Medical Device Act (Act No. 14330, December 2, 2016)
CHAPTER I GENERAL PROVISIONS
Article 1 (Purpose) The purpose of this Act is to promote efficient management of medical devices and further contribute to the improvement of public health by setting forth the matters concerning manufacture/import and sale, etc. of medical devices.
Article 2 (Definitions) (1) "Medical device", as referred to in this Act, shall mean any instrument/machine/device/material or other similar product, used alone or in combination, for human beings or animals, as specified in any of the following Subparagraph: provided that drugs and quasi-drugs, as defined in the Pharmaceutical Affairs Act, and prosthetic limbs/aids among the assistive devices for persons with disabilities, as defined in the Act on Welfare of Persons with Disabilities Article 65, are excluded here from:
1. A product used for the purpose of diagnosis/cure/alleviation/treatment or prevention of disease;
2. A product used for the purpose of diagnosis/cure/alleviation or supplement of injury or impairment;
3. A product used for the purpose of test/replacement or modification of anatomy or physiologic function; or
4. A product used for the purpose of contraception.
(2) "Technical document", as referred to in this Act, shall mean a set of documents describing quality of a medical device, such as performance and safety, and containing information on raw materials, structure, intended use, method of use, mechanism of action, precautions and test specifications, etc.
(3) "Medical device handler", as referred to in this Act, shall mean any of the following parties that handles medical devices as part of its business and that has obtained a license or filed a report pursuant to this Act, or a party that has opened a medical institution pursuant to the Medical Service Act, or a person who has opened a veterinary hospital pursuant to the Veterinarians Act:
1. A manufacturer of medical devices;
2. An importer of medical devices;
3. A repairer of medical devices;
4. A seller of medical devices; or
5. A lessor of medical devices.
(4) "Medical device standard code", as referred to in this Act, shall mean the number, barcode [including electronic tag (RFID tag)], etc. that are labeled on the

container, package, etc. of a medical device according to a standardized system for the purpose of identification and systematic/efficient management of medical devices. <Newly Enacted on December 2, 2016>

Article 3 (Product Classification and Designation) (1) The Minister of Food and Drug Safety shall classify and designate medical devices, in order to ensure systematic/reasonable management of their safety in accordance with their intended use and different levels of potential risks exposed on human bodies during use. <Amended on March 23, 2013>

(2) Matters necessary for the standards and procedures on product classification and designation of medical devices pursuant to Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

Article 4 (Relationship with other Acts)
Notwithstanding the provisions of this Act, installation/operation of radiation-emitting diagnostic devices and special medical devices shall be governed by Articles 37 and 38 of the Medical Service Act and Articles 17-3 and 17-4 of the Veterinarians Act.

CHAPTER II MEDICAL DEVICE COMMITTEE

Article 5 (Medical Device Committee) (1) Medical Device Committee shall be established within the Ministry of Food and Drug Safety to investigate/deliberate the matters provided by the following Subparagraph by the request of the Minister of Health and Welfare or the Minister of Food and Drug Safety: <Amended on March 23, 2013; January 28, 2015>

1. Matters concerning standard specifications of medical devices;
2. Matters concerning re-examination/re-evaluation of medical devices;
3. Matters concerning medical devices subject to tracking;
4. Matters concerning product classification and designation of medical devices;
5. Matters concerning scope of subcontracting for certification and report of medical devices; and
6. Other important matters concerning medical devices.

(2) Matters necessary for organization and operation, etc. of the Medical Device Committee shall be set forth by the Presidential Decree.

CHAPTER III MANUFACTURE, ETC. OF MEDICAL DEVICES

SECTION 1 Manufacturing Business

Medical Device Act (Act No. 14330, December 2, 2016)
Article 6 (Licenses, Etc. to Engage in Manufacturing Business) (1) A person seeking to engage in a business of manufacturing medical devices shall obtain a manufacturing business license from the Minister of Food and Drug Safety: provided that a person that falls under any of the following is not eligible for such manufacturing business license: <Amended on March 23, 2013; January 28, 2015>
1. A person who is mentally ill, as defined in Article 3 Subparagraph 1 of the Mental Health Act: provided that the foregoing does not apply to persons deemed competent by a medical specialist to engage in a manufacturing business;
2. A person who has been declared incompetent/quasi-incompetent, or bankrupt but has not yet been reinstated;
3. A person who is addicted to narcotics or other noxious substances;
4. A person who has been sentenced to imprisonment without forced labor or heavier punishment for violation of this Act and for whom execution of such sentence has not been completed or for whom execution of such sentence is not definitely exempt;
5. A person whose manufacturing business license had been revoked for violation of this Act and one year has not elapsed since the date of revocation.
(2) A person who has obtained a manufacturing business license pursuant to Paragraph (1) (hereinafter referred to as "manufacturer") shall obtain, for the medical device he/she intends to manufacture, a manufacturing license or a manufacturing certification, or shall file a report for manufacture, according to the following Subparagraphs: <Amended on March 23, 2013; January 28, 2015>
1. For medical devices whose potential risk to human body is low and are thus unlikely to harm human life or health even in the event of failure or malfunction and are designated and publicly notified by the Minister of Food and Drug Safety: a manufacturing license, a manufacturing certification or a report for manufacture is required for each product category; or
2. For medical devices other than those specified in Subparagraph 1: a manufacturing license, a manufacturing certification or a report for manufacture is required for each product item.
(3) When applying for a manufacturing business license pursuant to Paragraph (1), the applicant shall file an application for one or more manufacturing license or certification, or file a report for one (1) or more item, pursuant to each of the Subparagraphs of Paragraph (2).<Amended on January 28, 2015>
(4) A person seeking to obtain a manufacturing business license pursuant to Paragraph (1); or a person seeking to obtain a manufacturing license or certification or to file a manufacturing report pursuant to Paragraph (2) shall be equipped with the necessary facilities, manufacturing and quality management systems, as defined by the Decree of Prime Minister, before filing the applications or making the report: provided that the foregoing does not

apply to cases designated by the Decree of Prime Minister, such as, subcontracting quality control testing, manufacturing processes, etc.. <Amended on March 23, 2013; on January 28, 2015>

(5) A manufacturer seeking to obtain a manufacturing license or certification, or to file a report to manufacture pursuant to Paragraph (2) shall submit, to the Minister of Food and Drug Safety, as stipulated by the Decree of Prime Minister, necessary materials, such as, data on manufacturing and quality management systems, technical documents, clinical study data, etc..<Amended at on March 23, 2013; January 28, 2015>

(6) For a medical device, which is combined or composited with a drug or a quasi-drug and whose main function is equivalent to that of a drug or a quasi-drug, in the event a license has been granted or a report has been filed already, pursuant to Article 31 Paragraph (2) of the Pharmaceutical Affairs Act, for its manufacturing and sale, the manufacturing license or certification or the report to manufacture under Paragraph (2) shall be deemed granted or filed. <Amended at on January 28, 2015>

(7) A person seeking to obtain a manufacturing business license pursuant to Paragraph (1) shall hire a quality manager, as prescribed by the Decree of Prime Minister, to perform the duties under Article 6-2 (1). <Newly enacted on January 28, 2014>

(8) Necessary matters related to the eligibility/procedures/standards/conditions and management, etc. pertaining to the manufacturing business license under Paragraph (1), and the manufacturing license, the manufacturing certification, or the report to manufacture under Paragraph (2) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013; January 28, 2014; January 28, 2015>
[Enforcement Date: January 29, 2016] Of the amended provisions of Article 6 Paragraph (4) and (5), matters concerning manufacturing and a quality management system.

Article 6-2 (Matters to Be Observed, Etc. by Quality Managers) (1) A person responsible for quality, as defined in Article 6 Paragraph (7) (hereinafter referred to as "quality management representative"), shall be responsible for directing/supervising the employees engaged in medical device manufacturing and management of medical device manufacturing/quality/safety (including safety management of post-market side effect, etc.; the same shall apply in this Article hereinafter).

(2) A quality manager shall receive a periodic training, at least once a year, on the latest standard specifications on medical devices, quality management and safety management.

(3) Where necessary to prevent harm to public health, the Minister of Food and Drug Safety may order a quality manager to receive further training in

addition to annual training pursuant to Paragraph (2).

(4) In addition to the matters set forth in Paragraphs (1) through (3), matters related to the scope of duties, training including contents, hours, methods, procedures, and expenses, designation of a training institution, etc. shall be set forth by the Decree of Prime Minister.
[Newly enacted on January 28, 2014]

Article 6-3 (Restrictions on Manufacturing Licenses, Etc.) (1) A medical device product falling under any of the following Subparagraphs may not obtain a manufacturing license or certification, or file a report to manufacture:

1. A medical device product may not be approved again for the same purpose of use, same mechanism of action, with same raw materials, etc. if the same device was once revoked pursuant to Article 36 Paragraph (1), and if one year has not passed since the date of such revocation.

2. A medical device, which uses or contains raw materials designated by the Minister of Food and Drug Safety as having safety/efficacy problems, and which is used in direct/indirect contact with human body;

3. A medical device, which uses or contains raw materials with potentials for infection of diseases that may harm public health, i.e., bovine spongiform encephalopathy, and which is used in direct/indirect contact with human body and which is designated by the Minister of Food and Drug Safety; or

4. Other medical devices, which do not meet the standards for manufacturing license, manufacturing certification, or report for manufacture of medical devices as set forth and publicly notified by the Minister of Food and Drug Safety.

(2) A medical device that has any of the followings as its name may not obtain a manufacturing license or certification, or file a report for manufacture:

1. A name, which is not suitable for a medical device, or may mislead as a different product, or is exaggerated.;

2. A name, which plainly expresses indication, efficacy/effectiveness of a medical device; and

3. Other names, which are of a nature similar to Subparagraphs 1 and 2 and do not meet the standards set forth and publicly notified by the Minister of Food and Drug Safety.
[Newly enacted on January 28, 2015]

Article 6-4 (Designation of Technical Document Review Body, Etc.) (1) The Minister of Food and Drug Safety may, for assessment of conformity of technical documents, etc., to be submitted pursuant to Article 6 Paragraph (5), designate a professional review body (hereinafter "technical document review body") to perform the duties related to the review.

(2) A party, seeking to become designated as a technical document review body, shall meet the designation standards, such as hire of professional workforce needed for review, etc. and apply to the Minister of Food and Drug Safety .

