of the previous year to the KFDA Commissioner by April 15 every year in the manner specified by the Commissioner; provided, however, that if standardized customs schedule report is made under the 「Electronic Trade Facilitation Act」, such report may not be reported. <Amended on July 27, 2006 and May 29, 2009 respectively>

Article 21(Application) Articles 7 through 14 and Article 16 shall apply respectively for the importers and the imported products. In this case, "Attached Table 2" shall be deemed as "Attached Table 4", "Attached Table 3" as "Attached Table 5", "Manufacturer" as "Importer",

“Manufacturing” as “Import”, “Item 1 of Paragraph 1 of Article 5” of Paragraph 2 of Article 8 as “Items 1 and 2 of Paragraph 1 of Article 18”, and “notification (including a notification with electronic document)” as “notification (including a notification with electronic document) together with the documents under Item 2, Paragraph 1, Article 18(including documents in an electronic form)”.
[Full text amended on May 29, 2009]

Article 22 (Notification of Refurbishing Business, Etc.) ① A person who intends to refurbish medical devices as a business pursuant to Paragraph 1 of Article 15 of the Act shall submit a refurbishing business notification as per Attached Form No. 23 (including a notification in an electronic form) to the head of local food and drug administration having jurisdiction over the location of the place of the refurbishing business, together with the documents under each item of Paragraph 1 of Article 3 (including electronic documents). In this case, the head of local food and drug administration shall check the commercial registry certificates (only for a corporation) through the joint use of administrative information under Paragraph 1 of Article 36 of the 「Economic-Government Act」. <Amended on May 29, 2009 and September 1, 2010 respectively>

② If the head of local food and drug administration accepts a refurbishing business notification pursuant to Paragraph 1, he or she shall issue a notification acceptance letter as per Attached Form No. 24 to the person who filed such refurbishing business notification and describe the followings in the refurbishing business register: <Amended on May 29, 2009>

1. Notification acceptance number and date of acceptance;
2. Type of the medical device subject to refurbishing;
3. Name and the resident registration number of the refurbisher (in case of a corporation, name and the resident registration number of the representative of such corporation); and
4. Name and location of the place of refurbishing business (for corporations, location of its principal office).

③ If the refurbisher intends to amend the notified matters, he (or she) shall submit an amended notification as per Attached Form No. 25 (including a notification in an electronic form) to the head of local food and drug administration having jurisdiction over the location of the refurbisher, together with the reason for amendment and the documentary evidence (including electronic documents) and the existing notification acceptance letter. <Amended on July 27, 2006 and May 29, 2009 respectively>

④ The facilities and quality management system that shall be satisfied by a person who intends to file a refurbishing business notification pursuant to Paragraph 2 of Article 15 of the Act shall be as shown in Attached Table 6.

⑤ If the refurbisher closes or suspends business pursuant to Paragraph 4 of Article 15 of the Act, the refurbisher shall submit a notification as per Attached Form No. 22 (including a notification in an electronic form) to the head of local food and drug administration having jurisdiction over the location of the refurbisher, together with the existing notification acceptance letter, and if the person who suspended business intends to notify the resumption of business, such person shall submit a notification as per Attached Form No. 22 (including a notification in an electronic form) to the head of local food and drug administration having jurisdiction over the location of refurbisher. <Amended on July 27, 2006 and May 29, 2009 respectively>

⑥ When the head of local food and drug administration receives a notification under Paragraphs

3 and 5, he (or she) shall describe the notified matter in the relevant notification register and notification acceptance letter, respectively. <Amended on May 29, 2009>

Article 23 (Observances by the Repairer) Matters that shall be observed by the medical device refurbisher pursuant to Paragraph 4 of Article 15 of the Act shall be as follows:

1. The refurbisher shall not refurbish a medical device by changing it in a manner contrary to the approved or notified matters;
2. The refurbisher who has refurbished a medical device shall describe his (or her) name and address on the container or wrapper of such medical device;
3. The refurbisher shall notify the details of the refurbishing in writing to the person who requested refurbishing thereof; and
4. The refurbisher shall maintain the facilities and quality management system under Paragraph 4 of Article 22.

Article 24 (Notification of Sale Business or Rental Business) ① A person that intends to sell medical devices as a business or rent medical devices as a business pursuant to Paragraph 1 of Article 16 of the Act shall submit a notification as per Attached Form No. 26 (including a notification in an electronic form) to the city mayor, *Goon*-governor o*r Gu*-governor(meaning the or *Gu*-governor of an autonomous district unit; same hereinafter) who have jurisdiction over the location of the seller or renter, together with the documents under each item of Paragraph 1 of Article 3 (including electronic documents). In this case, the city mayor, *Goon*-governor o*r Gu*-governor shall check the commercial registry certificates (only for a corporation) through the joint use of administrative information pursuant to Paragraph 1 of Article 36 of the 「Electronic Government Act」. <Amended on May 29, 2009 and September 1, 2010 respectively>

② If the city mayor, *Goon*-governor o*r Gu*-governor accepts a medical device sale or rental business notification pursuant to Paragraph 1, they shall issue a notification acceptance letter as per Attached Form No. 27, and describe the following items in the sale business or rental business notification register.

1. Notification number and date of notification;
2. Name and the resident registration number of the seller or renter (in case of a corporation, name and the resident registration number of the representative of such corporation); and
3. Name and location of the business place.

