ENFORCEMENT RULE OF THE MEDICAL DEVICES ACT

[Enforcement Date Jul. 21, 2022.] [Ordinance of the Prime Minister No.1819, Jul. 20, 2022., Partial Amendment]

Ministry of Food and Drug Safety (Medical Device Policy Division) +82-43-719-3755

Article 1 (Purpose) The purpose of this Rule is to prescribe the matters mandated by the Medical Devices Act and the Enforcement Decree of that Act and matters necessary for the enforcement of said Act and Decree.

Article 2 (Standards for Classification and Designation of Classes) The standards and procedures for the classification and designation of the class of each medical device under Article 3 (2) of the Medical Devices Act (hereinafter the “Act”) shall be as specified in attached Table 1.

Article 3 (Procedures for Application for Manufacturing Business Permission) (1) A person who intends to obtain manufacturing business permission for medical devices under the main clause of Article 6 (1) of the Act shall submit an application in Attached Form 1 (including an application in electronic form) to the Commissioner of the Regional Office of Food and Drug Safety who has jurisdiction over the location of a factory, along with the following documents (including electronic documents). In such cases, where there exist at least two manufacturing factories in different locations, such person may submit the application to the Commissioner of the Regional Office of Food and Drug Safety with jurisdiction over either of such locations.

1. A medical certificate for which 6 months have not elapsed since the issuance date and which is issued by a medical doctor evidencing that he or she does not fall under the main clause of Article 6 (1) 1 of the Act or by a medical specialist evidencing that he or she falls under the proviso of that subparagraph (a corporation shall not submit such medical certificate);
2. A medical certificate for which 6 months have not elapsed since the issuance date and which is issued by a medical doctor evidencing that he or she does not fall under Article 6 (1) 3 of the Act (a corporation shall not submit such medical certificate);
3. A document verifying the qualifications of a quality manager under Article 6 (7) of the Act.

(2) Upon receipt of an application under Paragraph (1), the Commissioner of the Regional Office of Food and Drug Safety shall verify an applicant’s corporation registration certificate (limited to a corporation) through administrative data matching under Article 36 (1) of the Electronic Government Act.

(3) When an application for permission under Paragraph (1) meets the standards, the Commissioner of the Regional Office of Food and Drug Safety shall issue the license in Attached Form 2 to the applicant and state the following matters in the manufacturing business license register: <Amended on Oct. 22, 2019>

1. Permission number and permission date;
2. The name and resident registration number of the manufacturer (in case of a corporation, the name and resident registration number of its representative);
3. The name and location of the factory;
4. The name, resident registration number, and classification of qualifications of the quality manager.

Article 4 (Medical Devices Subject to Manufacturing Permission, Manufacturing Certification, or Manufacturing Notification) (1) Medical devices subject to manufacturing certification or manufacturing notification by item category under Article 6 (2) 1 of the Act shall be classified as follows:

1. Manufacturing certification by item category: Medical devices determined and publicly notified by the Minister of Food and Drug Safety, among Class II medical devices, the class of which is designated following Article 2 (hereinafter “class”);
2. Manufacturing notification by item category: Medical devices determined and publicly notified by the Minister of Food and Drug Safety, among Class I medical devices.

(2) Medical devices subject to manufacturing permission, manufacturing certification, or manufacturing notification by item under Article 6 (2) 2 of the Act shall be classified as follows:

1. Manufacturing permission by item: The following medical devices:
   (a) Class III and Class IV medical devices;
   (b) Medical devices excluding those under Subparagraph 1 of Paragraph (1), Item (c) of this subparagraph, and Subparagraph 2 of this paragraph, among Class II medical devices;
   (c) Medical devices that are essentially different from those already permitted, certified, or notified in terms of structure, principles, performance, intended uses, utilization methods, etc. among Class I and Class II medical devices;
2. Manufacturing certification by item: Medical devices determined and publicly notified by the Minister of Food and Drug Safety excluding those under Subparagraph 1 of Paragraph (1), among Class II medical devices;
3. Manufacturing notification by item: Medical devices excluding those under Subparagraph 2 of Paragraph (1) and Item (c) of Subparagraph 1 of this paragraph, among Class I medical devices.

Article 5 (Procedures for Manufacturing Permission) (1) A person who intends to obtain permission for medical device manufacturing under Article 6 (2) of the Act shall submit an application in Attached Form 3 (including an application in electronic form) to the Minister of Food and Drug Safety, along with the following documents (including electronic documents):

1. Documents evidencing that he or she secures facilities and manufacturing and quality management systems under Article 6 (4) of the Act;
2. Technical documents, clinical trial data, etc. (hereinafter “technical documents, etc.”) or a notice of the review result of technical documents, etc. under Article 9 (4) for which 2 years have not elapsed since the issuance date. Provided, That in cases falling under the proviso of Article 9 (1), a notice of the review result of technical documents, etc. shall be submitted;
3. A copy of a concluded contract for entrusting manufacturing processes or testing for quality management.

(2) When a product of which an application for a manufacturing permission is filed under Paragraph (1) is deemed to meet the standards, the Minister of Food and Drug Safety shall issue the applicant with a manufacturing license in Attached Form 4 and enter the following matters in the manufacturing permission register:

1. Permission number and permission date
2. The names (the product name, item name, and model name).

(3) The Minister of Food and Drug Safety shall determine and publicly notify the guidelines for preparing the attached documents required for the application for manufacturing business permission of medical devices under Article 3 (including conditional manufacturing business permission and permission for modification thereof) and documents required for the application for manufacturing permission under Paragraph (1) (including conditional manufacturing permission and permission for modification thereof), requirements for each document, the scope of exemption, and other details.

(4) If, while receiving an application for a manufacturing permission under Paragraph (1), the Minister of Food and Drug Safety receives an application for a new health technology assessment under Article 3-2 (2) of the New Health Technology Assessment Rules, or an application, etc. for \verification of eligibility for health care benefit or non-benefit, etc. under Article 9-2 (2) of the Rules on Standards for Health Care Benefits Covered by National Health Insurance, or a written objection under Article 9-2 (4) of the Rules on Standards for Health Care Benefits Covered by National Health Insurance, he or she shall, without delay, forward the relevant application, etc. to the Minister of Health and Welfare and the President of the Health Insurance Review and Assessment Service. In such cases, the Minister of Food and Drug Safety may mutually share data related to the relevant application for a manufacturing permission with the Minister of Health and Welfare or the President of the Health Insurance Review and Assessment Service; present opinions on the new health technology assessment and whether the manufacturing falls under medical care benefit items or non-benefit items; and refer to the data forwarded under Paragraph (5) when granting manufacturing permission. <Newly Inserted on Jul. 29. 2016., Apr. 13., 2020>

(5) When the Minister of Food and Drug Safety receives the results of the new health technology assessment, the results of the verification of whether the manufacturing falls under the health care benefit items or non-benefit items by the Minister of Health and Welfare and the President of the Health Insurance Review and Assessment Service following Article 4 (2) of the New Health Technology Assessment Rules or the main clause of Article 9-2 (3) and Paragraph (4) thereof of the Rules on Standards for Health Care Benefits Covered by National Health Insurance, he or she shall immediately notify the relevant applicant of such results, etc. <Newly inserted on Jul. 29, 2016>

(6) The matters prescribed in Paragraphs (4) and (5) shall also apply to the cases of conditional manufacturing permission granted under Article 7 (1) of the Act or permission for modification granted under Article 12 (1) of the Act. <Newly Inserted on Jul. 29, 2016>

(7) Except as provided in Paragraphs (4) through (6), details necessary for data and opinion provision, etc. among institutions shall be determined and publicly notified by the Minister of Food and Drug Safety. <Newly Inserted on Jul. 29, 2016>