(3) A technical document review body, designated pursuant to Paragraph (1), when reviewing technical documents, shall comply with the specifics set forth by the Decree of Prime Minister, such as preparation and issuance of notice of the result of technical document review and retention of records pertaining to that technical document review.

(4) Matters concerning the specific standards, procedures and methods, etc. for designation of a technical document review body shall be set forth by the Decree of Prime Minister.
[Newly enacted on December 29, 2015]
[Enforcement Date : December 30, 2016] Article 6-4

Article 7 (Conditional Approval, Etc.) (1) The Minister of Food and Drug Safety, when issuing a manufacturing business approval, a manufacturing approval or a manufacturing certification, or receiving a report to manufacture, may license, certify or receive the reports, on condition that the applicant secures, within a specific time period, the facilities and the manufacturing and quality management system pursuant to Article 6 Paragraph (4). <Amended on March 23, 2013; January 28, 2015>

(2) Matters necessary for the conditional approval, conditional certification or conditional report, etc., pursuant to Paragraph (1) shall be set forth by the Decree of Prime Minister.<Amended on March 23, 2013; January 28, 2015>
[Enforcement Date: Jan. 29, 2016] Of the amendments in Article 7 Paragraph (1), the matters concerning the manufacturing and quality management system.

Article 8 (Re-Examination of Newly Developed Medical Devices, Etc.) (1) In the event an product category or an product item, for which a manufacturing license is sought pursuant to Article 6 Paragraph (2), falls under any of the following Subparagraphs, the Minister of Food and Drug Safety may order, at the time of granting the license, the applicant to receive a re-examination for safety and efficacy of the product category or the product item within a specified time after it is marketed and may order the applicant to take the necessary measures as a result of the re-examination: <Amended on March 23, 2013; January 28, 2015>

1. A medical device, which is newly developed and is essentially different, in terms of the mechanism of action, functions, or intended use, from any item category or item, which has already been licensed, certified, or reported; or

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2. An orphan medical device, which targets a small number of patients in the domestic country, has special benefits and value in its intended use, and is designated by the Minister of Food and Drug Safety .
(2) A manufacturer of a medical device, for which a post-market re-examination has been ordered pursuant to Paragraph (1), shall apply for the re-examination within a time period designated by the Minister of Food and Drug Safety, which shall be from four (4) to seven (7) years from the date of the manufacturing license of the product category or the product item. In such cases, the application shall be accompanied by the record of use, reports of side effects and other data designated by the Decree of Prime Minister. <Amended on March 23, 2013>
(3) The matters related to the methods/procedures/time of the re-examination pursuant to Paragraphs (1) and (2) shall be set forth by the Decree of Prime Minister.<Amended on March 23, 2013>
Article 9 (Re-Evaluation) (1) Among the medical devices, for which a manufacturing approval or certification has been approved, or a report to manufacture has been filed pursuant to Article 6 Paragraph (2), as for those devices, for which re-review of safety and efficacy is deemed necessary by the Minister of Food and Drug Safety, the Minister may conduct re-evaluation and order necessary measures as a result of the re-evaluation. <Amended on March 23, 2013; January 28, 2015>
(2) The matters necessary concerning methods, procedures and standards of the re-evaluation pursuant to Paragraph (1) shall be set forth by the Decree of Prime Minister.<Amended on March 23, 2013>
Article 10 (Approval of Clinical Trial Plans, Etc.) (1) A person seeking to conduct a clinical trial using a medical device shall prepare a plan for the proposed clinical trial and obtain approval from the Minister of Food and Drug Safety, and the same shall apply to any revisions of the plan: provided that the foregoing does not apply to investigations designated by the Decree of Prime Minister, such as, clinical studies on marketed medical devices to observe the clinical effects of the approved features of those devices. <Amended on March 23, 2013>
(2) A person seeking to manufacture/import a medical device for clinical trial as approved pursuant to Paragraph (1) shall manufacture or import medical devices which have been manufactured in a manufacturing facility that meets the standards set forth by the Decree of Prime Minister. In such cases, notwithstanding Article 6 Paragraph (2) and Article 15 Paragraph (2), these medical devices may be manufactured or imported without an approval, a certification, or a report.<Amended on March 23, 2013; January 28, 2015>
(3) The Minister of Food and Drug Safety may designate a medical institution as a clinical trial institution, provided that the medical institution is established

under the Medical Services Act and is equipped with the facilities/the human resources and the equipment needed for clinical trials. <Amended on March 23, 2013>

(4) A person seeking to conduct a clinical trial pursuant to Paragraph (1) shall comply with each of the following Subparagraph: <Amended on March 23, 2013>

1. A clinical trial shall be conducted at a clinical trial institution designated under Paragraph (3);

2. Persons who are institutionalized in a facility designated by the Decree of Prime Minister, such as, social welfare facility, etc. , (hereinafter referred to as "institutionalized persons" in this Subparagraph) shall not be selected as subjects of clinical trials. The institutionalized persons, however, may be selected as subjects if it is inevitable, given the nature of the clinical trial, to select them as subjects and if the standards set forth by the Decree of Prime Minister are met.

3. Details of the clinical trial, potential harms to the health of the subjects during the trial, details of the compensations, procedures of the compensation, etc. shall be explained to the subjects and consent shall be obtained from the subjects.

(5) A clinical trial institution, designated pursuant to Paragraph (3) shall, when it conducts a clinical trial, comply with the details designated by the Decree of Prime Minister, such as, preparation and issuance of a report of clinical trial results, retention of records related to the clinical trial. <Amended on March 23, 2013>

(6) If the Minister of Food and Drug Safety deems that the clinical trial pursuant to Paragraph (1) poses, or is likely to pose, a serious risk to national health and hygiene and falls under any of the following Subparagraphs, he/she may change/revoke the clinical trial or take other necessary measures. However, the foregoing shall not apply to a case of Subparagraphs 4 or 5, where the safety, rights, or welfare of the subjects or the validity of the trial is not negatively impacted; or where the violation has not been repetitive or deliberate:<Amended on March 23, 2013; December 29, 2015>

1. A subject of the clinical trial may be exposed to an unanticipated and serious disease or damage;

2. A medical device for the clinical trial was provided for commercial purposes other than for the clinical trial ;

3. A medical device for the clinical trial is found to be ineffective;

4. Details of the approval or the amended approval pursuant to Paragraph (1) were violated; and

5. Other standards for management of clinical trial s of medical devices, set forth by the Decree of Prime Minister, were violated.

(7) Other than those set forth in Paragraphs (1) through (6), matters to be included in a clinical trial plan shall be designated by the Decree of Prime Minister and may include content, time, and method of consent by the subjects; standards for performing a clinical trial; standards and procedures for designation of a clinical trial institution; and matters related to Good Clinical Practices, etc.. <Amended on March 23, 2013; December 29, 2015>

Article 10-2 (Designation of Non-Clinical Test Institution, Etc.) (1) An institution seeking to conduct a non-clinical test on non-human subjects for the purposes of verification and validation of medical devices (hereinafter referred to as "non-clinical test institution") shall obtain designation by the Minister of Food and Drug Safety. In the event any modification is proposed regarding the specifics of the designation, the institution shall seek modified designation by the Minister of Food and Drug Safety pursuant to the Decree of Prime Minister.

(2) An institution seeking a designation as a non-clinical test institution pursuant to Paragraph (1) shall be equipped with facilities/professional workforce and equipment needed for the non-clinical test of medical devices, as designated by the Decree of Prime Minister.

(3) A non-clinical test institution, when it conducts non-clinical tests pursuant to Paragraph (1), shall comply with the details designated by the Decree of Prime Minister, such as, preparation and issuance of a non-clinical test report, retention of records related to non-clinical tests.

(4) Other than those set forth in Paragraphs (1) through (3), standards, procedures, and methods for designating a non-clinical test institution, and matters related to the operation, management, etc. of a non-clinical test institution shall be set forth by the Decree of Prime Minister.
[Newly enacted on December 29, 2015]
[Enforcement Date: December 30, 2016] Article 10-2

Article 11 (Pre-application Review of Manufacturing Approval, Report to Manufacture, Etc.) (1) A person seeking to obtain a manufacturing approval or certification, or to file a report for manufacture pursuant to Article 6 Paragraph (2); or a person seeking to conduct a clinical trial pursuant to Article 10, may request the Minister of Food and Drug Safety to review, in advance, the materials needed for approval, certification, reporting, licensing, etc. <Amended on March 23, 2013; January 28, 2015>

(2) The Minister of Food and Drug Safety, upon receiving the request for review pursuant to Paragraph (1), shall conduct the review and provide to the applicant a written notice of the results. <Amended on March 23, 2013>

(3) The Minister of Food and Drug Safety, when making decisions regarding approval, certification, report, licensing pursuant to Article 6 Paragraph (2) and

Article 10, shall consider the result of the review, as specified in Paragraph (2). <Amended on March 23, 2013; January. 28, 2015>

(4) Matters related to eligibility, scope, procedures, methods, etc. of the preliminary review specified in Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

Article 12 (Amendment of Approval, Etc.) (1) In the event of any changes, such as location, in the specifics of the license or certification granted or of the report to manufacture made pursuant to the main text of Article 6 Paragraph (1) or Paragraphs (2) and (5), a manufacturer shall obtain an approval or certification for such change or file an amended report to the Minister of Food and Drug Safety. <Amended on March 23, 2013; January. 28, 2014; January 28, 2015>

(2) The matters necessary concerning the procedures and standards for amending approvals, certifications, or reportings pursuant to Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013; January 28, 2015>

Article 13 (Obligations of Manufacturers) (1) A manufacturer shall be responsible for facility maintenance,manufacturing, and quality management systems pursuant to Article 6 Paragraph (4), and for complying with other matters related to production management, such as, self-test, etc. set forth by the Decree of Prime Minister. <Amended on March 23, 2013; January 28, 2015>

(2) A manufacturer shall report to the Minister of Health and Welfare and the Minister of Food and Drug Safety on the production performance of medical devices, as designated by the Decree of Prime Minister. <Amended on March 23, 2013>

(3) A manufacturer (including a representative or a director or any other employee of an incorporated manufacturer; and employees of non-incorporated manufacturer) shall not provide money, goods, benefits, labor, entertainment, or any other economic benefits (hereinafter referred to as "economic benefits, etc.") to any medical professionals, founders (including a representative or a director or any other employee of an incorporated manufacturer. The same shall apply in this Article) or employees of a medical institution, nor have any medical personnel, founders or employees of a medical institution obtain economic benefits, etc., for the purpose of promoting sales, such as, adoption of a medical device/induction of use/continuation of business, etc. Provided the foregoing does not apply to sampling, sponsoring academic conferences, supporting clinical trials, organizing product seminars, offering discounts as per the payment terms/conditions, or post-market surveillance (hereinafter referred to as "act of sampling, etc."), which fall under the scope of economic benefits defined by the Decree of Ministry of Health and Welfare, set forth in consultation with the Minister of Food and Drug Safety. <Amended on March 23, 2013; December 29, 2015>

(4) A manufacturer shall not interfere with its quality manager performing his/her duties; and shall not refuse, without justifiable reasons, any requests by the quality manager needed for performing his/her duties.<Newly enacted on January 28, 2014>
[Enforcement Date: January 29, 2016] Of the amended provisions of Article 13 Paragraph (1), matters related to manufacturing and quality management system.