③ If there is any change in the matters notified under Paragraph 1, the seller or the renter shall submit an amended notification as per Attached Form No. 28 (including a notification in an electronic form) to the city mayor, *Goon*-governor o*r Gu*-governor having jurisdiction over the location of seller or renter, together with the existing notification acceptance letter. <Amended on July 27, 2006, and May 29, 2009, respectively>

④ The dealer or renter intending to notify closure or suspension of business shall submit a notification as per Attached Form No. 22 (including a notification in an electronic form) to the city mayor, *Goon*-governor o*r Gu*-governor having jurisdiction over such seller or renter, together with the existing notification acceptance letter, and, if the person who suspended business intends to resume the business, such person shall submit a notification as per Attached Form No. 22 (including a notification in an electronic form) to the city mayor, Goon-governor or Gu-governor having jurisdiction over such seller or renter. <Amended on July 27, 2006 and May 29, 2009 respectively> o*r Gu*-governor having jurisdiction over such seller or renter. <Amended on July 27, 2006 and May 29, 2009 respectively>

⑤ The city mayor, *Goon*-governor o*r Gu*-governor, upon receipt of a notification under Paragraphs 3 and 4, shall describe the notified details in the relevant notification register and the relevant notification acceptance letter.

Article 24-2 (Exemption of notification for Sale Business Etc.) The medical devices that can be sold without notification pursuant to Item 4 of Paragraph 2 of Article 16 of the Act shall be as follows:

1. Condom; and
2. Cellular phones and household electronic appliances which incorporate a function of measuring blood glucose levels, or combine a blood glucose meter. [Newly added on July 6, 2007]

Article 25 (Observances by Sellers and Renters) Matters that shall be observed by sellers or renters pursuant to Article 17 of the Act, shall be as follows: <Amended on July 27, 2006 and May 29, 2009 respectively>

1. Sellers and renters shall not purchase Medical Devices from any other parties except manufacturers, importers, and sellers, with the exception of buying medical devices from a closing-down medical institution;
2. Sellers and renters shall prepare and keep the records on handling of defective medical devices and maintain them for one (1) year;
3. When using the name of business place, sellers and renters shall not use any of the following names or indications alone or together with the indication of their business place;
   A. Name or indication likely to be misunderstood as the business place of a manufacturer or importer;
   B. Name of the medical institution or similar name under Article 3 of the 「Medical Service Act」
4. Medical devices falling under any of the followings shall not be sold or rented, or stored or displayed for the purpose of sale or renting:
   A. Medical devices to which a test certificate under Item 6 of Paragraph 1 of Article 20 is not affixed;
   B. Contaminated or damaged medical devices or those ordered to be recalled or destroyed by the KFDA Commissioner or the head of local food and drug administration; and
   C. Those whose expiration date or valid term has expired.

Article 26 (Labeling of Containers, Etc.) The “containers or wrappers designated by the Ministerial Decree of the Ministry of Health and Welfare” in the proviso of Article 19 of the Act mean a medical device with narrow area or a medical device on the container or wrapper of which all the labeling items of Article 19 cannot be described, but on the external container or external packing or attached documents of which the labeling is described; provided that, even in such case, the product name and the name of the manufacturer or importer shall be described on the container or wrapper of such medical device. <Amended on March 3, 2008 and March 19, 2010 respectively>

Article 27 (Description on Attached documents) ① The “information determined by the Ministerial Decree of the Ministry of Health and Welfare” as provided in Item 4 of Article 21 of the Act shall mean the following items: <Amended on March 3, 2008 and March 19, 2010 respectively>

1. Matters of Item 1 or Items 3 and 5 of Article 19 of the Act;
2. Indication of “Medical Device”;
3. Purpose of use of the product;

4. Keeping or storage method;
5. In case of a single use only product, the indication of ´Single Use Only´;
6. If the product is entrustment of all manufacturing processes, name and address of the manufacturer or the importer (the person who entrusted the shall be indicated as a “person who requested manufacturing”, the entrusted person, as “Manufacturer”, and in case of , country and company name);
7. If packing is available in each one in a bundle, the model and manufacturer name, which shall be described in the smallest packing unit;
8. In case of medical devices reusable after sterilization, information concerning proper procedure for reuse including the cleaning, sterilization, packing, re-sterilization method, and the limit on the number of times of reuse;
9. In case of medical devices emitting radiation for medical treatment, matters concerning characteristics, types, strength, and diffusion of radiation; and
10. Other technical information such as the characteristics of the medical device.

② Notwithstanding Paragraph 1, information to be included in the attached documents of medical devices for clinical trial shall be as follows: <Amended on May 29, 2009>
1. Indication of “For a clinical trial”;
2. Product name and model name;
3. Manufacture number and date of manufacture (if the expiration date is specified, it may be described);
4. Keeping (storage) method;
5. Company name of the manufacturer or the importer (including the manufacturer or the country in case of entrusted manufacture or import, respectively); and
6. Indication of “Prohibition of use for any purposes other than clinical trial”

③ If the information on Items 1 through 7 of Paragraph 1 are described on the container or wrapper, or packing, such information may be omitted in the attached documents.

Article 28 (Method of Labeling) ① Pursuant to the provisions of Article 22 of the Act, labeling on the container, wrapper or external packing, etc. of a medical device, and on attached documents shall be written in Korean (Hangeul), and Chinese characters or foreign language may be written together in the same size as Hangeul; provided, however, that in case of medical devices for export, the foreign language of the country to which such medical devices are to be exported may be used for such labeling.