Article 6 (Procedures for Manufacturing Certification) (1) A person who intends to obtain manufacturing certification of medical devices under Article 6 (2) of the Act shall submit an application in Attached Form 5 (including an application in electronic form) to the head of the National Institute of Medical Device Safety Information established under Article 42 of the Act (hereinafter the “Institute”) entrusted with the affairs concerning certification under Article 44 (2) of the Act, along with the documents referred to in the subparagraphs of Article 5 (1) (including electronic documents). <Amended on Jun. 14, 2018>

(2) When medical devices of which an application for manufacturing is filed under Paragraph (1) are deemed to meet the standards, the head of the Institute shall issue the manufacturing certificate in Attached Form 6 to the applicant and shall enter the following matters in the manufacturing certification register: <Amended on Jun. 14, 2018>

1. Certification number and certification date;
2. The names (the product name, item name, and model name);

(3) The Minister of Food and Drug Safety shall determine and publicly notify the guidelines for preparing the attached documents required for the application for manufacturing certification under Paragraph (1) (including conditional manufacturing certification and certification of modification thereof), requirements for each document, the scope of exemption, and other details.

Article 7 (Procedures for Filing Manufacturing Notification) (1) A person who intends to file a manufacturing notification of medical devices under Article 6 (2) of the Act shall submit the notification in Attached Form 7 (including a notification in electronic form) to the head of the Institute entrusted with the affairs concerning notification under Article 44 (2) of the Act, along with the documents listed in Article 5 (1) 3. <Amended on Jun. 14, 2018>

(2) When a notification is filed under Paragraph (1), the head of the Institute shall enter the following matters in the manufacturing notification register: <Amended on Jun. 14, 2018>

1. Notification number and notification date;
2. The names (the product name, item name, and model name).

(3) The Minister of Food and Drug Safety shall determine and publicly notify the guidelines for preparing attached documents required to file a manufacturing notification under Paragraph (1) (including a conditional manufacturing notification and notification of modification thereof), requirements for each document, the scope of exemption, and other details.

Article 8 (Standards for Facilities and Manufacturing and Quality Management System) (1) Standards for facilities and manufacturing and quality management systems to be secured by a person who intends to obtain a manufacturing business permission, manufacturing permission, or manufacturing certification or file a manufacturing notification under the main clause of Article 6 (4) of the Act shall be as specified in Attached Table 2.

(2) ”Cases prescribed by Ordinance of the Prime Minister, such as those of entrusting testing for quality management or manufacturing processes” in the proviso of Article 6 (4) of the Act refers to cases where a person who intends to obtain a manufacturing business permission, manufacturing permission, or manufacturing certification or file a manufacturing notification entrusts manufacturing processes or quality management testing to a medical device testing and inspection institution under Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry (hereinafter “medical device

testing and inspection institution"), an institution conducting non-clinical studies under Article 10-2 (1) of the Act (hereinafter "institution conducting non-clinical studies"), or a manufacturer whose compliance is certified under subparagraph 2 (f) of Attached Table 2. In such cases, the person who intends to obtain manufacturing business permission, manufacturing permission, or manufacturing certification or file a manufacturing notification may not secure the facilities of a factory specified in Subparagraph 1 (a) of Attached Table 2 according to the following classifications: <Amended on May 1, 2017>

1. When manufacturing processes are entrusted: Manufacturing facilities and instruments related to the entrusted processes;
2. When quality management testing is entrusted to a medical device testing and inspection institution, an institution conducting non-clinical studies, or a manufacturer whose compliance is certified under Subparagraph 2 (f) of Attached Table 2: Laboratories for quality management, and facilities and instruments related to testing.

Article 9 (Review of Technical Documents) (1) A person who intends to obtain manufacturing permission or manufacturing certification may undergo a review in advance by the Minister of Food and Drug Safety regarding the compliance of technical documents, etc., which shall be submitted under Article 6 (5) of the Act. Provided, that in the cases of the medical devices that are essentially equivalent to those already permitted, certified, or notified in terms of structure, principles, performance, intended uses, utilization methods, etc. and fall under the items determined by the Minister of Food and Drug and Safety, the technical documents, etc. shall be reviewed by an institution for reviewing technical documents under Article 6-4 (1) of the Act (hereinafter "institution for reviewing technical documents"). <Amended on May 1, 2017>

(2) A person who intends to have technical documents, etc. reviewed under Paragraph (1) shall submit a written request for review in Attached Form 8 (including a written request for review in electronic form) to the Minister of Food and Drug Safety or the head of an institution for reviewing technical documents, along with the following data (including data in electronic form): Provided, That in the cases of the medical devices that are essentially equivalent to those already permitted in terms of structure, principles, performance, intended uses, utilization methods, etc. except for the medical devices determined and publicly notified by the Minister of Food and Drug Safety for which submission of data regarding clinical trials is deemed necessary, the data referred to in Subparagraphs 5 through 7 may not be submitted. <Amended Jun. 12, 2019, Dec. 31, 2020, Jun. 24, 2021>

1. Data regarding comparison between the medical devices and products already permitted;
2. Data regarding intended uses;
3. Data regarding operation principles;
4. The following data regarding test specifications, grounds for establishing such specifications, and actual measured values for the verification of the performance and safety of products: Provided, That when neither domestic nor international test specifications exist, data regarding test specifications established by the person who intends to have technical documents, etc. reviewed to verify the performance and safety of products, grounds for establishing such specifications, and actual measured values:
   (a) Data regarding electrical and mechanical safety;
   (b) Data regarding biological safety;
   (c) Data regarding radiation safety;
   (d) Data regarding safety of electromagnetic waves;
   (e) Data regarding performance;
   (f) Data regarding physical and chemical properties;
   (g) Data regarding stability;
5. Data regarding origins, discovery, and reasons for development;
6. Data regarding clinical trials;
7. Data regarding the current status of use, etc. in foreign countries.

(3) Notwithstanding Paragraph (2), a person who intends to have technical documents, etc. reviewed regarding in vitro diagnostic medical devices shall submit a written request for review in Attached Form 8 (including a written request for review in electronic form) to the Minister of Food and Drug Safety or the head of an institution reviewing technical documents, along with the following data (including data in electronic form): <Amended on Jan. 4, 2017, Jun. 24, 2021>

1. Data regarding reasons for development, measurement principles and methods, and the current status of domestic and international use;
2. Data regarding raw materials and manufacturing methods;
3. Data regarding intended uses;
4. Data regarding storage methods and the period of use or expiration date;
5. The following data to verify the performance of the products:
   A. Data regarding analytical performance tests;
   (b) Data regarding clinical performance tests;
   (c) Data regarding quality management tests;
   (d) Data regarding reference materials, specimen storage, etc.
6. Data regarding the safety of the handlers of in vitro diagnostic medical devices;

7. Data regarding the comparison between the medical devices and products already permitted or certified.

(4) Upon receipt of a request for review under Paragraph (2) or (3), the Minister of Drug and Food Safety or the head of an institution for reviewing technical documents shall review the relevant technical documents, etc. and notify the applicant of the results as prepared in Attached Form 9.