Article 13-2 (Submission of Outlay Report Regarding Details of Economic Benefits, Etc.) (1) A manufacturer shall prepare an outlay report detailing the economic benefits, etc. provided to medical professionals and/or medical institution founders or employees of medical institutions within three (3) months after a fiscal year ends and shall retain such report and relevant account books and evidence documents for five (5) years, as set forth by the Decree of the Minister of Health and Welfare.

(2) When deemed necessary by the Minister of Health and Welfare, the Minister may request submission of the outlay reports, account books and evidence documents provided by Paragraph 1. In the case, the manufacturer must respond to such request unless he/she has justifiable reasons. [Newly enacted on December 2, 2016]

Article 14 (Report of Permanent/Temporary Closure of Business, Etc.)
When a manufacturer, in the event of permanent/temporary closure of his/her manufacturing facility, re-opening of operation of a suspended facility, or any changes in other matters prescribed by the Decree of Prime Minister, shall report such fact to the Minister of Food and Drug Safety within thirty (30) days from the date of the permanent or temporary closure or re-opening or change: provided that the above shall not be applicable to suspension of business for a period less than one (1) month. <Amended on March 23, 2013>

SECTION 2 Import Business

Article 15 (Import Business License, Etc.) (1) A person seeking to engage in a business of importing medical devices shall obtain an import business license from the Minister of Food and Drug Safety. <Amended on March 23, 2013>

(2) A holder of import business license granted pursuant to Paragraph (1) (hereinafter referred to as "importer") shall obtain an import license or import certification, or file a report for importation for the medical devices that he/she seeks to import, according to the classifications provided by each of the following Subparagraphs: <Amended on March 23, 2013; January 28, 2015>

1. For medical devices whose potential risk to human body is low and are thus unlikely to harm human life or health even in the event of failure or malfunction and are designated and publicly notified by the Minister of Food and Drug Safety: import approval, import certification, or import report for each product category; or

2. For medical devices other than those specified in Subparagraph 1: import approval, import certification, or report for import is required for each product item.

(3) When applying for an import business license pursuant to Paragraph (1), the applicant shall submit an application for one or more import approval or certification, or file an import report for one or more item, pursuant to Paragraph (2). <Amended on January 28, 2015>

(4) A person seeking to obtain an import business license pursuant to Paragraph (1) or a person seeking to obtain an import approval or certification, or to file an import report pursuant to Paragraph (2) shall be equipped with the facilities necessary for conducting quality inspections and manufacturing and quality management system, as prescribed by the Decree of Prime Minister, before filing the applications or making the report: provided that the foregoing shall not apply to the cases designated by the Decree of Prime Minister, such as subcontracting quality control tests. <Amended on March 23, 2013; January 28, 2015>

(5) For a medical device, which is combined or composited with a drug or a quasi-drug and whose main function is equivalent to that of a drug or a quasi-drug, in the event a license has been granted or a report has been filed already, pursuant to Article 42 Paragraph (1) of the Pharmaceutical Affairs Act, the import license or certification or import shall be deemed already granted or an import report shall be deemed already accepted pursuant to Paragraph (2). <Amended on January 28, 2015>

(6) The proviso to Article 6 paragraph (1), Article 6 paragraph (5)/paragraph (7)/and paragraph (8), Article 6-2, Article 6-3, Article 7 through Article 9, Article 11 through Article 13, Article13-2, and Article 14 shall apply mutatis mutandis to the medical devices imported pursuant to Paragraphs (1) through (5) and the importers of such medical devices. In such cases, the term "manufacturing" shall be construed as "import," "manufacturing business license" as "import business license," "manufacturing approval" as "import approval", "manufacturing certification" as "import certification", " report to manufacture" as "report to import" "production management" as "import management," and "manufacturer" as "importer," respectively. <Amended on January 28, 2014; January 28, 2015; December 2, 2016;>

[Enforcement Date: January 29, 2016] Matters concerning manufacturing and quality management system among the amended provisions of Article 15

Paragraph (4).

SECTION 3 Repair Business

Article 16 (Report of Repair Business) (1) A person seeking to engage in a business of repairing medical devices (hereinafter referred to as "repairer") shall file a report of his/her repair business to the Minister of Food and Drug Safety, as prescribed by the Decree of Prime Minister: provided that such a report is not needed if a person, who has obtained a manufacturing license or certification or has filed a report for manufacture pursuant to Article 6 Paragraph (2), or who has obtained an import license/import certification/has filed a report for import pursuant to Article 15 Paragraph (2), performs a repair of the medical device manufactured or imported by himself/herself. <Amended no March 23, 2013; January 28, 2015>

(2) A person seeking to file a report of his/her repair business pursuant to Paragraph (1) (including a person seeking to repair the medical devices imported by himself/herself pursuant to the proviso to the said Paragraph) shall be equipped with facilities and quality management system, as prescribed by the Decree of Prime Minister: provided that the foregoing shall not apply to cases designated by the Decree of Prime Minister, such as subcontracting quality control tests. <Amended on March 23, 2013>

(3) The scope of the items, standards and conditions necessary for acceptance of the report of repair business under Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

(4) The proviso to Article 6 Paragraph (1), and Article 12, Article 13, and Article 14 shall apply mutatis mutandis to the report pursuant to Paragraph (1). In such cases, the term "manufacture" shall be construed as "repair," "manufacturing business license" as "report of repair business," "production management" as "repair management," and "manufacturer" as "repairer," respectively.

SECTION 4 Sales Business and Rental Business

Article 17 (Report of Sales Business, Etc.) (1) A person seeking to engage in the business of selling medical devices (hereinafter referred to as "seller") or a person seeking to engage in the business of leasing medical devices (hereinafter referred to as "lessor") shall file a report of each place of his/her sale or rental business to governors of special self-governing provinces, or heads of Si/Gun/Gu (which shall refer to the head of self-governing Gu; the same shall apply hereinafter) having jurisdiction over that place of business, as set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

(2) In any of the following cases, the report pursuant to Paragraph (1) shall not be required: <Amended on March 23, 2013>

1. Where a manufacturer or an importer of medical devices sells or leases the medical devices that he/she manufactured or imported to a medical device

handler;

2. Where a person who filed a report of the sales business under Paragraph (1) engages in a rental business;

3. Where a person who opened a pharmacy or is a drug wholesaler sells or leases medical devices; or

4. Where a person sells contraception devices or medical devices for self-diagnosis in places other than medical institutions, as prescribed by the Decree of Prime Minister.

(3) As for the report pursuant to Paragraph (1), Article 6 Paragraph (1) Subparagraphs 2/4/5, and Article 12 to Article 14 shall apply mutatis mutandis. In such cases, the term "manufacture" shall be construed as "sale or lease," "manufacturing business license" as "report of a sales business or a rental business," and "manufacturer" as "seller or lessor" respectively.

Article 18 (Obligations of sellers, Etc.) (1) A person qualified to sell or lease medical devices pursuant to this Act shall comply with the method of ensuring quality of the medical devices at his/her place of business and with other instructions for keeping commercial trade in order, as prescribed by the Presidential Decree. <Amended on March 23, 2013>

(2) A seller/lessor (including a representative or a director or any other employee of an incorporated business; and employees of non-incorporated business) shall not provide economic benefits, etc. to any medical personnel, founders (including a representative or a director or any other employee of an incorporated manufacturer), employee of a medical institution for the purpose of promoting sales or lease, such as, adoption of a medical device, induction of use, continuation of deal, etc.: Provided the foregoing shall not apply to providing samples, etc. which falls under the scope of economic benefits defined by the Decree of Ministry of Health and Welfare in consultation with the Minister of Food and Drug Safety. <Amended on March 23, 2013; December 29, 2015>

(3) For seller/lessor under Paragraph (2), Article 13-2 shall apply mutatis mutandis. In such case, the "manufacturer" shall be deemed as the "seller or lessor".<Newly enacted on December 2, 2016>
[Enforcement Date : June 3, 2017] Article 18 Paragraph (3)

CHAPTER IV HANDLING, ETC. OF MEDICAL DEVICES

SECTION 1 Standards

Article 19 (Standard Specifications)
The Minister of Food and Drug Safety may set forth standard specifications including scope of application, shape or structure, test specifications, and labeling,

etc. for medical devices, for which the quality standards are deemed necessary. <Amended on March 23, 2013>
SECTION 2 Labeling and Advertisements
Article 20 (Labeling on Container, Etc.) A container or an outer package of a medical device shall have each of the following descriptions, provided that the above shall not apply to a container or an outer package designated otherwise by the Decree of Prime Minister: <Amended on March 23, 2013; January 28, 2015; December 29, 2015; December 2, 2016;>
1. Name and address of the manufacturer or the importer;
2. If imported, the manufacturer (name of the country of manufacture and the manufacturer);
3. Approval (certification or report) number and name (product name, title of product group and model name). Product name is applicable only when available.
4. The lot number and the date of manufacture (expiry date, if it exists, may be stated in lieu of the date of manufacture);
5. Weight or packing unit;
6. The mark of "medical device"; and
7. If for single-use only, the mark of “single-use only" and "do not re-use."
8. Medical device standard code set forth by the Minister of Food and Drug Safety in consultation with the Minister of Health and Welfare
Article 21 (Labeling on Outer Package, Etc.) In the event the labeling on a container or an outer package of a medical device, as per Article 20, is covered by an outer container or package and is unreadable, the same information shall be also indicated on the outer container or package.
Article 22 (Information in Package Insert) (1) A package insert of a medical device shall include the information provided by the following Subparagraphs: <Amended on March 23, 2013>
1. Instructions for use and precautions;
2. Instructions for maintenance and inspection, if maintenance checks are necessary;
3. Information designated by the Minister of Food and Drug Safety pursuant to Article 19; and