② When the product name, name of the manufacturer or importer, etc. are included in the container, wrapper or packing of the medical device, marking in Braille may accompany the labeling under Paragraph 1.

Article 29 (Scope of Medical Device Advertisement, Etc.) ① The following advertisements shall be deemed to be prohibited advertisements under each item of Paragraph 2 of Article 23 of the Act.
1. Advertisements saying that physicians, dentists, oriental doctors, pharmacists, college professors, etc. are designating, authorizing, recommending, instructing, or using the medical device, with the exception of advertisement saying that the national or local government and other public agencies are designating and using the medical device for the purpose of citizens’ health;
2. Advertisements likely to cause a foreign product to be misunderstood as a domestic product, or cause a domestic product to be misunderstood as a foreign product;

3. Advertisements in which the result of use is expressed or implied through comparison of before/after use etc. or the indications are shown or implied with threatening expressions in advertising the efficacy or performance;
4. Advertisements that slander other products or are suspected of slandering other products irrespective of the fact;
5. Advertisements taking advantage of a letter of appreciation or personal experience of the user, or utilizing the expressions “Purchase and orders flooding in”, and other similar expressions;
6. Advertisements describing “Definite guarantees” etc. in advertising the efficacy and effectiveness, or using absolute expressions of “Best”, “Optimal”, etc.;
7. Advertisements likely to cause a medical device to be misunderstood as one which is not a medical device; and
8. Advertisements indicating such symptom of a disease or such surgery scene in a threatening manner as is related to efficacy or effectiveness or purpose of use of the medical device.

② The “organizations designated by the Ministerial Decree of the Ministry of Health and Welfare” as provided in Paragraph 2 of Article 23-2 of the Act shall mean corporations or unions designated and published by the KFDA Commissioner among corporations or unions related to medical devices which have been licensed or approved to be founded by the Minister of Health and Welfare or the KFDA Commissioner, pursuant to Article 32 of the 「Civil Law」 or Article 32 of the 「Small and Medium Enterprise Cooperatives Act」 .<Amended on April 2, 2007 and March 3, 2008 and May 29, 2009 and March 19, 2010 respectively>

Article 30(Designation of Medical Devices Subject to Tracking and the Management Criteria) ① The medical devices to be designated as Medical Devices Subject to Tracking under each item of Paragraph 1 of Article 25 of the Act shall be as follows: <Amended on May 29, 2009>
1. A Medical device which is intended to be implanted in the human body for more than one year; or
   A. Implantable pacemaker;
   B. Permanently implanted electrode connected to an implantable pacemaker;
   C. Artificial heart valve;
   D. Implantable defibrillator;
   E. Implantable infusion pump; and
   F. Other medical devices specified and published by the KFDA Commissioner as needing to be located.
2. Life sustaining or life supporting medical device which may be used outside medical institutions:
   A. Respirator (only for constant use)
   B. Deleted <May 29, 2009>; and
   C. Other medical devices specified and published by the KFDA Commissioner as needing to be located.

②If the KFDA Commissioner grants a product manufacture license or a product import license in respect of the Medical Devices Subject to Tracking under Paragraph 1, the Commissioner shall indicate “Medical Device subject to Tracking” in such license.

Article 31 (Records, Etc. of Medical Devices Subject to Tracking) ① Matters that are required to be recorded pursuant to Paragraph 3 of Article 26 of the Act by (i) a manufacturer, importer, seller, renter, or refurbisher of a Medical Device Subject to Tracking (hereinafter referred to as “handler”), and (ii) a person using a Medical Device Subject to Tracking who has established a

medical institution or who is a medical doctor, oriental medicine doctor or a dentist (hereinafter referred to as "user"), shall be as follows:

1. Matters that shall be recorded by the handling person
   A. Quantity of manufactured and imported products by models and units of manufacture, and date of manufacture and import (only for manufacturers and importers);
   B. Quantity of sale or rent by models and units of manufacture, date of sale or rent, and name and address of the seller or renter;
   C. Date of refurbishing by models and units of manufacture, and company name and address of the person who requested refurbishing (only for refurbishers); and
   D. Other matters necessary to prevent damage to health and sanitation
2. Matters that shall be recorded by the user
   A. Name, address, date of birth, and sex of the patient who uses the Medical Device subject to Tracking;
   B. Name, manufacture number (or its substitute) of the Medical Device Subject to Tracking;
   C. Date when the Medical Device subject to tracking is used;
   D. Name and location of the medical institution where the Medical Device is used; and
   E. Other matters necessary to prevent damage to health and sanitation

② When the handler or user of the Medical Device Subject to Tracking is asked to submit records and data concerning the Medical Device Subject to Tracking from the KFDA Commissioner, such handler or user they shall submit such records and data within 10 days.

③ When the handler or user of the Medical Device Subject to Tracking prepares the records under Paragraph 1, such handler or user shall keep such records confidential.

④ The records on the Medical Device Subject to Tracking under Paragraph 1 shall be kept until the following times:

1. When the medical device cannot be used any more due, e.g., to the death of the patient who used the Medical Device Subject to Tracking; and
2. When the need for keeping of the records no longer exists because there is no need for tracking.