(5) The Minister of Food and Drug Safety shall determine and publicly notify the guidelines for preparing the attached documents necessary to review technical documents, etc.; requirements for each attached document and procedures for and scope of exemption thereof; scope of, standards and procedures for review; management standards for clinical performance tests; and other details. <Amended on Jan. 4, 2017>

Article 10 (Exemption from Manufacturing Business Permission for Medical Devices) The following medical devices may be manufactured without manufacturing business permission under Article 6 (1) of the Act or without manufacturing permission, manufacturing certification, or manufacturing notification under Paragraph (2) of that Article: <Amended on Jun. 15, 2016, Jun. 14, 2018, Dec. 31, 2018>

1. A medical device subject to clinical trials for which approval of a clinical trial protocol is granted under the main clause of Article 10 (1) of the Act;
2. A separate medical device required for clinical trials for which approval of a clinical trial protocol may not be granted under the proviso of Article 10 (1) of the Act;
3. A separate medical device required for clinical trials regarding drugs, etc. for which approval of a clinical trial protocol shall be granted under Article 34 of the Pharmaceutical Affairs Act;
4. A medical device manufactured to obtain manufacturing permission or manufacturing certification for medical devices or file a manufacturing notification for medical devices;
5. A medical device used for research purposes, such as product development;
6. A medical device determined and publicly notified by the Minister of Food and Drug Safety, such as a medical device for self-use or for relief operations, etc.;
7. Deleted. <Dec. 31, 2018>
8. A medical device determined and publicly notified by the Minister of Food and Drug Safety which is used in clinical laboratories and is deemed suitable by the Minister based on the evaluations of quality management systems, inspection performance, competence, etc. (referring to places where the diagnosis, inspection, etc. of diseases are conducted; hereinafter the same shall apply).

Article 11 (Qualifications for Quality Managers) (1) A person who intends to obtain manufacturing business permission under Article 6 (1) of the Act shall assign at least 1 quality manager to each factory.

(2) The affairs of a quality manager may be performed by a person with any of the following qualifications: <Amended on Jun. 15, 2016, Apr. 13, 2020>

1. A person with a license classified as follows under the Medical Service Technologists Act:
   (a) When manufacturing or importing eyeglass lenses or contact lenses: Opticians;
   (b) When manufacturing or importing materials used in dental clinics: Dental technicians or dental hygienists;
   (c) When manufacturing or importing radiation-generating devices: Radiological technologists;
   (d) Deleted. <May 1, 2020>
   (e) When manufacturing or importing medical devices required for physical therapy or rehabilitation training: Physical therapists.
2. A person with qualifications as a biomedical engineer or quality management engineer under the National Technical Qualifications Act;

2-2. A person with qualifications as a regulatory affairs (RA) specialist of medical devices accredited by the Minister of Food and Drug Safety under Article 19 (1) of the Framework Act On Qualifications;

3. A person who has earned a bachelor's degree (including a person deemed to have an educational attainment equal to or higher than such degree under statutes or regulations; hereinafter, in this Article, the same shall apply) from a school under the subparagraphs of Article 2 of the Higher Education Act (excluding a junior college under Subparagraph 4 of that Article; hereinafter, in this Article, "university, college, etc.") and who has majored in the field of natural science, engineering, or medicine under Article 2 (9) of the Regulations on the Establishment and Operation of Universities and Colleges (hereinafter, in this Article, "field related to medical devices");
4. A person who has earned a bachelor's degree from a university, college, etc. in a field not related to medical devices and who has earned a master's degree or higher from a graduate school under Article 29 of the Higher Education Act in a field related to medical devices;
5. A person who has earned a bachelor's degree from a university, college, etc. in a field not related to medical devices and has engaged in quality management work for at least 1 year in a company that manufactures or imports medical devices;
6. A graduate of a junior college under Subparagraph 4 of Article 2 of the Higher Education Act (including a person deemed to have an educational attainment equal to or higher than such college under statutes or regulations; hereinafter, in this Article, the same shall apply) who has majored in a field related to medical devices and has engaged in quality management work for at least 1 year in a company that manufactures or imports medical devices;
7. A graduate of a junior college under Subparagraph 4 of Article 2 of the Higher Education Act who has majored in a field not related to medical devices and has engaged in quality management work for at least 3 years (2 years for graduates of a junior college whose term of school years is 3 years under Article 48 (1) of the Higher Education Act) in a company that manufactures or imports medical devices;
8. A graduate of a high school or high technical school under Subparagraph 3 of Article 2 of the Elementary and Secondary Education Act (including a person deemed to have an educational attainment equal to or higher than such school under statutes or regulations, but excluding a person falling under Subparagraph 9) who has engaged in quality management work for at least 5 years in a company that manufactures or imports medical devices;

9. A graduate of a high school tailored to industry demands in a field related to medical devices under Article 90 (1) 10 of the Enforcement Decree of the Elementary and Secondary Education Act who has engaged in quality management work for at least 3 years in a company that manufactures or imports medical devices;
10. A person who has engaged in quality management work for at least 6 years in a company that manufactures or imports medical devices.

(3) Where a manufacturer has 2 or more quality managers under Paragraph (1), the work shall be divided and the limits of the responsibilities of each quality manager shall be specified.

Article 12 (Scope of Duties of Quality Managers) (1) The scope of duties to be performed by quality managers under Article 6-2 (1) of the Act shall be as follows:

1. Inspecting the hygiene of employees thoroughly and providing them with the education and training necessary to produce and import medical devices with excellent quality;
2. Supervising whether employees receive education and training under Subparagraph 1;
3. Preparing standard work guidelines to manufacture medical devices in accordance with the standards for manufacturing and quality management systems specified in Subparagraph 2 of Attached Table 2 and requiring employees to manufacture medical devices according to such guidelines;
4. Thoroughly conducting the tests, inspections, or examinations required for the processes from the warehousing of raw materials to the release of finished products; preparing and keeping manufacturing management records and quality management records for each manufacturing unit; and retaining such records for 5 years from manufacturing dates (referring to a period corresponding to the life cycle of a product, where such life cycle exceeds 5 years);
5. Evaluating the results of the quality management of manufacturing factories and determining whether to ship the products;
6. Dealing with affairs related to the establishment, implementation, and maintenance of quality management systems in accordance with standards for manufacturing and quality management systems specified in Subparagraph 2 of Attached Table 2;
7. Managing the facilities of manufacturing factories in a sanitary manner so as not to cause any harm to health and hygiene and preventing cross-contamination, contamination from the outside, etc.;
8. Managing and supervising objects that are likely to cause any harm so that they are not placed in working places and preventing substances hazardous to public health from being generated in the working place;
9. Handling other affairs determined and publicly notified by the Minister of Food and Drug Safety, which are related to manufacturing management, quality management, and safety management, among the matters to be observed by the manufacturers under Article 27 (1).

(2) When a quality manager ceases to engage in quality management work in the relevant working places, he or she may submit a notification of his or her status of not working as a quality manager in Attached Form 10 (including a notification in electronic form) to the head of the competent regional office of food and drug safety.

(3) No quality manager shall concurrently engage in affairs other than those referred to in Paragraph (1); Provided, that the shame shall not apply in any of the following cases:

1. When he or she handles affairs not affecting the duties of a quality manager;
2. When a manufacturer concurrently engages in import business and a quality manager of the manufacturing company handles the affairs of a quality manager of the import company.

Article 13 (Content and Hours of Education for Quality Managers) (1) The content of education under Article 6-2 (2) of the Act shall be as follows:

1. The latest standard specifications for medical devices;
2. Statutes, regulations, systems, and technology necessary for safety management, such as ensuring the safety and effectiveness of medical devices;
3. Statutes, regulations, systems, and technology necessary for the manufacture and quality management of medical devices;
4. Other matters determined by the Minister of Food and Drug Safety for the manufacturing management, quality management, and safety management of medical devices.

(2) At least 8 hours of education shall be provided per year.