Medical Device Act (Act No. 14330, December 2, 2016)
4. Other information designated by the Decree of Prime Minister.
(2) The package insert under Paragraph (1) may be furnished in the form of electronic media such as diskette or CD, or a printed manual.
Article 23 (Precautions for Labeling) Information specified in Article 20 through Article 22 shall be indicated at a place more noticeable than other texts, articles, pictures or design, and shall be written in accurate Korean language, using terminologies that are easy to read and understand, as prescribed by the Decree of Prime Minister. <Amended on March 23, 2013>
Article 24 (Prohibition, Etc. of Labeling and Advertisements) (1) None of the information provided by the following Subparagraphs shall be indicated or written on a container, an outer package, packing material, or a package insert of a medical device: <Amended on January 28, 2015>
1. False or misleading information;
2. Performance, efficacy, or effect, which are not approved or certified, or are different from the report filed pursuant to Article 6 Paragraph (2) or Article 15 Paragraph (2); and
3. Instructions for use or use period that may cause harm health or hygiene.
(2) No one shall advertise the information provided by any of the following Subparagraphs in connection with advertisements of medical devices: <Amended on March 23, 2013; January 28, 2015>
1. A false or exaggerative advertisement of the name, method of manufacture, performance, efficacy, effect, or mechanism of a medical device;
2. An advertisement that uses an article, which may mislead to thinking that a medical doctor, a dentist, an oriental medicine doctor, veterinarian or any other person guarantee, recommend, officially recognize, guide, or acknowledge the performance, efficacy or effect of a medical device, or is using a medical device;
3. An advertisement that uses articles, photographs, designs, which suggests the performance, efficacy or effect of a medical device, or uses other suggestive means;
4. An advertisement that suggests abortion with respect to a medical device, or uses obscene documents or designs;
5. An advertisement related to the name, method of manufacture, performance, efficacy or effect of a medical device that are not approved or certified, or are different from the report filed pursuant to Article 6 Paragraph (2) or Article 15 Paragraph (2): provided that medical devices falling under the proviso to Article

26 Paragraph (1) may be advertised in accordance with the procedures, methods, and scope, specified and publicly notified by the Minister of Food and Drug Safety; or

6. An advertisement that was not deliberated or is different from the content deliberated pursuant to Article 25 Paragraph (1).

(3) Necessary matters related to the scope of descriptions, labeling, and advertisements of medical devices pursuant to Paragraphs (1) and (2) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

Article 25 (Deliberation of Advertisements) (1) A person who intends to advertise a medical device shall undergo a deliberation in advance with the Minister of Food and Drug Safety in accordance with the standards/methods and procedures of the deliberation set forth by the Minister of Food and Drug Safety. <Amended on March 23, 2013>

(2) The Minister of Food and Drug Safety may entrust the work of deliberation under Paragraph (1) to an organization designated by the Decree of Prime Minister. <Amended on March 23, 2013>

SECTION 3 Handling

Article 26 (General Prohibitions) (1) No one shall repair, sell, lease, provide, or use any unapproved, uncertified, or unreported medical device pursuant to Article 6 Paragraph (2) or Article 15 Paragraph (2), nor manufacture, import, repair, store or display any such unapproved, uncertified, or unreported medical device with an intent to sale, lease, provide, or use it. Provided, the foregoing shall not apply to medical device that is manufactured, imported, stored, or displayed, in accordance with the procedures and methods set forth by the Decree of Prime Minister, for the purpose of showcasing it in a fair, exhibition, exposition. <Amended on March 23, 2013; January 28, 2015>

(2) No one shall manufacture, import, sell or lease medical devices falling under any of the cases provided by the following Subparagraphs: <Amended on March 23, 2013; January 28, 2015>

1. A medical device, which is inconsistent with the details of its approval, certification or report, granted or filed pursuant to Article 6 Paragraph (2), Article 12, or Article 15 Paragraph (2)/Paragraph (6);

2. A medical device, which is, entirely or partly, unclean or contaminated by pathogenic microbes, or includes any deteriorated or decayed substances; or

3. A medical device ordered to destroy, no longer used, or with a canceled approval, etc., by the Minister of Food and Drug Safety or governors of special self-governing provinces, or heads of Si/Gun/Gu pursuant to Article 34 through Article 36 as it has caused or is likely to cause harm to public health

(3) A repairer, when repairing a medical device, shall not alter its performance, structure, electrical rating, external appearance, dimensions, etc., that have been approved, certified, or reported pursuant to Article 6 Paragraph (2), Article 12, or Article 15 Paragraph (2)/Paragraph (6). <Amended on January 28, 2015>

(4) No person, when using a medical device, shall alter or remodel the device to be different from its approval, certification, or report, granted or filed pursuant to Article 6 Paragraph (2), Article 12, or Article 15 Paragraph (2)/Paragraph (6). Provided, the foregoing shall not apply to any of the cases provided by the following Subparagraphs: <Amended on March 23, 2013; January 28, 2015>

1. A medical device, which is designated by the Decree of Prime Minister, has been manufactured or imported by its manufacturer or importer, and has been altered or remodeled in accordance with an amended license, an amended certification, or an amended report, granted or filed pursuant to Article 12 or Article 15 Paragraph (6); or

2. A medical device altered or remodeled by an individual, to the extent not affecting the safety and efficacy of the device, for his/her convenience of use.

(5) No repairer/seller, or lessor shall repair, sellsale, or lease; or store/display for the purpose of repairing/selling/leasing; any of the following medical devices: <Amended on January 28, 2015>

1. A medical device, which is inconsistent with the details of its approval, certification or report, granted or filed pursuant to Article 6 Paragraph (2), Article 12, Article 15 Paragraph (2)/(6), or Article 16 Paragraph (1); or

2. A medical device, which is in violation of Article 24 Paragraph (1).

(6) A founder of a medical institution shall not use in a clinical trial a medical device that has not been approved by the Minister of Food and Drug Safety for use in a clinical trial pursuant to Article 10. <Amended on March 23, 2013>

(7) No one shall make any indication, on an outer package/package, or package insert of any non-medical device, which may mislead a reader to think that such a product has a function, efficacy, or effect similar to that of a medical device; nor shall sell or lease; or store or display for the purpose of sale or lease such product bearing misleading information or advertisement.

Article 27 (Testing) (1) The Minister of Food and Drug Safety may have a medical device tested on safety, performance, etc. before granting an approval or certification or before accepting a report pursuant to Article 6 Paragraph (2), Article 12, or Article 15 Paragraph (2)/(6) or after ordering an inspection pursuant to Article 33. <Amended on March 23, 2013; January 28, 2015>

(2) The Minister of Food and Drug Safety may require testing under Paragraph (1) to be conducted at a testing institution of medical devices, designated by the Minister of Food and Drug Safety pursuant to the Act on Testing and Inspection in the Food and Drug Industry Article 6 Paragraph (2) Item 4. <Amended on March 23, 2013; July 30, 2013>

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Title changed on July 30, 2013

Article 28 (Designation, Etc. of Quality Management Inspection Body) (1) The Minister of Food and Drug Safety may inspect facilities and manufacturing and quality management system to verify the matters provided by the following Subparagraphs: <Amended on March 23, 2013; January 28, 2015>

1. Whether a person seeking a manufacturing business license pursuant to Article 6 Paragraph (1) or a person seeking a manufacturing approval or certification, or a report for manufacture pursuant to Article 6 Paragraph (2) is equipped with facilities and manufacturing and quality management system pursuant to the main text of Article 6 Paragraph (4);

2. Whether a manufacturer maintains its facilities and manufacturing and quality management system pursuant to Article 13 Paragraph (1) and obey other obligations concerning production management;

3. Whether a person seeking an import business license pursuant to Article 15 Paragraph (1) or a person seeking an import approval or certification, or a report for import pursuant to Article 15 Paragraph (2) is equipped with facilities and manufacturing and quality management system with respect to the manufacturing site of imported medical devices pursuant to the main text of Article 15 Paragraph (4); and

4. Whether an importer maintains facilities and the manufacturing and quality management system with respect to the manufacturing site of imported medical devices under Article 13 Paragraph (1) applied mutatis mutandis pursuant to Article 15 Paragraph (6), and obey other obligations concerning import management.

(2) The Minister of Food and Drug Safety may designate an organization to conduct inspection on facilities and manufacturing and quality management

systems under Paragraph (1) (hereinafter referred to as "quality management inspection body"). <Amended on March 23, 2013; January 28, 2015>

(3) A person seeking to be designated as a quality management inspection body pursuant to Paragraph (2) shall have professional workforce needed to inspect facilities and manufacturing and quality management systems. <Amended on January 28, 2015>

(4) The quality management inspection body designated as per Paragraph (2) shall obey the matters provided by the Decree of Prime Minister, such as, preparation and submission of reports of quality management inspection results to the Minister of Food and Drug Safety, keeping- records related to inspections on facilities and quality management systems, etc. after inspecting facilities and manufacturing and quality management systems. <Amended on March 23, 2013; January 28, 2015>

(5) Other than those specified in Paragraphs (1) through (4), matters related to the requirements, procedures/methods of designating quality management inspection body shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>
[Enforcement Date: January 29, 2016] Of the amendments in Article 28 Paragraphs (1) through (4), matters concerning manufacturing and quality management systems.