Article 32 (Reporting of Adverse Side Effects) ① A person who intends to report matters concerning adverse side effects of the a medical device under Paragraph 1 of Article 27 of the Act shall report as provided below and maintain the relevant data for two (2) years:

1. Within 7 days, if the Medical Device causes death or a life-threatening adverse side effect; in this case, details shall be additionally reported within 8 days from the date of initial reporting; and
2. Within 15 days, if a medical device causes adverse side effects specified in the following or results in adverse reactions;
   A. If hospitalization or extension of the hospitalization period is needed;
   B. In case that a medical device causes a disorder which is impossible to recover from or results in serious disablement or malfunction; and
   C. When a medical device causes congenital malformation or abnormality

② Details concerning report and management of adverse side effects shall be specified and published by the KFDA Commissioner.

Article 32-2 (Criteria and Procedure for Recall of Harmful Medical Devices, Etc.) ① If a medical device being repaired or sold or rented by a refurbisher, seller, and renter causes harm

to the human body or is suspected of being likely to cause harm to the human body under Paragraph 2 of Article 27 of the Act (such medical device, “to-be-recalled medical device”), such refurbisher, seller, and renter of a medical device shall immediately stop refurbishing, selling or renting such medical device and notify such fact to the manufacturer or the importer of the medical device (hereafter “required recaller”).

② The required recaller shall confirm under which of the following medical devices fall the medical devices suspected of being to-be-recalled medical device under Paragraph 2 of Article 27 of the Act and (ii) the medical devices notified under Paragraph 1, among the medical devices that such required recaller sold or rented after manufacturing or importing them:

1. Medical devices the use of which causes an incurable serious adverse side effect or death, or is likely to cause it;
2. Medical devices causing or likely to cause temporary or medical adverse side effects which are curable by use of medical devices; and
3. Medical devices not conforming to the standard specifications under Article 18 of the Act, although adverse side effects hardly occur by use of such medical devices.

③ If, as a result of confirmation under Paragraph 2, a medical device falls under any of the items of Paragraph 2, the required recaller shall take an action such as immediately stopping the sale of such medical device, and submit a recall plan form as per Attached Form No. 28-2 to the KFDA Commissioner within the following time periods from the date of such confirmation under Paragraph 2. In this case, the required recaller may submit a recall plan using a computer program specified by the KFDA Commissioner:

1. Medical devices under Item 1 of Paragraph 2: Within 5 days
2. Medical devices under Items 2 and 3 of Paragraph 2: Within 15 days.

④ If the required recaller reports a recall plan under , the following documents shall be attached:

1. Copy of the manufacture/import record for the product, and records of sales volume for each seller, dates of sale, amounts of rent for each renter, dates of rent, etc.;
2. A notice of recall plan to be notified under Paragraph 3 of Article 32-3; and
3. Documents stating the reason for recall.

⑤ When the required recaller prepares a recall plan under Paragraph 3, the expected end date of recall shall be within 30 days from the start of recall; provided, however, that if it is deemed that recall is impossible within the term, the reason shall be revealed and the recall period may exceed 30 days.

⑥ If the KFDA Commissioner deems that the recall plan reported pursuant to Paragraphs 3 and 4 is insufficient, the KFDA Commissioner may order the required recaller to supplement the recall plan.[Newly added on June 26, 2009]

Article 32-3 (Public Announcement of Recall Plan, Etc.) ① When a required recaller receives an order for public announcement of a recall plan from the KFDA Commissioner pursuant to Paragraph 3 of Article 27 of the Act, such required recaller shall publicly announce the recall plan, as follows:

1. Medical Devices under Item 1 of Paragraph 2 of Article 32-2: A public announcement made on broadcasting, daily newspaper or any mass media of an equivalent or higher level (including the media recognized by the KFDA Commissioner in consideration of purpose of use, instructions for use, etc. of the to-be-recalled medical device)

2. Medical devices under Item 2 of Paragraph 2 of Article 32-2: public announcement on medical or medical engineering journals, or any media of an equivalent or higher level
3. Medical devices under Item 3 of Paragraph 2 of Article 32-2: public announcement on the company's Internet homepage or any media of an equivalent or higher level

② The KFDA Commissioner may publish, on its Internet homepage, the name of the required recaller, product name, manufacture number, date of manufacture, shelf life, expiration date, and reason for recall.

③ The required recaller shall notify the refurbisher, seller or renter or a person who has established a medical institution, to the extent that such refurbisher, seller, renter or person handles to-be-recalled medical devices (hereinafter "to-be-recalled medical device handler"), of the recall plan by means of a visit, mail, telephone, telegram, e-mail, fax, or public announcement through mass media, and shall keep data proving the notification for two (2) years from the date when recall is terminated.

④ The to-be-recalled medical device handler, who is notified of a recall plan under Paragraph 3, shall take an action such as returning the to-be-recalled medical device, prepare a recall confirmation letter as per Attached Form No. 28-3, and send it to the required recaller for the to-be-recalled medical device.

⑤ The KFDA Commissioner may construct and operate a computer program to offer information concerning the to-be-recalled medical devices and recommend the to-be-recalled medical device handlers, etc. to install such program.[Newly added on June 26, 2009]

Article 33 (Sampling, Etc.) ①In case of collecting articles or medical devices pursuant to Paragraph 1 of Article 28 of the Act, a receipt of collection as per Attached Form No. 29 shall be issued to the person from whom they are collected.

② If special testing of articles collected under Paragraph 1 is necessary, a testing agency may be requested to conduct such test.