(3) A quality manager shall receive education conducted by an institution offering education for quality managers under Article 14 (1) within 6 months from the date of commencement of work: Provided, That this shall not apply when he or she completes the provided education in the pertinent year before working as a quality manager. <Amended on Jun. 24, 2021>

Article 14 (Designation of Institutions Offering Education for Quality Managers) (1) An institution that intends to be designated as an institution offering education for quality managers (hereinafter “institution offering education”) under Article 6-2 (5) of the Act shall satisfy the following requirements: <Amended on Jan. 21, 2022>

1. Being the Information Institute or medical device-related institutions or organizations publicly announced by the Minister of Food and Drug Safety;
2. Having specialists, such as an education manager who manages and supervises the overall operation of necessary education, personnel necessary for operating education, etc.;
3. Having an educational facility and the equipment necessary for providing education.

(2) A person who intends to apply for an institution’s designation under Article 6-2 (5) of the Act shall submit an application for designation as an institution offering education for quality managers of medical devices in Attached Form 11 to the Minister of Food and Drug Safety, along with the following documents and data: <Amended on Jan. 21, 2022>

1. Data regarding the current status of the operational organization and personnel to provide education;
2. Data regarding the current retention status of educational facilities and equipment;

3. Evidentiary data regarding the calculation of tuition fees;
4. Regulations on the implementation of education;
5. Basic educational plans.

(3) Upon receipt of an application under Paragraph (2), the Minister of Food and Drug Safety may conduct a fact-finding survey to evaluate whether the details of such application satisfy the requirements for designation under Paragraph (1). <Amended on Jan. 21, 2022>

(4) When the Minister of Food and Drug Safety designates an institution offering education, he or she shall issue the applicant with a certificate of designation in Attached Form 12. <Amended on Jun. 14, 2018>

(5) When an institution offering education intends to modify its designated name, location, or representative under Paragraph (4), it shall submit to the Minister of Food and Drug Safety an application for the modification of designation as an institution offering education for quality managers of medical devices in Attached Form 11-2 within 30 days from the date reasons for such modification occur, along with a certificate of designation as an institution offering education for quality managers of medical devices and documents verifying modified matters. <Newly inserted on Jun. 14. 2018, Jan. 21. 2022>

(6) The Minister of Food and Drug Safety may modify the designation of an institution offering education after verifying an application, etc. prescribed in Paragraph (5). In such cases, he or she shall issue a certificate of designation as an institution offering education for quality managers of medical devices, stating the modified matters therein. <Newly inserted on Jun 14, 2018>

(7) When the Minister of Food and Drug Safety designates an institution offering education under Paragraph (4) or modifies designation under Paragraph (6), he or she shall publicly announce the fact that such institution is designated or designation is modified, and the name and location of the institution and the name of its representative on the website, etc. of the Ministry of Food and Drug Safety. <Newly inserted on Jun. 14, 2018>

(8) An institution offering education may receive tuition fees from educatees in consideration of the expenses incurred in education, such as expenses for educational materials or on-site training and stipends for instructors. In such cases, the head of the institution offering education shall determine tuition fees so as to not exceed actual expenses. <Amended on Jun. 14, 2018>

(9) Except as provided in Paragraphs (1) through (8), details of qualifications for the designation as an institution offering education and other matters necessary for the designation, management, etc. of such institution shall be determined and publicly notified by the Minister of Food and Drug Safety. <Amended on Jun. 14. 2018, Jan. 21, 2022>

Article 15 (Compliance for Institutions Offering Education) An institution offering education shall comply with the following matters in accordance with Article 6-2 (6) of the Act:

1. To formulate an annual educational plan including educatees and educational content for the following year in accordance with the basic educational plan under Article 14 (2) 5 and to submit it to the Minister of Food and Drug Safety before the following business year commences;
2. To provide education in accordance with the annual educational plan in Subparagraph 1;
3. To develop educational materials and provide them to educatees;
4. To issue a certificate with a person who completes the education, to record matters regarding the provision of education, such as a list of persons who have completed the education, and to retain such records for 2 years from the date such matters are recorded;
5. To report records regarding the provision of education of the preceding year to the Minister of Food and Drug Safety by January 31 of the following year.

(2) Required details regarding the establishment of an educational plan or methods of education provision prescribed in each subparagraph of Article 1 shall be determined and publicly notified by The Minister of Food and Drug Safety.

[Wholly Amended on Jan. 21, 2022]

Article 15-2 (Designation of Institutions for Reviewing Technical Documents) (1) An institution that intends to be designated as an institution for reviewing technical documents under Article 6-4 (1) of the Act shall meet the standards for designation determined and publicly notified by the Minister of Food and Drug Safety, such as the organization and personnel necessary to review technical documents, etc. for each field and operational standards.

(2) A person who intends to apply for the designation of an institution as an institution for reviewing technical documents shall submit to the Minister of Food and Drug Safety an application for the designation as an institution for reviewing technical documents on medical devices in Attached Form 12-2 (including an application in electronic form), along with the following documents (including electronic documents):

1. Documents regarding the current status of organization and personnel (for the current status of personnel, including documents evidencing qualifications and work experience);
2. Documents regarding operational standards;
3. Documents regarding fields for reviewing technical documents, etc.;
4. Documents determined and publicly notified by the Minister of Food and Drug Safety, which evidence financial capabilities to review technical documents, etc.

(3) Upon receipt of an application under Paragraph (2), the Minister of Food and Drug Safety may conduct a fact-finding survey to evaluate whether the details of such application meet the standards for designation.

(4) When the Minister of Food and Drug Safety designates an institution for reviewing technical documents, they shall issue the applicant with a certificate of designation as an institution for reviewing technical documents on medical devices in Attached Form 12-3.

(5) When an institution for reviewing technical documents intends to modify any of the following matters, it shall submit to the Minister of Food and Drug Safety an application for the modification of designated matters of an institution for reviewing technical documents on medical devices in Attached Form 12-4 (including an application in electronic form) within 30 days from the date reasons for such modification occur, along with a certificate of designation as an institution for reviewing technical documents on medical devices and documents verifying modified matters (including electronic documents):

1. The representative of the institution for reviewing technical documents;
2. The name and location of the institution for reviewing technical documents;
3. Fields for reviewing technical documents, etc.

(6) When the Minister of Food and Drug Safety modifies the designation of an institution for reviewing technical documents, he or she shall issue a certificate of designation as an institution for reviewing technical documents on medical devices, stating the modified matters therein.

(7) When the Minister of Food and Drug Safety designates an institution for reviewing technical documents or modifies designation thereof, he or she shall publicly announce the name, location, representative, etc. of the institution on the website, etc. of the Ministry of Food and Drug Safety.

(8) Details regarding the scope of the documents to be submitted under Paragraph (2) shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly Inserted on May 1, 2017]

Article 15-3 (Compliance for Institutions for Reviewing Technical Documents) "Matters prescribed by Ordinance of the Prime Minister" in Article 6-4 (3) of the Act refer to the following:

1. The operational standards of institutions for reviewing technical documents determined and publicly notified by the Minister of Food and Drug Safety shall be observed;
2. The results of the review of technical documents shall be reported to the Minister of Food and Drug Safety, as determined and publicly notified by the Minister of Food and Drug Safety;
3. A copy of a notice of the review result of technical documents and records regarding the review of such documents shall be retained for 5 years from the date of notification of the technical document review's results;
4. Other matters determined and publicly notified by the Minister of Food and Drug Safety regarding the preparation, issuance, etc. of a notice of the review result of technical documents shall be observed.