CHAPTER V Management

Article 29 (Medical Device Subject to Tracking) (1) The Minister of Food and Drug Safety may select for separate management among any of the medical devices provided by the following Subparagraphs those devices that need to know location (hereinafter referred to as "medical device subject to tracking") as they could be fatal to human body potentially during use with side effects or defects: <Amended on March 23, 2013>

1. A medical device that is inserted into a human body for one (1) year or longer; or

2. A life-supporting medical device that can be used in places outside of medical institutions;

(2) Matters related to the criteria for designation or management of the medical devices subject to tracking, specified in Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

Article 30 (Preparation, Retention, Etc. of Records) (1) A manufacturer, importer, seller, lessor, or repairer of a medical device subject to tracking (hereafter referred to as "handler" in this Article), a founder of a medical institution that handles medical device subject to tracking and medical doctor, dentist, oriental medicine doctor, etc. who work in such medical institution (hereinafter referred to as "user" in this Article) shall prepare and retain the records pertaining to medical devices subject to tracking as provided by the following Subparagraphs and submit such records to the Minister of Food and Drug Safety as

prescribed by the Decree of Prime Minister: <Amended on December 29 2015>

1. Handlers: the records of manufacture, sale (including purchase), lease or repair of the medical devices subject to tracking; and

2. Users: the records enabling the tracing of the medical devices subject to tracking down to the patients who use them.

(2) A handler or a user may not refuse the orders of the Minister of Food and Drug Safety, such as, requests for submission of information, etc., without justifiable reasons.<Amended on March 23, 2013>

(3) Matters necessary for preparation and retention of the records pursuant to Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

Article 31 (Management of Side Effects) (1) A medical device handler shall immediately report such information to the Minister of Food and Drug Safety in the event of recognizing an occurrence or a likelihood of death or a serious side effect on human body during use of medical device and shall retain the records thereof. <Amended on March 23, 2013>

(2) A manufacturer, importer, repairer, seller, or lessor of a medical device (hereinafter referred to as "manufacturer, etc.") shall recall or take measures needed to recall a device without delay in the event of becoming aware that the medical device, due to its quality defect, etc., has caused, or is likely to cause, harm to human body. In such cases, the manufacturer or importer shall establish a recall plan considering side effects on human body, etc., as prescribed by the Decree of Prime Minister, and report such plan in advance to the Minister of Food and Drug Safety. <Amended on March 23, 2013>

(3) The Minister of Food and Drug Safety, upon receipt of a medical device recall plan as per the latter part of Paragraph (2), may order the manufacturer or importer to announce such plan to the public.<Amended on March 23, 2013>

(4) As a result of the report submitted pursuant to Paragraph (1) or the latter part of Paragraph (2) pertaining to a medical device that has caused or is deemed likely to cause death or a serious side effect on human body, the Minister of Food and Drug Safety shall notify the founders of the medical institutions that used the device about the side effect and the recall plan, etc. of the device. <Newly enacted on January 28, 2015>

(5) The founder of a medical institution, upon receipt of the notification pursuant to Paragraph (4), shall notify via visit, mail, telephone, electronic mail, or fax, etc., the patients who have used the medical device for their treatments about the side effect and the recall plan, etc. In such cases, the founder shall submit to the Minister of Food and Drug Safety an evidence of such notification made to the patients. <Newly enacted on January 28, 2015>

(6) The Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu may reduce or exempt an administrative

disposition provided by Article 36 on the manufacturer, etc. who have faithfully executed a recall or measures needed for recall pursuant to Paragraph (2), as prescribed by the Decree of Prime Minister. <Amended on March 23, 2013; January 28, 2015>
(7) Matters related to the procedures and content of side effect reporting under Paragraph (1), the standards, procedures/methods of recall, and the contents of a recall plan under Paragraph (2), the method of public announcement pursuant to Paragraph (3), the criteria/procedures/method of notification under Paragraph (4), and the content/procedures/method of notification and the procedures/method of evidence submission under Paragraph (5) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013; January 28, 2015>
Article 31-2 (Report of Medical Device Supply Information, Etc.) (1) When a medical device manufacturer, importer, seller, or lessor has supplied medical devices to medical institutions, medical device sellers, or lessors, it shall report such supply information to the Minister of Food and Drug Safety as set forth by the Decree of Prime Minister in consultation with Minister of Health and Welfare.
(2) The Minister of Health and Welfare may request the Minister of Food and Drug Safety provide the information submitted pursuant to Paragraph (1).
(3) The Minister of Food and Drug Safety may organize and operate a consultation body consisting of employees of relevant organizations, such as, Ministry of Health and Welfare, etc., for the purpose of utilizing such information on distribution of medical devices.
Article 31-2 (Establishment of Medical Device Information Consolidation System, Etc.) (1) The Minister of Food and Drug Safety may establish and operate an electronic information processing system (hereinafter referred to as "Medical Device Information Consolidation System") for the purpose of recording and managing efficiently the information pertaining to medical devices from approval to manufacture, import, sales, and use.
(2) A manufacturer, etc. shall register the information necessary to the systematic and efficient management of medical devices that is provided by Paragraph (1), such as, medical device standard codes, information on medical devices, etc., with the Medical Device Information Consolidation System as set forth by the Decree of Prime Minister.
(3) A manufacturer, etc. shall obey the standards set forth by the Decree of Prime Minister (hereinafter referred to as "Standards of Medical Device Information Consolidation System") in their registration and management of the information provided by Paragraph (2).
(4) The Medical Device Information Consolidation System may use other information systems relevant to medical devices in electronic connection.
(5) Other matters necessary to the establishment, operation, management, etc., of the Medical Device Information Consolidation System shall be set forth by the Decree of Prime Minister.

Article 31-4 (Designation/Operation of Medical Device Information Consolidation Center, Etc.) (1) The Minister of Food and Drug Safety may designate according to the matters set forth by the Presidential Decree an expert institution or organization to be assigned to conducting the tasks of collecting, surveying, processing, using, or providing information on medical devices and of establishing, operating, etc. for the Medical Device Information Consolidation System provided by Article 31-3 (hereinafter referred to as "Medical Device Information Consolidation Center").

(2) The head of Medical Device Information Consolidation Center may request only when necessary national governments, local autonomous governments, public institutions, medical device handlers, etc. provide data or information relevant to the tasks specified in Paragraph (1), such as, verification of authenticity of the reported/submitted information. In the case, a person who has been was requested to provide data or information shall respond to such request unless he/she has justifiable reasons, and a fee for the use of the data provided to the Director of Medical Device Information Consolidation Center by such person shall be exempt.

(3) The Minister of Food and Drug Safety and the Minister of Health and Welfare may have the head of Medical Device Information Consolidation Center report of the status of medical device management.

(4) The Minister of Food and Drug Safety may provide the entire or partial expenses used to the Medical Device Information Consolidation Center.

(5) Matters necessary for the operation, etc. of the Medical Device Information Consolidation Center shall be set forth by the Decree of Prime Minister. <Newly enacted on December 2, 2016>

CHAPTER VI SUPERVISION

Article 32 (Reports and Inspections, Etc.) (1) The Minister of Health and Welfare, the Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu may have, when deemed necessary, medical device handlers, medical device technical document review bodies, clinical trial institutions, non-clinical test institutions, or quality management inspection organizations to provide necessary reports, or have relevant public officials to do the following activities provided by the following Subparagraphs: <Amended on March 23, 2013> [Enforcement Date: December 30, 2016] Article 32

1. Enter the premises of medical institutions, factories, warehouses, shops, or offices that handle medical device, the premises of medical device technical document review bodies, clinical trial institutions, non-clinical test institutions, or quality management inspection bodies, or any other places where medical devices are handled as part of business, inspect their facilities, relevant logbooks, documents, or other items, or ask questions to relevant persons; and

2. Take out a minimum quantity of medical devices that are suspicious of be falling under any of the Subparagraphs of Article 34 Paragraph (1) or medical devices needed for test or quality check.

(2) A public official who intends to enter a premise, conduct an inspection, ask questions, take out medical devices pursuant to Paragraph (1) shall carry and present to the relevant persons an evidence of his/her authority.

(3) Matters related to the scope and evidence of the authorities and duties of the public officials under Paragraphs (1) and (2) shall be set forth by the Decree of Prime Minister in consultation with the Minister of Health and Welfare. <Amended on March 23, 2013>

Article 33 (Inspection Orders)

The Minister of Food and Drug Safety may order a medical device handler to have a medical device tested by non-clinical test institution designated under Article 10-2 Paragraph (1) or by medical device testing or inspection institution designated by the Minister of Food and Drug Safety pursuant to Article 6 Paragraph (2) Subparagraph 4 of the Act on Testing and Inspection in the Food and Drug Industry, if the device is deemed to have potentials of causing harm to public health. <Amended on March 23, 2013; July 30, 2013; December 29, 2015>

[Enforcement Date: December 30, 2016] Article 33

Article 34 (Orders for Recall/Destroy and Public Announcement, Etc.) (1) To a medical device falling under any of the following Subparagraphs, the Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu may order, depending on the level of risk, a manufacturer, etc. to recall, destroy or other disposals in a manner that can prevent a harm to public hygiene, or make a public announcement of such fact: <Amended on March 23, 2013>

1. A medical device that has been sold, stored, displayed, manufactured or imported to violate Article 26; and

2. A medical device that is deemed to have potentials of causing serious damages or fatal effects on public health.

(2) If the order pursuant to Paragraph (1) is not executed, or if urgent for public health, the Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu may have relevant public officials destroy, boxing, seal, or take other necessary actions about that medical device. In such cases, Article 32 Paragraph (2) shall apply mutatis mutandis. <Amended on March 23, 2013>

(3) Matters related to the standards and methods, manner of public announcement, etc. of recall, destruciton, etc. corresponding to the level of risk of a medical device falling under Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

Medical Device Act (Act No. 14330, December 2, 2016)
Article 35 (Orders of Stop Using, Etc.) In the event a medical device is found to be nonconforming as a result of the test pursuant to Article 33, or have potentials of falling under any of the Subparagraphs of Article 34 Paragraph (1), the Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu may order a founder of a medical institution or a veterinary hospital to take necessary measures, i.e., stop using, repair, etc. <Amended on March 23, 2013>
Article 35-2 (Corrective Order) If a manufacturer did not prepare the outlay report as provided by Article 13-2 Paragraph (1) (including cases where Article 15 Paragraph (6) or Article 18 Paragraph (3) are applied mutatis mutandis) or fails to retain outlay reports, relevant logbooks, or evidence documents, the Minister of Health and Welfare may order for correction within a specified period of time. <Newly enacted on December 2, 2016>
Article 36 (Revocation of Approvals, Etc. and Suspension of Business Activities, Etc.) (1) In the event a manufacturer, etc. applies to any of the following Subparagraphs, an order of the cancel of approval or certification, of the closure of a place of business, of the ban on the manufacture, import, sale of the relevant product item or product category, or of the suspension of the entire or part of business activities up to one (1) year may be ordered by the Minister of Food and Drug Safety on manufacturers/importers or repairers, or by governors of special self-governing provinces, or heads of Si/Gun/Gu on sellers or lessors. Provided, the approval or certification shall be cancelled or the place of business shall be closed in cases of Subparagraphs (1), (22), or (23): <Amended on March 23, 2013; August 13, 2013; January 28, 2015; December 12, 2016;>
1. Where a manufacturer, etc. fell under any Subparagraph of Article 6 Paragraph (1) (for sellers and lessors, limited to Subparagraphs (2)/(4) or (5) of Article 6 Paragraph (1)). Provided, the foregoing shall not apply, if an successor has transferred his/her status as a manufacturer, etc. within six (6) months pursuant to Article 47 Paragraph (2);
2. Where a manufacturer, etc. manufactured or imported a medical device without obtaining an approval or certification, or without filing a report, to violate Article 6 Paragraph (2) or Article 15 Paragraph (2);
3. Where a manufacturer, etc. was not equipped with the facilities and the manufacturing and quality management system pursuant to the main texts of Article 6 Paragraph (4) and Article 15 Paragraph (4), or the facilities and the quality management system pursuant to the main text of Article 16 Paragraph (2);