Article 34 (Certificate of Medical device surveillance officer) An official mark evidencing the identity of the government official concerned under Paragraph 2 of Article 28 of the Act (including the applicable cases under Paragraph 3 of Article 30 of the Act) shall be as shown in Attached Form No. 30.

Article 35 (Criteria for Administrative Disposition) The criteria for administrative measures under Paragraph 3 of Article 32 of the Act shall be as described in Attached Table 7.

Article 36 (Qualifications and Scope of Duties of Medical Device Surveillance Officers) ① The medical device surveillance officers under Article 35 of the Act shall be appointed by the KFDA Commissioner, a city mayor, *Goon*-governor o*r Gu*-governor from among government officials who fall under one of the followings:
1. A person who graduated from one of the departments of medicine, pharmacy, dental medicine, oriental medicine, veterinary medicine, or medical engineering in a college or university, or a person who has qualifications equivalent to or higher than it; and
2. A person who has experience in healthcare administration for more than one (1) year

② Duties of the medical device surveillance officer shall be as follows:

1. Duties of medical device surveillance officers belonging to the KFDA Commissioner or the head of local food and drug administration: post surveillance of medical device manufacturers, importers and refurbishers, and collection and testing of medical devices; provided, however, that if a nationwide investigation is necessary or there is a need for systematic investigation, the medical device surveillance officers may perform the tasks under Item 2 below; and
2. Duties of medical device surveillance officers belonging to a city mayor, *Goon*-governor o*r* *Gu*-governor: post surveillance of medical device sellers and renters.

Article 37 (Renewal of License Etc.) A person who desires to renew a license or notification acceptance letter pursuant to Article 41 of the Act shall submit an application as per Attached Form No.31 (including an application in an electronic form) together with the existing license or notification acceptance letter, to the following persons: <Amended on July 27, 2006 and May 29, 2009 respectively>:

1. In the case of renewal of a manufacturing /import business license for medical devices, and a product manufacture/import license for medical devices: the KFDA Commissioner;
2. In the case of renewal of an acceptance letter for a product manufacture notification for medical devices, a product import notification for medical devices and a refurbishing business notification for medical devices: the head of local food and drug administration having the jurisdiction over the location of the manufacturer, importer, refurbisher; and
3. In the case of renewal of an acceptance letter for a sale/rental business notification for medical devices: the city mayor, *Goon*-governor o*r* *Gu*-governor having the jurisdiction over the location of the seller or the renter.

Article 38 (Reissue of License Etc.) ① If a medical device manufacturer, importer, refurbisher, seller or renter lost the license or notification acceptance letter or they cannot use it, or there is a change in the items described on it, such medical device manufacturer, importer or refurbisher shall submit an application (including an application in an electronic form) as per Attached Form No. 32 Form, together with the license or notification acceptance letter (only in the cases that they cannot use it or a there is a change in the items described on it), to (i) (in the case of a medical device manufacturer, importer or refurbisher) the KFDA Commissioner or the head of local food and drug administration having the jurisdiction over the manufacturer, importer or refurbisher, and (ii) (in the case of a medical device seller or renter) the city mayor, *Goon*-governor o*r* *Gu*-governor having the jurisdiction over the location of such seller or renter.<Amended on July 27, 2006 and May 29, 2009 respectively>

② In case of reissue of a license or a notification acceptance letter under Paragraph 1, the KFDA Commissioner or the head of local food and drug administration, or the city mayor, *Goon*-governor o*r* *Gu*-governor shall describe the reason for reissue in the relevant register.

③ A person who desires to get certification or confirmation of the license or notification, etc. under Articles 6 and 14 of the Act shall submit an application for certification or an application for confirmation (each including an application in an electronic form, and in case of a foreign language, including a translation) to the KFDA Commissioner or the head of local food and drug administration having the jurisdiction over the location of the manufacturer or the importer. <Amended on July 27, 2006 and May 29, 2009 respectively>

Article 39 (Fees) ① Fees under Article 42 of the Ac shall be as provided in Attached Table 8; provided, however, that if there is a change in the granted license or the filed notification and the reason for such change is not attributable to the person who files an for an amended license or files an amended notification (such as a change in such person's location due to a

reform of the administrative districts), such person shall be exempt from such fees.

② When the fees under Paragraph 1 are paid to a national agency, payment shall be made with a revenue stamp (with respect to duties under the jurisdiction of the KFDA Commissioner, cash or a proof of cash payment), or when the fees are paid to a local government, payment shall be made with a revenue stamp of such local government. In this case, payment may be made by means of e-money, e-payment, etc. using telecommunication network. <Amended on July 27, 2006 and May 29, 2009 respectively>

Article 40 (Administrative Default Fine**)** The criteria for imposition of an administrative default fine under Article 47 of the Act shall be as shown in Attached Table 9. [full text amended on May 29, 2009]

ADDENDUM <Number 291, July 28, 2004>

Article 1 (Effective Date) These Regulations shall take effect from the date of promulgation.

Article 2 (Transitional Measures on Observances by the Manufacturer) A person who obtained a manufacturing business license for medical instruments under the Pharmaceutical Affairs Act as of these Regulations taking effect, shall make sure that they shall comply with, by May 30, 2007, the standards for manufacturing and quality management of medical devices under Attached Table 3 under Item 6 of Paragraph 1 of Article 15 hereof.