[Newly Inserted on May 1, 2017]

Article 16 (Application for Conditional Permission) (1) A person who intends to obtain conditional manufacturing business permission under Article 7 (1) of the Act shall submit an application in Attached Form 1 to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of a factory, along with the following documents. In such cases, the Commissioner of the Regional Office of Food and Drug Safety shall verify a corporation registration certificate (limited to a corporation), a certified copy of the land register, and a certified copy of the building register through administrative data matching under Article 36 (1) of the Electronic Government Act: <Amended on Jan. 21, 2022>

1. When manufacturing facilities are installed in newly constructed buildings, documents verifying the ownership of land (when the ownership can be verified with a certified copy of the land register, such verification shall be in lieu of the attached documents) or a copy of a lease contract;
2. When manufacturing facilities are installed in existing buildings, documents verifying the ownership of such buildings (when the ownership can be verified with a certified copy of the building register, such verification shall be in lieu of the attached documents) or a copy of a lease contract;
3. The documents listed in the subparagraphs of Article 3 (1).

(2) A person who intends to obtain conditional manufacturing permission under Article 7 (1) of the Act shall submit an application in Attached Form 3 (including an application in electronic form) to the Minister of Food and Drug Safety, along with the documents listed in Article 5 (1) 2 (including electronic documents).

(3) A person who intends to obtain conditional manufacturing certification under Article 7 (1) of the Act shall submit an application in Attached Form 5 (including an application in electronic form) to the head of the Institute, along with the documents listed in Article 5 (1) 2 (including electronic documents). <Amended on Jun. 14, 2018>

(4) A person who intends to file a conditional manufacturing notification under Article 7 (1) of the Act shall submit a notification in Attached Form 7 (including a notification in electronic form) to the head of the Institute. <Amended on Jun. 14, 2018>

(5) Upon granting conditional manufacturing business permission, conditional manufacturing permission, or conditional manufacturing certification or upon receipt of a conditional manufacturing notification, the Minister of Food and Drug Safety, the Commissioner of the Regional Office of Food and Drug Safety, or the head of the Institute shall state the matters prescribed in Articles 3 (3), 5 (2), 6 (2), or 7 (2) and the conditions of permission, certification, or notification in the manufacturing business permission register, manufacturing permission register, manufacturing certification register, or manufacturing notification register; and shall issue a conditional license for manufacturing businesses in Attached Form 13, a conditional license for manufacturing in Attached Form 14, or a conditional certificate of manufacturing in Attached Form 15. <Amended on Jun. 14, 2018>

Article 17 (Notification and Verification of Compliance with Conditions) (1) When a person who has obtained conditional permission or certification or filed a conditional notification under Article 16 complies with the conditions of permission, certification, or notification, he or she shall submit documents evidencing such compliance to the Minister of Food and Drug Safety, Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the factory, or head of the Institute. <Amended on Jun. 14, 2018>

(2) Upon receipt of the documents prescribed in Paragraph (1), the Minister of Food and Drug Safety, Commissioner of the Regional Office of Food and Drug Safety, or head of the Institute shall verify whether the relevant conditions are complied with within 20 days from the date of submission of such documents; issue a manufacturing business license under Article 3 (3), a manufacturing license under Article 5 (2), or a manufacturing certificate under Article 6 (2) instead of a conditional license for manufacturing business, a conditional license for manufacturing, or a conditional certificate of manufacturing under Article 16 (5), respectively; and enter the date of compliance with the conditions in the notification register. <Amended on Jun. 14, 2018>

Article 18 (Medical Devices Exempt from Post-Market Surveillance) (1) When the Minister of Food and Drug Safety intends to require the applicant for manufacturing permission under Article 8 (1) of the Act to conduct surveillance on the safety and effectiveness of the relevant medical device (hereinafter "post-market surveillance"), he or she shall state the period of the

post-market surveillance on the manufacturing permission. <Amended on Jan. 21, 2022>

(2) The Minister of Food and Drug Safety may exempt post-market surveillance of any of the following medical devices following the proviso of Article 8 (1), with the exception of its subparagraphs, of the Act, after deliberation by the Medical Devices Committee under Article 5 (1) (hereinafter the "Medical Devices Committee"): <Amended on Jan. 21, 2022>

1. Newly developed Class I and Class II medical devices;
2. Newly developed medical devices that received permission, etc. in foreign countries of which the level of safety management is deemed by the Minister of Food and Drug Safety to be equal or higher than the safety management in the Republic of Korea and have been used in foreign countries following the standards publicly notified by the Minister of Food and Drug Safety;

③ Deleted. <Jan. 21, 2022>

④ Deleted. <Jan. 21, 2022>

⑤ Deleted. <Jan. 21, 2022>

[Title Amended on Jan. 21, 2022]

Article 18-2 (Approval of Post-Market Surveillance Protocol) (1) A person who intends to obtain approval for a post-market surveillance protocol following the former part of Article 8 (3) of the Act shall submit to the Minister of Food and Drug Safety, at least 30 days before the market launch of the medical device, an application for the approval of a medical device post-market surveillance protocol in Attached Form 16, along with the post-market surveillance protocol which includes the purpose, period, method, and number of the subjects of the post-market surveillance and data on the institution that plans to conduct such surveillance.

(2) A person who intends to obtain approval for the modification of post-market surveillance following the latter part of Article 8 (3) of the Act shall submit to the Minister of Food and Drug Safety an application for the approval of modification of a medical device post-market surveillance protocol in Attached Form 16, along with the following documents:

(a) A modification protocol of the post-market surveillance;

(b) Documents verifying modifications.

(3) When the Minister of Food and Drug Safety receives an application for the approval or modification of a post-market surveillance protocol under Paragraph (1) or (2), he or she shall determine whether to issue the approval within 6 months from the date of application and shall notify the applicant of his or her decision.

(4) When the Minister of Food and Drug Safety approves a post-market surveillance protocol under Paragraph (3), he or she shall issue the applicant with a medical device post-market surveillance approval certificate in Attached Form 16-2 and include the modifications in the changes and disposition, etc. section of the certificate.

(5) Except as provided in Paragraphs (1) through (4), details regarding the guidelines for preparing documents required for the application for the approval or modification of a post-market surveillance protocol, etc. shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly Inserted on Jan. 21, 2022]

Article 18-3 (Methods and Procedures for Periodic Reports of Post-Market Surveillance) (1) A person who intends to report the data collected during post-market surveillance, the status of the execution of the surveillance, etc. following Article 8 (4) of the Act shall submit to the Minister of Food and Drug Safety a periodic report on medical device post-market surveillance in Attached Form 16-3 within the period prescribed in Paragraph (2), along with the following documents:

1. Primary data, including a record of observations on the subject of the post-market surveillance;
2. Data regarding the result of analysis and assessment on the post-market surveillance;
3. Data regarding the side effects of the medical device subject to post-market surveillance.

(2) The report under Paragraph (1) shall be submitted every 6 months in the first year and every year from the second year, and the deadline for the report shall be 2 months from the end of the period covered by each report.

(3) Notwithstanding Paragraph (2), the document submitted with the application for review under Article 8-2 (1) of the Act may be in lieu of the last report of the post-market surveillance period.

(4) Details regarding the guidelines, etc. for preparing documents to be submitted with the report under Paragraphs (1) and (3) shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly Inserted on Jan. 21, 2022]

Article 18-4 (Submission of Post-Market Surveillance Results) (1) The "Data prescribed by Ordinance of the Prime Minister" in Article 8-2 (1) of the Act refers to data on the status of domestic and foreign sales and permission in foreign countries.

(2) A person who requests for review following Article 8-2 (1) of the Act shall submit an application for the review of post-market surveillance results in Attached Form 16-4 to the Minister of Food and Drug Safety, along with the following documents:

1. Investigation data on the usage performance according to the post-market surveillance results regarding the safety and effectiveness of the medical device after its domestic market launch;
2. Data from the Republic of Korea and foreign countries on the side effects and safety of medical devices subject to post-market surveillance, which includes cases of the side effects of such devices;
3. Data on domestic and foreign sales and permission in foreign countries.