Medical Device Act (Act No. 14330, December 2, 2016)
4. Where a manufacturer, etc. failed in implementing any of the conditions under Article 7 Paragraph (1);
5. Where a manufacturer, etc. does not receive a re-examination, does not take measures required by a re-examination, or is found to lack safety or efficacy as a result of a re-examination, to violate Article 8;
6. Where a manufacturer, etc. did not undergo re-evaluation, did not take necessary measures ordered as a result of re-evaluation, or has been determined not to be safe or effective as a result of a re-evaluation to violate Article 9;
7. Where a manufacturer, etc. manufactures a medical device, or imports a medical device that was manufactured, in a facility that is not in compliance with the standards to violate Article 10 Paragraph (2);
8. Where a manufacturer, etc. failed in amending approvals or certifications, or a report to violate Article 12 Paragraph (1) (including the cases where Article 15 Paragraph (6), Article 16 Paragraph (4), or Article 17 Paragraph (3) are applied mutatis mutandis);
9. Where a manufacturer, etc. did not obey his/her obligations pertaining to the manufacturing and quality management or to production management, import management, or repair management to violate Article 13 Paragraph (1) (including the cases where Article 15 Paragraph (6) or Article 16 Paragraph (4) are applied mutatis mutandis);
9-2. Where a manufacturer, etc. did not submit medical device production performance report, import report, etc. to violate Article 13 Paragraph (2) (including cases where Article 15 Paragraph (6) is applied mutatis mutandis)
10. Where a manufacturer, etc. provided economic benefits, etc., to violate Article 13 Paragraph (3) (including the cases where Article 15 Paragraph (6) are applied mutatis mutandis) or Article 18 Paragraph (2);
11. Where a manufacturer, etc. did not observe the requirements related to the maintenance of market order, etc., to violate Article 18 Paragraph (1);
12. Where a manufacturer, etc. did not observe the labeling requirements provided by Articles 20 through 23;
13. Where a manufacturer, etc. prints markings or writings on a container, an outer package, packing material, or a package insert of a medical device, to violate Article 24 Paragraphs (1) and (3);
14. Where a manufacturer, etc. advertised a medical device to violate Article 24 Paragraphs (2) and (3);
15. Where a manufacturer, etc. failed in recording or in retaining such records, or ignored an order of providing information, etc. violate Article 30;
16. Where a manufacturer, etc. failed in reporting an side effect or in retaining such records to violate Article 31 Paragraph (1);

Medical Device Act (Act No. 14330, December 2, 2016)
17. Where a manufacturer, etc. failed in implementing a recall, taking necessary actions to recall or reporting of a recall plan violate Article 31 Paragraph (2), or did not obey an order for announcement of a recall plan, to violate Article 31 Paragraph (3);
17-2. Where a manufacturer, etc. did not report or falsely reported information on the supplied medical devices violate Article 31-2 Paragraph (1);
17-3. Where a manufacturer, etc. did not register information with the Medical Device Information Consolidation System to violate Article 31-3 Paragraph (2), or did not comply with the Management Standards for the Medical Device Information Consolidation System to violate Paragraph 3 of the same Article
18. Where a manufacturer, etc. refused, obstructed, or evaded the entry into the premise, inspection, asking questions, or taking out samples by a relevant public official pursuant to Article 32 Paragraph (1);
19. Where a medical device has been determined to have caused or have potentials of causing harm to public health as a result of testing conducted pursuant to Article 32 or Article 33;
20. Where a manufacturer, etc. failed in following any order issued pursuant to Article 33, Article 34, or Article 35;
21. Where a manufacturer, etc. manufactured, imported, repaired, sold, or leased a medical device that has caused or has potentials of causing harm to public health or a medical device that is deemed to have no performance, efficacy or effect;
22. Where a manufacturer, etc. had no facility or place of business at the location approved or reported under this Act; or
23. Where a manufacturer, etc. continued his/her business during the period of business suspension.
(2) Notwithstanding Paragraph (1), in cases of Subparagraphs (5)/(6), if the manufacturer or the importer is not responsible for the status of the medical device, and if it is deemed that the purpose of the approval, certification or report can be achieved by changing raw materials, structure, etc., the only changes of such aspects may be ordered. <Amended on January 28, 2015>
(3) The Minister of Food and Drug Safety may also issue an administrative disposition pursuant to Paragraph (1), if an order for change under Paragraph (2) is not obeyed. <Amended on March 23, 2013>
(4) On the cases described in Paragraph (1) Subparagraph 18, the Minister of Health and Welfare may request the Minister of Food and Drug Safety to order the cancel of approval or certification, the closure of a place of business, the ban on manufacture, import, sale of the product item or product category, or the suspension of business. <Amended on March 23, 2013; January 28, 2015>

(5) The criteria for the administrative dispositions pursuant to Paragraphs (1) through (3) shall be set forth by the Decree of Prime Minister. <Newly enacted on March 23, 2013>

[Enforcement Date: January 29, 2016] Of the amendments of Article 36 Paragraph (1), matters concerning manufacture and quality management system.

Article 37 (Revocation of Designation, Etc.) (1) In the event a technical document review body, a clinical trial institution, a non-clinical test institution, or a quality management inspection body, designated pursuant to Article 6-4 Paragraph (1), Article 10 Paragraph (3), Article 10-2 Paragraph (1) or Article 28 Paragraph (2), falls under any of the following Subparagraphs, the Minister of Food and Drug Safety may revoke its designation or order a suspension of its business for a period of time not exceeding six (6) months. Provided, such designation shall be revoked in a case of Subparagraphs (1)/(2) or (5): <Amended on March 23, 2013; July 30, 2013; December 29, 2015>

1. Where a designation was obtained through false or other corruptive means;

2. Where, by intention or gross negligence, a false report of a technical document review result/clinical investigation result/non-clinical test results was prepared or issued, or a false report of a quality management inspection results was prepared or reported;

3. Where the requirements for designation under Article 6-4 Paragraph (2), Article 10 Paragraph (3), Article 10-2 Paragraph (2) or Article 28 Paragraph (3) are not maintained;

4. Where the requirements under Article 6-4 Paragraph (3), Article 10 Paragraph (5), Article 10-2 Paragraph (3) or Article 28 Paragraph (4) are not obeyed; or

5. Where business activities were undertaken during the period of suspension of business.

(2) Once revocation issued pursuant to Paragraph (1), the institution may not be re-designated for the three (3) years from the date of revocation.

(3) The criteria for the administrative dispositions pursuant to Paragraph (1) shall be set forth by the Decree of Prime Minister. <Amended on March 23, 2013>

Article 38 (Imposition of Administrative Sanction Fines) (1) In cases, where an order for business suspension is required under Article 36 Paragraph (1) or Paragraph (3), if such suspension is likely to cause significant inconvenience to the users of medical devices or jeopardizes public interest, the Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu may impose an administrative sanction fine not exceeding 50 million Won in lieu of the business suspension, as prescribed by the Presidential Decree. <Amended on March 23, 2013>

(2) Matters related to the types of violations subject to an administrative sanction fine under Paragraph (1), the amount of a fine according to the level of the

offensiveness, the method of collecting the fine, etc. shall be set forth by the Presidential Decree.

(3) The Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu may, if necessary for collection of administrative sanction fine, request in a letter describing the information provided by the following Subparagraphs the head of a competent tax authority provide information for taxation: <Amended on March 23, 2013>

1. Personal information of the taxpayer;

2. Purpose of using the information; and

3. Information on the revenues of the taxpayer for the basis of an administrative sanction fine.

(4) In the event a person fined under Paragraph (1) failed in paying the administrative sanction fine by the deadline, the Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu shall, pursuant to the Presidential Decree, revoke the imposition of the fine under Paragraph (1), and, instead, suspend the business pursuant to Article 36 Paragraph (1) or Paragraph (3), or collect the administrative sanction fine pursuant to the procedures for collection of delinquent national tax or as per the Act on the Collection, etc. of Local Non-Tax Revenues. Provided, if suspension of business under Article 36 Paragraphs (1) or (3) is impossible due to the permanent closure of business pursuant to Article 14, collection shall be pursued pursuant to the procedures for collection of delinquent national tax or as per Act on the Collection, etc. of Local Non-Tax Revenues. <Amended at on March 23, 2013; August 6, 2013>

(5) The administrative sanction fines collected pursuant to Paragraphs (1) and (4) shall belong to the national government or to the local autonomous government to which the collecting authority belongs.