Article 3 (Transitional Measures on Import Business License and Observances by the Importer) A person who obtained a product import license or a product import notification for medical instruments pursuant to the Pharmaceutical Affairs Act as of these Regulations taking effect, shall obtain an import business license by May 30, 2005 under Article 17 hereof, and make sure they shall comply with, by May 30, 2007, the standards for import and quality management under Attached Table 5 under Item 4 of Paragraph 1 of Article 20 hereof.

Article 4 (Transitional Measures on Application for License, Etc.) The Pharmaceutical Affairs Act shall apply to the grant or approval of license and acceptance of notification for a person who submitted an application for license, an for an amended license, a request for safety and efficacy review, a request for review of specifications and test methods, an for approval, a notification, etc. pursuant to the Pharmaceutical Affairs Act as of these Regulations taking effect.

Article 5 (Amendments to Other Relevant Laws by this Act) ① The Enforcement Regulations on the Organization of the Ministry of Health and Welfare and the agencies and organizations under its supervision shall be amended as follows:

In Items 4 and 5 of Paragraph 5 of Article 8, “Drugs, quasi-drugs, and medical instruments” and “Medical instruments and cosmetics” shall be amended to “Drugs, quasi-drugs, and medical devices” and “Medical devices and cosmetics”, and in Item 6 of the same paragraph, “The Central Pharmaceutical Affairs Review Committee” shall be amended to the “Central Pharmaceutical Affairs Review Committee and the Medical Device Committee”.

In Item 6 of Paragraph 9 of Article 9, “Related to dental medical instruments” shall be amended to “Related to dental medical devices”.

② The rules on request for test in the KFDA and the Korea Center for Disease Control and Prevention shall be amended as follows:

Item 1 of Paragraph 1 of Article 3 shall be amended as below, and in Item 3 of the same

paragraph, “Quasi-drugs and medical instruments” shall be amended to “Quasi-drugs, and Medical Devices under Paragraph 7 of Article 6, Paragraph 5 of Article 14, and Article 18 of the Medical Device Act”.

In Item 1, 3, 4, and 5 of Article 4, “medical instruments” shall be amended to “medical devices”, respectively.

③ The Enforcement Regulations of the Ministerial Decree for Facilities of Pharmacies, Manufacturers, Importers, and Sellers of Drugs Etc. shall be amended as follows:

In the title of Article 10, the “Manufacturer who manufactures medical instruments or hygienic products” shall be amended to the “Hygienic product manufacturer”.

Paragraph 5 of Article 12 shall be deleted.

In Article 14, the “Business office of druggists, oriental druggists, drug dealers, and medical instrument sales business” shall be amended to the “Business office of druggists, oriental druggists, and drug dealers”.

In Item 1, Paragraph 1, Article 15, “Manufacturing of quasi-drugs and manufacturing of medical instruments” shall be amended to “Manufacturing of quasi-drugs”, the proviso of the sub-item A of the same item shall be deleted, and in Item 2 of Paragraph 2, “Manufacture of drugs, etc. (except medical instruments)” shall be amended to “Manufacturing of drugs etc.”, and Item 3 of the same paragraph shall be deleted.

④ The Enforcement Regulations of the Pharmaceutical Affairs Act shall be amended as follows:

In Paragraph 1 of Article 21, “Drugs, quasi-drugs, or medical instruments” shall be amended to “Drugs or quasi-drugs”, and in Item 8 of the paragraph, “preparations or medical instruments containing the ingredient” shall be amended to “preparations containing the ingredient”, and Item 11 of the same paragraph shall be deleted.

Item 2 of Clause 2 of Article 21 shall be as follows:

2. Pharmaceutical raw materials for the purpose of a clinical trial, a comparator for a clinical trial (including placebo)

In Paragraph 1 of Article 22, the “Application for manufacturing business license for drugs and medical instruments” shall be amended to the “Application for manufacturing business license for drugs”, and Item 4 of the same paragraph shall be deleted.

Item 3 of Paragraph 1 of Article 23 and Paragraph 4 of Article 24 shall be deleted, respectively.

In Article 26, “Designation of medical instruments (including categorizations by class), manufacturing business of drugs, etc.” shall be amended to “Manufacturing business of drugs, etc.”

Item 9 through 11 of Paragraph 1 of Article 27, the proviso of Paragraph 2 of Article 27 and Paragraph 5 of Article 27 shall be deleted, respectively.

Item 7 of Paragraph 2 of Article 28 shall be amended as follows:

7. Code name of the drugs for clinical trial or general names of the main ingredients, pharmaceutical raw materials and the quantity, preparation, etc thereof.

Item 10 of Paragraph 1 of Article 29 shall be amended as follows:

10. For use of drugs for clinical trial, they shall be prepared, satisfying the standards for manufacturing and quality management of drugs described in Attached Table 4 and the standards for manufacturing and quality management of biological preparations described in Attached Table 4-4.

In Paragraph 1 of Article 32, “Conditional manufacturing business of drugs or medical instruments” shall be amended to “Conditional manufacturing business of drugs.”

In Paragraph 1 of Article 34, “Manufacturing business license for drugs or medical instruments” shall be amended to “Manufacturing business license for drugs”.

Paragraph 1 of Article 36 shall be amended as follows:

① A drug manufacturer who intends to set up a business place pursuant to Paragraph 4 of Article 26 of the Act shall have a pharmacist or an oriental pharmacist who controls the business place (hereafter "business manager").