(3) The Minister of Food and Drug Safety shall notify the applicant the result of the review conducted after deliberation by the Medical Devices Committee within 6 months from the date of application in the form of notification in Attached Form 17, following Paragraph (2).

(4) Details regarding the guidelines, etc. for preparing documents to be submitted with the report under Paragraph (2) shall be determined and publicly notified by the Minister of Food and Drug Safety.
[Newly inserted on Jan. 21, 2022]

Article 18-5 (Measures Including Recall and Destruction after the Post-Market Surveillance Results) (1) When the Minister of Food and Drug Safety intends to order necessary measures, including sales suspension, recall, destruction, etc. following Article 8-2 (2) of the Act, he or she shall notify the manufacturer of the medical device subject to post-market surveillance of the following matters:
1. The name of the medical device;
2. The content of and reason for the measure.
(2) Upon receipt of the notification under Paragraph (1), the manufacturer of the medical device subject to post-market surveillance shall implement the relevant measure within 30 days from the date of the notification and notify the result of the implementation to the Minister of Food and Drug Safety.
[Newly inserted on Jan. 21, 2022]

Article 19 (Methods and Procedures for Re-evaluation) (1) When the Minister of Food and Drug Safety intends to re-evaluate medical devices following Article 9 of the Act, he or she shall determine items subject to re-evaluation after deliberation by the Medical Devices Committee and publicly announce the following matters on the website of the Ministry of Food and Drug Safety:
1. Items subject to re-evaluation;
2. The period for applying for re-evaluation;
3. The details of the data required for re-evaluation.
(2) A manufacturer of medical devices falling under the items subject to re-evaluation shall submit an application for re-evaluation of medical devices in Attached Form 18 (including an application in electronic form) to the Minister of Food and Drug Safety during the application period for re-evaluation under Paragraph (1) 2, along with the data mentioned in Paragraph (1) 3 (including data in electronic form).
(3) Upon receipt of an application for re-evaluation under Paragraph (2), the Minister of Food and Drug Safety shall re-evaluate the relevant items, allow the perusal of the draft results of re-evaluation for at least 1 month so as to provide an opportunity for the manufacturer of the relevant items subject to re-evaluation to respond to such results, and publicly announce the results of re-evaluation on the website of the Ministry of Food and Drug Safety.
(4) Details regarding the guidelines for preparing the data to be submitted, the requirements for each data and the scope of exemption, the scope of re-evaluation, and the standards for conducting re-evaluation, etc. under Paragraphs (2) and (3) shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 20 (Approval of Clinical Trial Protocols) (1) A person who intends to obtain approval for a clinical trial protocol following Article 10 (1) of the Act or a person who intends to modify the approved clinical trial protocol shall submit to the Minister of Food and Drug Safety an application for the approval of a clinical trial protocol in Attached Form 19 (including an application in electronic form) or an application for the approval of the modification of a clinical trial protocol in Attached Form 20 (including an application in electronic form) and a written approval for a clinical trial protocol, respectively, along with the following documents (including electronic documents) and data (including data in electronic form): Provided, That when the person applies for the approval of modification of the clinical trial protocol, he or she need not submit the data mentioned in Subparagraphs 2 and 3, as determined and publicly notified by the Minister of Food and Drug Safety: <Amended on Oct. 22, 2019, May 1, 2020>
1. A clinical trial protocol or a modified clinical trial protocol;
2. Data evidencing that medical devices subject to clinical trials are manufactured in compliance with the standards for facilities and manufacturing and quality management systems under Attached Table 2;
3. The data mentioned in Subparagraphs 2 through 5 of Article 9 (2).
(2) A clinical trial protocol under Paragraph 1 (1) shall include the following matters:
1. The titles of clinical trials;
2. The name and location of a clinical trial institution;
3. The names and positions of clinical trial principal investigators, subinvestigators, and joint researchers;
4. The name and position of the person who manages medical devices for clinical trials;
5. The name and address of the person who intends to conduct a clinical trial;
6. The objectives and background of clinical trials;
7. The outlines of the medical devices subject to clinical trials (including the intended uses, relevant illnesses, or indications for use);
8. The standards for the selection and exclusion of, and the number of, persons who are subject to the application of the medical devices subject to clinical trials or persons who participate in the clinical trial as the members of a control group (hereinafter “subjects”) and the grounds therefor;
9. The periods for clinical trials;
10. The methods for clinical trials (including usage, methods for use, periods of use, combination therapy, etc.);
11. Items for observation, items for clinical tests, and methods for observational tests;
12. Expected side effects and precautions for use;
13. The standards for suspension and elimination;
14. The standards and methods of evaluating effectiveness and the methods for interpreting effectiveness (based on the methods for statistical analysis);

15. The standards and methods for evaluating the safety, including side effects, and the reporting methods;
16. The form of written consent from a subject;
17. The agreement on compensation for victims;
18. Matters regarding the treatment of the subjects after conducting clinical trials;
19. Measures to protect the safety of subjects;
20. Other matters necessary to conduct clinical trials safely and scientifically.

(3) Any of the following trials shall be excluded from approval from the Minister of Food and Drug Safety under Article 10 of the Act:

1. A trial for observing clinical effects and investigating adverse events regarding the permitted matters of medical devices on the market;
2. A trial for collecting data about safety and effectiveness regarding the permitted performance and intended uses, etc. of medical devices on the market;
3. Deleted. <May 1, 2020>
4. Any other trials using medical devices on the market which are determined by the Minister of Food and Drug Safety as there is no direct correlation with safety or it is not likely to cause ethical problems.

(4) When an application for approval of a clinical trial protocol submitted under Paragraph (1) is deemed appropriate following the review thereof, the Minister of Food and Drug Safety shall issue a written approval of a clinical trial protocol in Attached Form 21 to the applicant, and when the Minister approves the modification of the clinical trial protocol, he or she shall state the modified matters in the columns for modification and disposition in the written approval.

(5) Details regarding the guidelines for preparing the data to be submitted with the application for the approval of a clinical trial protocol or approval of modification thereof, the scope of data to be exempt, the requirements, standards, and procedures for approval, etc. under Paragraphs (1) through (4) shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 21 (Standards and Procedures for Designating Clinical Trial Institutions) (1) A clinical trial institution under Article 10 (3) of the Act (hereinafter “clinical trial institution”) shall be any of the following medical institutions: <Amended on Apr. 13, 2020>

1. A general hospital under Article 3 (2) 3 (e) of the Medical Service Act;
2. A training hospital, training dental clinic, or oriental medical hospital under the Regulations on the Training and Recognition, etc. of Qualifications of Medical Specialists, the Regulations on the Training and Recognition, etc. of Qualifications of Dentists, or the Regulations on the Training and Recognition, etc. of Qualifications of Oriental Medical Doctors;
3. A specialized hospital designated following Article 3-5 of the Medical Service Act;
4. A hospital with personnel, facilities, etc. meeting the standards for the designation of a training hospital or training dental clinic for a single specialization under Article 4 (2) 1 (a) of the Enforcement Decree of the Act on the Improvement of Training Conditions and Status of Medical Residents, or Article 7 (2) 2 of the Regulations on the Training and Recognition, etc. of Qualifications of Dentists;
5. A clinical trial center in a high-tech medical complex designated following the Special Act on the Designation and Support of High-Tech Medical Complexes.