Article 39 (Hearings)
The Minister of Food and Drug Safety, governors of special self-governing provinces, or heads of Si/Gun/Gu shall hold a hearing before issuing and administrative dispositions provided by any of the following Subparagraphs: <Amended on March 23, 2013; January. 28, 2015>

1. Revocation of approval or certification, closure of place of business, ban on manufacture, import, or sale of product item or category, or suspension of all or part of business pursuant to Article 36; or

2. Revocation of designation pursuant to Article 37.

Article 40 (Medical Device Surveillance Officer) (1) Medical device surveillance officers shall be appointed at the Ministry of Health and Welfare, the

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Ministry of Food and Drug Safety, special cities/metropolitan cities/provinces/special self-governing provinces and Si/Gun/Gu (Gu shall mean an autonomous Gu; the same shall apply hereinafter) in order to perform the duties of the relevant public officials pursuant to Article 32 Paragraph (1) and Article 34 Paragraph (2). <Amended on March 23, 2013>
(2) Medical device surveillance officers under Paragraph (1) shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, mayors of special cities/mayors of metropolitan cities/governors of provinces/ governors of special self-governing provinces, or heads of Si/Gun/Gu from among the public officials affiliated with the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, special cities/metropolitan cities/provinces/special self-governing provinces or Si/Gun/Gu. <Amended on March 23, 2013>
(3) Matters related to qualifications and appointment and scope of duties, etc. of the medical device surveillance officers in Paragraphs (1) and (2) shall be set forth by the Decree of Prime Minister in consultation with the Minister of Health and Welfare. <Amended on March 23, 2013>
Article 40- 2 (Consumer Medical Device Surveillance Officers) (1) The Minister of Food and Drug Safety, mayors of special cities/mayors of metropolitan cities/governors of provinces/ governor of special self-governing provinces, or heads of Si/Gun/Gu may, for management of safe medical devices, appoint a person who is knowledgeable about medical devices, a person who completed certain level of education or a member or an employee of an association or organization related to medical devices or a consumer organization registered under Article 29 of the Framework Act on Consumers and who is recommended by the head of the organization to consumer medical device surveillance officer.
(2) The duties of consumer surveillance officer of medical devices appointed pursuant to Paragraph (1) (hereinafter referred as "consumer medical device surveillance officer of ") shall be as follows:
1. Support the medical device surveillance officers pursuant to Article 40 Paragraph (1) monitoring, sampling, inspection of medical devices, etc.;
2. Report or provide relevant materials to the competent administrative authority in a case where a medical device in circulation does not comply with the labeling standard or violates regulation banning false or exaggerated advertisement; and
3. Other activities pertaining to the management of medical devices, designated by the Decree of Prime Minister.
(3) Consumer medical device surveillance officer shall not abuse his/her authority in performing duties set forth in each Subparagraph of Paragraph (2).

(4) The Minister of Food and Drug Safety, mayors of special cities/mayors of metropolitan cities/governors of provinces/ governors of special self-governing provinces, or heads of Si/Gun/Gu shall provide the consumer medical device surveillance officers appointed pursuant to Paragraph (1) with trainings needed to perform the duties as consumer medical device surveillance officer.

(5) The Minister of Food and Drug Safety, mayors of special cities/mayors of metropolitan cities/governors of provinces/ governors of special self-governing provinces, or heads of Si/Gun/Gu shall dismiss a consumer medical device surveillance officer who falls under any of the following Subparagraphs:

1. Where he/she retired or was dismissed from the organization that recommended him/her;

2. Where he/she did a wrongful act or abused his/her authority in relation to the duties specified in each Subparagraph of Paragraph (2); or

3. Where he/she can no longer perform duties due to reason, such as, disease, injury, etc.

(6) When a consumer medical device surveillance officer enters alone a business place of a medical device seller or lessor to perform his/her duties under Paragraph (2) Subparagraph 1, he/she shall obtain a prior approval from the Minister of Food and Drug Safety, mayors of special cities/mayors of metropolitan cities/governors of provinces/ governors of special self-governing provinces, or heads of Si/Gun/Gu.

(7) When a consumer medical device surveillance officer enters alone a business place of a medical device seller or lessor upon the approval provided by under Paragraph (6), he/she shall carry and present to the relevant persons the letter of approval and the evidence of his/her identification.

(8) Matters related to qualifications, scope of duties and training, etc. for consumer medical device surveillance officers shall be set forth by the Decree of Prime Minister.

(9) The Minister of Food and Drug Safety may subsidize entirely or partially expenses necessary to operating consumer medical device surveillance officers within budget available.

[Newly enacted on December 29, 2015.]

CHAPTER VII SUPPLEMENTARY PROVISIONS

Article 41 (Research and Development for Development of Medical Device Industry)

The Minister of Health and Welfare or the Minister of Food and Drug Safety may entrust to the Korea Health Industry Development Institute, pursuant to the Korea Health Industry Development Institute Act, research and development projects for establishing the infrastructure of quality evaluation of medical devices, supporting the standardization of specifications of medical devices, and promoting development of the medical device industry and may subsidize

the expenses necessary to such activities. <Amended on March 23, 2013>
Article 42 (Establishment of Medical Device Information and Technology Assistance Center) (1) The Medical Device Information and Technology Assistance Center (hereinafter referred to the "Center") shall be established for the purpose of providing comprehensive assistance for information and /technology regarding domestic and international trends in new medical device development, clinical information, etc. in Domestic and overseas, and of performing duties related to the certification of medical devices. <Amended on January 28, 2015>
(2) The Center shall be a legal person.
(3) Other than those specified in this Act, the provisions of the Civil Act related to incorporated foundations shall apply mutatis mutandis to the Center.
(4) Matters needed for operation of the Center, etc. shall be set forth by the Presidential Decree.
Article 43 (Activities of the Center) (1) The Center shall perform the activities provided by the following Subparagraphs: <Amended on March 23, 2013; January 28, 2015>
1. Provide information or technical assistance related to medical devices, such as, research on international specifications, collection, analysis, management of domestic and international information for advancement of medical device technologies;
2. Support clinical trials for commercialization of newly developed devices;
3. Provide education and public campaign, or supports related to information on quality management system, such as risk management, and approval, certification, reporting;
4. Support globalization of standard specifications for advancement of medical device management;
5. Duties entrusted by the Minister of Food and Drug Safety pursuant to Article 44 Paragraph (2); and
6. Other tasks related to assistance in information and technology of medical devices, which is deemed necessary by the Minister of Food and Drug Safety.
(2) The Minister of Food and Drug Safety may subsidize the activities of the Center performed pursuant to Paragraph (1). <Amended on March 23, 2013>
Article 43-2 (Revocation of Certification/Report) (1) In the event a medical device certified or reported pursuant to Article 6 Paragraph (2) or Article 15 Paragraph (2), falls under any of the following Subparagraphs, the Minister of Food and Drug Safety may revoke the certification granted or the report accepted. The certification or the report must be revoked in a case applied to Subparagraph 1:
1. Where a false or other corrupt means was used to obtain certification or to file a report;

2. Where a serious defect was found in the quality management or performance of a medical device, manufactured under certification or report; or

3. Where a medical device has harmed or is likely to harm public health, or where a medical device is found to be ineffective.

(2) Matters related to the procedures and methods of the revocation under Paragraph (1), etc. shall be set forth by the Decree of Prime Minister.
[Newly enacted at on January 28, 2015]

Article 43-3 (Guidance/Supervision, Etc. of the Center) (1) The Minister of Food and Drug Safety may, if needed for supervision of the Center, may require the Center to report its activities, submit data, or may issue other orders as needed and may have his staff enter the office of the Center and inspect books and/or documents, etc.

(2) The public official who enters and inspects as per Paragraph (1) shall carry and present to related personnel an evidence of his/her authority.

(3) The Minister of Food and Drug Safety shall set up and execute an annual plan for guidance or supervision in order to verify the adequacy of the tasks of the Center, entrusted under Article 44 Paragraph (2).

(4) Other matters necessary for guidance or supervision of the Center shall be set forth by the Decree of Prime Minister.
[Newly enacted on January 28, 2015]

Article 44 (Delegation and Entrustment of Authority) (1) The authorities of the Minister of Food and Drug Safety, set forth in this Act, may be partly delegated to the heads of the regional offices of the Ministry of Food and Drug Safety, mayors of special cities/mayors of metropolitan cities/governors of provinces/ governors of special self-governing provinces, or heads of Si/Gun/Gu, or heads of public health clinic, as prescribed by the Presidential Decree. <Amended on March 23, 2013; January 28, 2015>

(2) The Minister of Food and Drug Safety may entrust the duties related to certification or reporting of medical devices set forth in this Act to the Center, as prescribed by the Decree of Prime Minister. In the case, the Minister of Food and Drug Safety shall, upon deliberation by the Medical Devices Committee, establish and make public a guideline on the products of which certification and reporting to be entrusted and its scope among the medical devices of low or negligible level of potential risk to human body during use. <Newly enacted on January 28, 2015>

Article 44-2 (Deemed Public Officials in Punishment)
The executives or employees of the Center engaged in the duties entrusted by the Minister of Food and Drug Safety pursuant to Article 44 Paragraph (2) shall be deemed public officials when applying Article 127 and Articles 129 through 132 of the Criminal Act.

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[Newly enacted on January 28, 2015]
Article 45 (Protection of Submitted Materials) (1) In the event a person submitting materials pursuant to Articles 6 through 10, Articles 11, 12, or 15 makes a written request for protection of the materials submitted, the Minister of Food and Drug Safety shall not disclose that materials. Provided, such materials may be disclosed if it is deemed necessary for public interest. <Amended on March 23, 2013>
(2) A person, who read and/or reviewed the submitted data, on which protection was requested under Paragraph (1), shall not disclose the materials externally.
Article 46 (Special Provisions for Medical Devices for Animals) Among the responsibilities of the Minister of Health and Welfare and the Minister of Food and Drug Safety pursuant to this Act, the responsibilities for the medical devices used exclusively for animals shall belong to the Minister of Agriculture, Food and Rural Affairs. Such terms of "Minister of Health and Welfare" or "Minister of Food and Drug Safety" in this Act shall be read as the "Minister of Agriculture, Food and Rural Affairs", and "Decree of Prime Minister" or "Decree of Ministry of Health and Welfare" as "Decree of Ministry of Agriculture, Food and Rural Affairs". In such cases, the Minister of Agriculture, Food and Rural Affairs, when sets forth a Decree of Ministry of Agriculture, Food and Rural Affairs, shall consult in advance with the Minister of Health and Welfare or the Minister of Food and Drug Safety. [Fully Amended on March 23, 2013]
Article 47 (Succession of Standing of Manufacturers, Etc.) (1) In the event a manufacturer, etc. dies or transfers his/her business, or in the event an incorporated manufacturer, etc. merges with others, the heir or the transferee of the business, a surviving corporation of the merger or a new corporation established by the merger shall succeed to the standing of the manufacturer, etc. The transferee, the surviving corporation, or the new corporation shall not fall under any of the following Subparagraphs:
1. Where a manufacturer, an importer, or a repairer falls under any of the Subparagraphs of Article 6 Paragraph (1); or
2. Where a seller or a lessor falls under Article 6 Paragraph (1) Subparagraphs (2)/(4), or (5).
(2) In the event an successor who takes over the standing of a manufacturer, etc. pursuant to Paragraph (1), falls under any Subparagraphs of Paragraph (1), the business shall be transferred to a third party within six (6) months of the date of commencing the succession.
(3) In the event a manufacturer or an importer transfers his/her business related to medical devices, approved, certified, or reported pursuant to Article 6

Paragraph (2)/(6), or Article 15 Paragraph (2)/(5), the transferee shall succeed to the standing of the manufacturer or importer with respect to the approval, certification, or report of that product category or product item. <Amended on January 28, 2015>

Article 48 (Succession of Effects of Administrative Sanctions)

In the event of a succession of the business standing under Article 47, the effects of administrative dispositions imposed on the former manufacturer, etc. shall be succeeded to the transferee, the surviving corporation or the new corporation established by the merger and remain effective for one (1) year from the date of the disposition. If the proceedings of the disposition are on progress, such proceedings may apply to the transferee, the surviving corporation or the new corporation established by the merger. Provided, this shall not apply in the case that the new manufacturer, etc. (excluding the succession of standing by inheritance) were not aware of such dispositions or violations at the time of the succession.