Paragraph 3 of Article 38 shall be amended as described below, and in Paragraph 4 of the same article, "Medical instruments or quasi-drugs" shall be amended to "Quasi-drugs", and "KFDA Commissioner in the case of a manufacturing manager for medical instruments by attaching documents" shall be amended to "by attaching documents".

③ A person who can control manufacturing affairs of quasi-drugs falling under Item 1 of Paragraph 7 of Article 2 of the Act is as follows:

1. A physician or a pharmacist, or a person who graduated from the department of chemistry, chemical engineering, or fiber engineering, or related department of university; and
2. A person who graduated from ay of the departments described in Item 1 above in a junior college and worked in the manufacture of quasi-drugs for more than two (2) years.

Item 12, Paragraph 1, Paragraphs 2 and 3 of Article 40 shall be deleted, respectively.

In Paragraph 2 of Article 43, "Biological preparations, medical instruments, or quasi-drugs" shall be amended to "Biological preparations or quasi-drugs".

Item 7 of Paragraph 1 of Article 44 shall be amended as follows:

7. Pharmaceutical raw materials for the purpose of a clinical trial, a comparator for a clinical trial (including placebo), etc.

Paragraphs 3 and 4 of Article 46, Paragraph 4 of Article 57, and Articles 59, 60 and 77 shall be deleted, respectively.

Paragraph 1 of Article 83 shall be amended to:

① If, pursuant to Paragraph 1 of Article 26 of the Act, Article 34 of the Act, or Paragraph 3 of Article 35 of the Act, a manufacturer, importer or seller of drugs, etc. intends to obtain an amended license or file an amended notification, such manufacturer, importer, or seller shall submit the following or notification to (i) the KFDA Commissioner (in the case of a medical high pressure gas manufacturing business, herb medicine manufacturing business, quasi-drugs manufacturing business, and products subject to notification other than pharmaceutical raw materials subject to notification), or (iii) the city mayor or *Do*-governor(in the case of sellers of drugs), together with the license or the notification acceptance letter, and a statement of the reason for such amendment and the documentary evidence therefor; provided, however, that if the KFDA Commissioner gives directions to amend the product license or a product notification by the specified time limit pursuant to Paragraph 1 of Article 69 of the Act the result of drug re-evaluation under Article 26-3 of the Act, adjustment based on the result of safety and efficacy review under Article 27, or the result from the safety information management under Article 40, the KFDA Commissioner or the head of local food and drug administration shall be deemed to have granted an amended license or accepted an amended notification.

1. In the case of amendment of the manufacturing business: an application as per Attached Form No. 59
2. In the case of amendment of the sale business: a notification as per Attached Form No. 11-2
3. In the case of a change of product: an application as per Attached Form No. 61 or a notification as per Attached Form No. 15 (in the case of pharmaceutical raw materials subject to notification, Attachment Number 15-2 Form)

In Paragraph 1 of Article 84, "A person who has established a pharmacy, a manufacturer of drugs etc., a drug seller or a medical instruments seller" shall be amended to "A person who has established a pharmacy, a manufacturer of drugs etc., or a drug seller", and "A license or notification acceptance letter for manufacturing business of drugs etc., sale business of drugs, or

sale business of medical instruments" shall be amended to "A license of manufacturing business of drugs etc. or sale business of drugs".

In Paragraph 1 of Article 93, "A drug seller, a medical instruments seller, and a manufacturer of drugs etc." shall be amended to "A drug seller and a manufacturer of drugs etc.", and "A person who has established a pharmacy and a medical instruments seller or a person who makes a preparation for retail pharmacy" shall be amended to "A person who established a pharmacy or a person who makes a preparation for retail pharmacy".

In Paragraph 2 of Article 96, "A person who established a pharmacy, a drug seller a medical instruments seller, or a manufacturer of drugs etc." shall be amended to "A person who established a pharmacy, a drug seller, or a manufacturer of Drugs etc."

ADDENDUM (Partial Amendment of the Ministerial Decree such as the Enforcement Regulations of the Act on Dietary Supplements for Joint Use of Administrative Information and Reduction of Documents) <Item Number 363, July 3, 2006>

These Regulations shall take effect from the date of promulgation.

ADDENDUM <Number 366, July 27, 2006>

These Regulations shall take effect from the date of promulgation.

ADDENDUM <Number 391, April 2, 2007>

These Regulations shall take effect from April 5, 2007.

ADDENDUM <Number 407, July 6, 2007>

These Regulations shall take effect from July 7, 2007.

ADDENDUM (Enforcement Regulations on the Organization of the Ministry of Health, Welfare and Family Affairs, and the Agencies and Organizations under its Supervision) <Number 1, March 3, 2008>

Article 1 (Effective Date) These Regulations shall take effect from the date of promulgation.

Article 2 shall be omitted

Article 3 (Amendment to Other Relevant Acts) ① through <62> shall be omitted.

<63> Part of the Enforcement Regulations of the Medical Device Act shall be amended as follows:

In Article 26, Paragraph 1 of Article 27 other than each item thereof, and Paragraph 2 of Article 29, the "Ministerial Decree of the Ministry of Health and Welfare" shall be amended to the "Ministerial Decree of the Ministry of Health, Welfare and Family Affairs".

In Paragraph 2 of Article 29, the "Minister of Health and Welfare" shall be amended to the "Minister of Health, Welfare and Family Affairs".

<64> through <94> shall be omitted.