(2) A person who intends to apply for the designation of a clinical trial institution shall submit an application for the designation as a clinical trial institution for medical devices in Attached Form 22 (including an application in electronic form) to the Minister of Food and Drug Safety along with the following documents (including electronic documents):

1. Deleted. <Dec. 31, 2018>
2. Regulations on administrative procedures, etc. necessary for clinical trials;
3. Regulations on the operation of an institutional review board for clinical trials under Subparagraph 6 of Attached Table 3 and documents regarding the organization thereof (if the review has been entrusted to an outside designated institutional review board under item (e) of that subparagraph, a contract for the entrustment shall be attached thereto);
4. Regulations on entrusted review, when the person intends to operate a designated institutional review board following Subparagraph 6 (e) of Attached Table 3 to be entrusted with review of clinical trials conducted by another clinical trial institution;
5. Documents evidencing that the person falls under any of the subparagraphs of Paragraph (1).

(3) Upon receipt of an application under Paragraph (2), the public official in charge shall verify a corporation registration certificate (limited to a corporation) and a license for opening a medical institution through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That when an applicant does not consent to the verification of the license for opening a medical institution, the public official shall ensure that such applicant attaches a copy thereof. <Amended on Dec. 31, 2018>

(4) Upon receipt of an application under Paragraph (2), the Minister of Food and Drug Safety may conduct a fact-finding survey to evaluate whether the details of such application meet the standards for designation.

(5) When the Minister of Food and Drug Safety designates a clinical trial institution, he or she shall issue a certificate of designation as a clinical trial institution for medical devices in Attached Form 23 to the applicant.

(6) When a clinical trial institution intends to modify designated matters, it shall submit an application for modification of the designation as a clinical trial institution for medical devices in Attached Form 24 to the Minister of Food and Drug Safety within 30 days from the date reasons for such modification occur, along with a certificate of designation as a clinical trial institution for medical devices and documents verifying modified matters.

(7) When the Minister of Food and Drug Safety modifies the designation of a clinical trial institution, he or she shall state the modified matters in a certificate of designation as a clinical trial institution for medical devices.
(8) When the Minister of Food and Drug Safety designates a clinical trial institution or modifies designation thereof following Paragraph (5) or (7), he or she shall publicly announce the name, location, representative, etc. of the clinical trial institution on the website, etc.
(9) Details necessary for the designation, operation, management, etc. of a clinical trial institution shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 22 (Collective Facilities) A "Collective facility prescribed by Ordinance of the Prime Minister, such as a social welfare facility" in the main clause of Article 10 (4) 2 of the Act refers to any of the following facilities: <Amended on Jun. 12, 2019>

1. Child welfare facilities under Article 52 (1) 1, 2, 3, and 5 of the Child Welfare Act;
2. Residential homes for persons with disabilities under Article 58 (1) 1 of the Act on Welfare of Persons with Disabilities;
3. Mental health improvement facilities under Subparagraph 4 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients (limited to those with protection rooms, in cases of mental medical institutions);
4. Residential welfare institutions for senior citizens (excluding welfare houses for senior citizens) and medical and welfare institutions for senior citizens (excluding geriatric hospitals) established following Article 34 of the Social Welfare Services Act;
5. Welfare institutions for senior citizens under Article 32 (1) 1 and 2 of the Welfare of Senior Citizens Act and Article 34 (1) 1 and 2 of that Act;
6. Mother-and-child family welfare facilities (support for basic living and self-support living), father-and-child family welfare facilities (support for basic living and self-support living), unmarried mother-and-child family welfare facilities (support for basic living), and temporary support welfare facilities under Article 19 of the Single-Parent Family Support Act;
7. Support facilities for victims, etc. of commercial sex acts under Article 9 (1) 1 and 2 of the Act on the Prevention of Commercial Sex Acts and Protection, etc. of Victims;
8. Protection facilities for victims of sexual violence under Article 12 of the Sexual Violence Prevention and Victims Protection Act;
9. Shelters for victims of domestic violence under Article 7 of the Act on the Prevention of Domestic Violence and Protection, etc. of Victims;
10. Facilities established by a person who obtains permission for a rehabilitation service following Article 67 of the Act on Probation, etc. (limited to those with committal facilities);
11. Correctional facilities under the Administration and Treatment of Correctional Institution Inmates Act and the Act on the Execution of Criminal Penalties in the Armed Forces and the Treatment of the Military Inmates;
12. Juvenile reformatories and Juvenile Classification Review Boards under the Act on the Treatment of Protected Juveniles, etc.;
13. Detention facilities under Article 52 (2) of the Immigration Act.

Article 23 Deleted. <Jun. 15, 2016>

Article 24 (Standards for Conducting Clinical Trials) (1) Following Article 10 (7) of the Act, clinical trials shall be conducted according to the following standards and the Good Clinical Practice for Medical Devices specified in Attached Table 3:

1. Clinical trials shall be conducted safely and scientifically according to a clinical trial protocol;
2. Clinical trials shall be conducted in a clinical trial institution designated by the Minister of Food and Drug Safety;
3. Clinical trial principal investigators shall be selected from among those with expertise, ethical discipline, and considerable experience in conducting clinical trials of the relevant medical devices;
4. An explanation shall be provided to subjects of clinical trials regarding clinical trial details and the details of and procedures for compensation for potential harm that could affect the health of the subjects during the clinical trials and other relevant matters, and written consent thereto shall be obtained from the subjects: Provided, That when it is impracticable to obtain consent from a subject because of his or her lack of comprehension and communication ability or other reasons, consent shall be obtained from a person with parental authority, guardian, etc.;
5. Safety measures for subjects of clinical trials shall be prepared;
6. Medical devices for clinical trials shall not be used for purposes other than clinical trials: Provided, that the same shall not apply to cases prescribed by the Minister of Food and Drug Safety, such as when the medical devices are used for patients with life-threatening and critical illnesses, including terminal cancer;
7. Clinical trials shall commence within 2 years from the date the approval of a clinical trial protocol or approval of modification thereof was obtained;
8. Clinical trial investigators shall be provided with clinical trial data books before conducting the clinical trials, as determined by the Minister of Food and Drug Safety;
9. When new data, information, etc. on safety and effectiveness is obtained, clinical trial investigators shall be informed thereof without delay and it shall be examined whether or not to reflect this new data, etc.;
10. Medical devices for clinical trials that are appropriately manufactured according to the standards for facilities and manufacturing and quality management systems under Attached Table 2 shall be used;
11. When adverse events occur while using a medical device, a person who has obtained approval of a clinical trial protocol shall report them to the Minister of Food and Drug Safety according to the Good Clinical Practices for Medical Devices specified in Attached Table 3;
12. Specimens shall be provided on condition of anonymity when clinical trials using the following specimens (hereinafter "leftover specimen") are conducted and consent under Subparagraph 4 is not obtained:
    (a) Human-derived specimens remaining after being used for the purpose of diagnosis or treatment at a medical institution;
    (b) Human-derived specimens remaining after being collected and used for specific research purposes for which a specimen provider has given comprehensive consent to the secondary use of specimens for other purposes.
13. Other matters determined by the Minister of Food and Drug Safety for the proper execution of a clinical trial shall be

observed.

(2) Regarding the status of a clinical trial, a person who has obtained approval for a clinical trial protocol shall submit a report on the status of clinical trial execution in Attached Form 25 (including a report in electronic form) to the Minister of Food and Drug Safety by the end of February each year, along with summarized data related to the safety evaluation of medical devices for clinical trials under Subparagraph 8 (q) (i) of Attached Table 3; and when the clinical trial is completed, he or she shall submit a report in Attached Form 26 (including a report in electronic form) to the Minister of Food and Drug Safety within 20 days from the date of completion. <Amended on Oct. 22, 2019>

(3) A clinical trial sponsor or the head of a clinical trial institution shall retain the clinical trial protocol and the records and data regarding the clinical trial execution (including electronic documents) for the periods classified as follows:

1. Data related to clinical trials for manufacturing or import permission, or permission for modification thereof: 3 years from the permission date;
2. Other data related to clinical trials: 3 years from the date of the completion of clinical trials.