Article 49 (Renewal of Approval/Reports, Etc.)

A manufacturer, etc. shall renew his/her certificate of approval or certification, or a written acceptance of report, as prescribed by the Decree of Prime Minister. <Amended on March 23, 2013; January 28, 2015>

Article 50 (Fees)

A person who falls under any of the following Subparagraphs shall pay fees, as prescribed by the Decree of Prime Minister: <Amended on March 23, 2013; January 28, 2015>

1. A person seeking to obtain a approval or certification, or to file a report pursuant to this Act;
2. A person seeking to amend the information approved, certified or reported pursuant to this Act.
3. A person seeking to receive a review of technical documents, safety, efficacy, etc. or a re-examination of a newly developed medical device, etc. pursuant to this Act;
4. A person seeking to receive a pre-application review pursuant to Article 11; or
5. A person seeking to receive a deliberation of advertising material of a medical device pursuant to Article 25.

CHAPTER VIII PENALTIES

Article 51 (Penalties) (1) A person who violated Article 26 Paragraph (1) shall be imprisoned with labor for a period of time not longer than five (5) years or fined not exceeding fifty (50) million Won.

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(2) The imprisonment with labor and the fine under Paragraph (1) may be imposed concurrently.
Article 52 (Penalties) (1) A person who falls under any of the following Subparagraphs shall be imprisoned with labor for a period of time not longer than three (3) years or fined not exceeding thirty (30) million Won: <Amended on December 2, 2016>
1. A person who violated Article 10 Paragraph (1) / the former part of Paragraph (2) / Paragraph (4), Article 12 Paragraph (1) (including cases where Article 15 Paragraph (6) or Article 16 Paragraph (4) are applied mutatis mutandis), Article 13 Paragraph (1), the main text of Article 16 Paragraph (1), Article 17 Paragraph (1), Article 24 Paragraphs (1)/(2), Article 26 Paragraphs (2) through (7), and Article 45 Paragraph (2); or
2. A person who refused, obstructed, or evaded the destroy, boxing, sealing, and other necessary measures, performed by a competent public offial, pursuant to Article 34 Paragraph (2).
(2) The imprisonment with labor and the fine under Paragraph (1) may be imposed concurrently.
Article 53 (Penalties) A person, who violated Article 13 Paragraph (3) (including cases where Article 15 Paragraph (6) are applied mutatis mutandis) or Article 18 Paragraph (2), shall be imprisoned with labor for a period of time not longer than three (3) years or fined not exceeding thirty (30) million Won.
Article 53-2 (Penalties) A person who falsely prepared or issued a clinical trial report, a non-clinical test report or a quality management inspection report, pursuant to Article 10 Paragraph (5), Article 10-2 Paragraph 3 or Article 28 Paragraph (4), shall be imprisoned with labor for a period of time not longer than one (1) year or fined to an amount of money not exceeding ten (10) million Won. <Amended on December 2, 2016> [Newly enacted on December 29, 2015]
Article 54 (Penalties) A person that falls under any of the following Subparagraphs shall be fined to an amount of money not exceeding five (5) million Won: <Amended on January 28, 2015>
1. A person who violated Article 18 Paragraph (1), Articles 20 through 23, Article 30 Paragraphs (1)/(2), or Article 31 Paragraphs (1)/(5);
2. A person who refused, obstructed, or evaded the entry into premise, sampling products, closure of business, or other necessary actions, performed by a competent public official, pursuant to Article 32 Paragraph (1), or Article 36 Paragraphs (1)/(2);
3. A person who violated an order for inspection, recall, destroy, public announcement, suspension of use, or suspension of business, pursuant to Article 33,

Article 34 Paragraph (1), Article 35, or Article 36 Paragraphs (1)/(2); or

4. A person who committed a violation that fall under Article 37 Paragraph (1) Subparagraphs 1/2/5.

Article 54-2 (Penalties) (1)
A person, who violated Article 6 Paragraph (7) (including cases where Article 15 Paragraph (6) is applied mutatis mutandis), Article 6-2 Paragraph (1) (including cases where Article 15 Paragraph (6) is applied mutatis mutandis) or Article 13 Paragraph (4) (including cases where Article 15 Paragraph (6) is applied mutatis mutandis), shall be fined to an amount of money not exceeding three (3) million Won. <Amended on December 2, 2016>

(2) A person who falls under any of the following Subparagraphs shall be fined to an amount of money not exceeding two (2) million Won: <Newly established on December 2, 2016>

1. A person who failed in preparing an outlay or failed in retaining the outlay reports, relevant books, or evidence of documents to violate Paragraph 1, Article 13-2 (including the cases where Paragraph 6, Article 15 or Paragraph 3, Article 18 is applied mutatis mutandis)

2. A person who falsely prepared an outlay report pursuant to Paragraph 1, Article 13-2 (including the cases where Paragraph 6, Article 15 or Paragraph 3, Article 18 is applied mutatis mutandis)

3. A person who did not observe the request for submit of outlay report, relevant books or evidence of documents pursuant to Paragraph 2, Article 13-2 (including the cases where Paragraph 6, Article 15 or Paragraph 3, Article 18 is applied mutatis mutandis)
<Newly enacted on January 28, 2014>

Article 55 (Vicarious Penalty)
In the event of any of the violations in Articles 51 through 54, has been committed by a representative of a corporation, an agent, an employer, or other persons employed by a corporation or an individual, in relation to the affairs of such corporation or individual, that corporation or individual shall also be fined, in addition to the punishment of that individual perpetrator, under the relevant provisions: provided that this shall not apply if the corporation or individual was not negligent in exercising due attention and supervision so as to prevent such violation.

Article 56 (Administrative Negligence Fines) (1) A person who falls under any of the following Subparagraphs shall be imposed to an administrative negligence fine at an amount not exceeding one (1) million Won: <Amended on January 28, 2014; January 28, 2015; December 2, 2016;>

1. A person who did not receive training, in violation of Article 6-2 Paragraph (2) or (3) (including cases where Article 15 Paragraph (6) is applied mutatis

mutandis);

1-2. A person who did not report the outcome of production or importation of medical devices, etc., in violation of Article 13 Paragraph (2) (including cases where Article 15 Paragraph (6) is applied mutatis mutandis);

2. A person, who did not report of the temporary shutdown/permanent temporary closure of business, in violation of Article 14 (including cases where Article 15 Paragraph (6), Article 16 Paragraph (4) or Article 17 Paragraph (3) are applied mutatis mutandis); or

2-2. A person who did not report or falsely reported the information on supplied medical devices in violation of Paragraph 1, Article 31-2

2-3. A person who failed in registering information on medical devices with the Medical Device Information Consolidation System in violation of Paragraph 2, Article 31-3 or does not comply with the Management Standards for Medical Device Information Consolidation System in violation of Paragraph 3 of the same Article.

3. A person who did not renew his/her approval, certification, or written acceptance of report, in violation of Article 49.

(2) Administrative negligence fines under Paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, mayors of cities, or heads of Gun/Gu, as prescribed by the Presidential Decree. <Amended on March 23, 2013>

ADDENDA <No. 13698, 29. Dec, 2015>

Article 1 (Enforcement Date)
This Act shall enter into force from the date of promulgation. Each of the following Subparagraphs shall enter into force on the separately specified dates as below:

1. The amendments in Article 6-4, Article 10-2, Article 32, Article 33, Article 37 and Article 53-2: one (1) year after the date of the promulgation; and

2. The amendments in Article 13 and Article 18: three (3) months after the date of the promulgation.

Article 2 (Application to Persons Who Provided Economic Benefits, Etc.) The amendments in Article 13 Paragraph 3 and Article 18 Paragraph 2 shall apply from the first person who provides economic benefits, etc. after the enforcement of the amendment.

Article 3 (Application to Changes in Labeling of Container, Etc.) The amendments in Article 20 Subparagraph (3) shall apply from the first medical device that

is manufactured or imported after the enforcement of this Act.

Article 4 (Transitional Measures related to Technical Document Review Body) A technical document review body designated under the former provisions at the time of the enforcement of this Act shall be deemed to have been designated under the amended provisions of Article 6-4 Paragraph (1).

Addendum <Act No. 14330, December 2, 2016>

Article 1 (Effective Date) This Act shall come into force within five years from the date of its promulgation as set forth by the Decree of Prime Minister. Provided, the amended provisions specified in Article 13-2, Paragraph 6 of Article15, Paragraph 3 of Article 18, Article 35-2, and Paragraph 2 of Article 54-2, shall take effect six months after the date of its promulgation and the amended Regulations in Paragraph 1 in Article 51, Paragraph 1 of Article 52, and Article 53 shall take effect from the date of its promulgation.

Article 2 (Preparation for Enforcement) Prior to enforcement of this Act, the Minister of Food and Drug Safety may take necessary measures for establishment and operation of the system for registration of information on medical devices.

Article 3 (Examples of Application for Submission of Outlay Report, etc.) The amended provisions in Article 13-2 shall take effect from the following fiscal year of the fiscal year to which the effective date of the amended regulation belongs.

Article 4 (Application of Changes in Labeling of Container, Etc.) The amendments in Subparagraph 8 of Article 20 shall be applied to the medical devices that are initially manufactured or imported after the enforcement of this Act.

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Article 5 (Special Provisions for a Pilot Program) (1) The Minister of Food and Drug Safety may conduct pilot programs before the enforcement of this Act for the purpose of implementing efficiently the program as per Article 31-2 and Article 31-3.
(2) The Minister of Food and Drug Safety may provide administrative and financial supports for pilot programs as per Paragraph 1.
(3) Matters necessary for implementation of pilot programs as per Paragraph 1 shall be determined by the Minister of Food and Drug Safety.