ADDENDUM (The Enforcement Regulations on the Organization of the Ministry of Health, Welfare and Family Affairs and the Agencies and Organizations under its

Supervision) <Item 84, December 31, 2008>

Article 1 (Effective Date) These Regulations shall take effect from January 1, 2009.

Article 2 (Amendment to Other Relevant Acts) Paragraphs ① through ② shall be omitted.

③ Part of the Enforcement Regulations of the Medical Device Act shall be amended as follows: In Item 5 of Paragraph 1 of Article 20, the "Minister of Industry and Energy" shall be amended to the "Minister of Knowledge Ecomony".

④ through ⑥ shall be omitted.

ADDENDUM <Number 112, May 29, 2009>

Article 1 (Effective Date) These Regulations shall take effect after 3 months from the date of promulgation.

Article 2 (Transitional Measures on Criteria for Administrative Disposition) Regarding administrative disposition against violation committed prior to these Regulations taking effect, if the criteria became stricter than the existing ones, the previous Regulations shall be applied; if the criteria became less strict, these Regulations as amended shall be applied.

Article 3 (Amendment to Other Relevant Regulations) Part of the regulations on safe management of diagnostic x-ray system shall be amended as follows:
The partial proviso other than each item of Paragraph 1 of Article 4 shall be amended to the following:
Provided, however, that when a person intends to obtain a product manufacture license or product import license for medical devices pursuant to Paragraph 1 of Article 5 and Paragraph 1 of Article 18 of the 「Enforcement Regulations of the Medical Device Act」 or intends to import secondhand medical devices pursuant to Item 6 of Paragraph 1 of Article 20 of the Regulations, the medical devices may be used without being subject to the tests under the main body if a test including the test items of Attached Table 1 is conducted by a testing agency registered with the KFDA and the related test report is submitted.

ADDENDUM <Number 118, June 26, 2009>

These Regulations shall take effect from June 27, 2009.

ADDENDUM <Item 1, March 19, 2010>

Article 1 (Effective Date) These Regulations shall take effect from the date of promulgation. <omission of the proviso>

Article 2 shall be omitted.

Article 3 (Amendment to Other Relevant Acts) ① through <56> shall be omitted.
<57> Part of the Enforcement Regulations of the Medical Device Act shall be amended as follows:
In Article 26, Paragraph 1 of Article 27 other than each item thereof, and Paragraph 2 of Article 29 the "Ministerial Decree of the Ministry of Health, Welfare and Family Affairs" shall

be amended to the “Ministerial Decree of the Ministry of Health and Welfare”.
In Paragraph 2 of Article 29, the “Minister of Health, Welfare and Family Affairs” shall be amended to the “Minister of Health and Welfare”.
<58> through <84> shall be omitted.

ADDENDUM (Partial Amendment of the Ministerial Decree such as the Enforcement Regulations of the Act on Dietary Supplements for Joint Use of Administrative Information and Reduction of Documents)
<No. 118, September 1, 2010>

These Regulations shall take effect from the date of promulgation.

[Attached Table 1] <Amended on May 29, 2009>

Criteria and Procedure for Classification and Designation of Medical Devices

(Related to Article 2)

1. Criteria for classification of medical devices
   A. The KFDA Commissioner shall classify Medical Devices into the following four through review by the Medical Device Committee according to the purpose of use and the degree of potential risk to the human body. In this case, if the medical device is pertinent to two or more grades, it shall be categorized into the grade of the highest risk
      1) Class 1: Medical Devices with little potential risk
      2) Class 2: Medical Devices with low potential risk
      3) Class 3: Medical Devices with medium serious potential risk
      4) Class 4: Medical Devices with high risk
   B. The decision criteria for potential risk of sub-item A are as follows:
      1) Duration of device contact with the body
      2) Degree of Invasiveness
      3) Whether the device delivers medicinal products or energy to the patient and
      4) Whether the device delivers medicinal products or energy to the patient
   C. Detailed criteria for risk related to sub-items A and B shall be specified and notified by the KFDA Commissioner.
2. Procedure for designation of class
   The KFDA Commissioner shall classify Medical Devices by instruments, machines, apparatus, and materials into large classification group, each large group into mid classification groups having similar raw material, manufacturing process, and quality control system, and each mid

classification group into small classification group by products m whose function is exercised independently, and each class shall be specified and notified by products classified as small classification group.

3. Procedure of application for reclassification and designation of class

A. If it is deemed by the KFDA Commissioner that there is application by the party concerned etc. or need for reclassification, the KFDA Commissioner may reclassify class of product through a review by the Medical Device Committee.

B. Upon reclassification, the degree of potential risk and the appropriateness under the following criteria shall be examined:

1) Whether the description of the product, purpose, use, principle, features, function, etc. of the applied device fall under the descriptions of similar or the same products and

2) Whether the safety and performance of applied device are fully secured, compared to the already classified, designated, and managed products

C. If a person or entity who is to apply for reclassification of the class shall attach the following data to an application with Attached Form No. 33 and submit to the KFDA Commissioner.

1) Data on technical document, etc.

2) Data on comparative analysis of technical characteristics including structure, principle, performance, purpose of use, and instructions for use with other medical devices with similar to those subject to reclassification

D. The KFDA Commissioner, when received application for reclassification as pursuant to sub-item C, shall review and decide it in 90 days from the date of receipt, and then give a notice to the applicant of the result and notify to the public.