(4) Notwithstanding the main clause of Paragraph (1) 4, a clinical trial may be conducted without consent from the subjects of the clinical trial by obtaining approval from an institutional review board for clinical trials if the clinical trials use leftover specimens and satisfy all the following requirements: Provided, That the same shall not apply when consent from a person with parental authority, guardian, etc. shall be obtained following the proviso of Paragraph (1) 4:

1. When it is impracticable to obtain consent from a subject of the clinical trial;
2. When no compelling reason exists for the subjects to withhold consent, and even without consent from the subjects, it is highly unlikely that the clinical trial would place them at risk.

(5) Details regarding the standards, etc. for designating clinical trial institutions under Paragraph (1) shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 24-2 (Designation of Institutions Conducting Non-Clinical Studies) (1) A person who intends to apply for the designation of an institution as an institution conducting non-clinical studies following Article 10-2 (1) of the Act shall satisfy the standards for the designation determined and publicly notified by the Minister of Food and Drug Safety, such as specialized personnel, facilities, and instruments necessary for each area of non-clinical study.

(2) A person who intends to apply for the designation of an institution as an institution conducting non-clinical studies shall submit an application for designation as an institution conducting non-clinical studies of medical devices in Attached Form 26-2 (including an application in electronic form) to the Minister of Food and Drug Safety, along with the following documents (including electronic documents):

1. Documents regarding the current status of the organization and personnel (for the current status of personnel, including documents evidencing qualifications and work experience);
2. Documents regarding the current status of equipment, instruments, and facilities;
3. Documents evidencing that non-clinical studies have been conducted as determined and publicly notified by the Minister of Food and Drug Safety to evidence that the person is capable of conducting non-clinical studies.

(3) Upon receipt of an application under Paragraph (2), the Minister of Food and Drug Safety may conduct a fact-finding survey to evaluate whether the details of such application meet the standards for designation.

(4) When the Minister of Food and Drug Safety designates an institution conducting non-clinical studies, he or she shall issue the applicant with a certificate of designation as an institution conducting non-clinical studies of medical devices in Attached Form 26-3.

(5) When an institution conducting non-clinical studies intends to modify any of the following matters, it shall submit an application for the modification of designated matters of an institution conducting non-clinical studies of medical devices in Attached Form 26-4 (including an application in electronic form) to the Minister of Food and Drug Safety within 30 days from the date reasons for such modification occur, along with a certificate of designation as an institution conducting non-clinical studies of medical devices and documents verifying the modified matters (including electronic documents):

1. The representative and operating officers of the institution conducting non-clinical studies;
2. The name and location of the institution conducting non-clinical studies;
3. Areas of non-clinical studies.

(6) When the Minister of Food and Drug Safety modifies designation of an institution conducting non-clinical studies, he or she shall state the modified matters in a certificate of designation as an institution conducting non-clinical studies of medical devices and issue such certificate.

(7) When the Minister of Food and Drug Safety designates an institution conducting non-clinical studies or modifies such designation, he or she shall publicly announce the name, location, representative, etc. of the institution conducting non-clinical studies on the website, etc. of the Ministry of Food and Drug Safety.

(8) Details regarding the scope of documents to be submitted under Paragraph (2) shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on May 1, 2017]

Article 24-3 (Compliance for Institutions Conducting Non-Clinical Studies) "Matters prescribed by Ordinance of the Prime Minister" in Article 10-2 (3) of the Act refers to the following matters:

1. Preparing a non-clinical study protocol and conducting non-clinical studies according to such protocol;
2. Requiring a person unassociated with the relevant non-clinical study to conduct an inspection or audit in order to ensure the credibility of non-clinical studies;
3. Evidencing that a non-clinical study has been conducted in compliance with the Good Clinical Practice for Non-Clinical Studies determined and publicly notified by the Minister of Food and Drug Safety;

4. Retaining data and records related to non-clinical studies for the periods classified as follows:
(a) Studies for permission of medical devices or permission for modification thereof, or studies for certification of medical devices or certification of modification thereof: 5 years from the date of issuance of a non-clinical study report;
(b) Studies for other purposes: 3 years from the date of issuance of a non-clinical study report.

[Newly inserted on May 1, 2017]

Article 25 (Subject Matters of Preliminary Examinations) (1) Subject matters and scope of a preliminary examination under Article 11 of the Act shall be as follows:

1. Matters regarding technical documents, etc. of newly developed medical devices or orphan medical devices under the subparagraphs of Article 8 (1) of the Act;
2. Other matters regarding the technical documents, etc. of medical devices for which the Minister of Food and Drug Safety deems that preliminary examinations are necessary.

(2) A person who intends to request a preliminary examination following Article 11 of the Act shall submit an application for a preliminary examination of medical devices in Attached Form 27 (including an application in electronic form) to the Minister of Food and Drug Safety or the head of the Institute according to the following classifications: <Amended on Jun. 14, 2018>

1. A person who intends to obtain manufacturing permission for medical devices following Article 6 (2) of the Act or undergo a clinical trial following Article 10 of the Act: The Minister of Food and Drug Safety;
2. A person who intends to obtain manufacturing certification or to file a manufacturing notification: The head of the Institute.

(3) The Minister of Food and Drug Safety or the head of the Institute shall inform the applicant of the results of a preliminary examination as prepared in the notice of the results of a preliminary examination of medical devices in Attached Form 28. <Amended on Jun. 14, 2018>

(4) Except as provided in Paragraphs (1) through (3), the details necessary for the procedures, methods, etc. for preliminary examinations shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 26 (Application for Permission for Modification of Permitted Matters) (1) Following Article 12 (1) of the Act, when any modification is made to matters for which manufacturing business permission is granted, a manufacturer shall submit an application for permission for modification in Attached Form 29 to the Commissioner of the Regional Office of Food and Drug Safety within 30 days from the date such modification is made, along with the data classified as follows. <Amended on Jan. 21, 2022>

1. When the location of a factory is modified or another factory is added, a copy of a contract for entrustment (limited to when manufacturing processes or testing are entrusted) and data evidencing the compliance with the standards for facilities and manufacturing and quality management systems under Attached Table 2 [excluding the manufacturing factories of medical devices that are developed and manufactured merely in the form of software that has obtained permission or certification or for which notification is filed]);
2. When a quality manager is replaced, data verifying the qualifications under Article 11 (2) of the replaced quality manager

(2) Upon receipt of an application under Paragraph (1), the Commissioner of the Regional Office of Food and Drug Safety shall verify a corporation registration certificate (limited to a corporation) through administrative data matching under Article 36 (1) of the Electronic Government Act. <Amended on Jun. 15, 2016>

(3) Following Article 12 (1) of the Act, when any modification is made to matters regarding manufacturing permission or manufacturing certification granted or a manufacturing notification filed, a manufacturer shall submit an application for permission for modification in Attached Form 30 to the Minister of Food and Drug Safety and submit an application for certification of modification in Attached Form 31 or a notification in Attached Form 7 to the head of the Institute, respectively, along with the following documents: <Amended on Jun. 14. 2018, Jan. 21, 2022>

1. Documents verifying modified matters (including electronic documents);
2. Documents under Article 5 (1) 2, when modification is made to any important matter that affects the safety or effectiveness of products, such as the design, materials, chemical components, energy sources, and manufacturing processes of medical devices;
3. A copy of the contract for entrustment (limited to when manufacturing processes or testing are entrusted) and data evidencing the compliance with the standards for facilities and manufacturing and quality management systems under Attached Table 2, when the location of a factory of the relevant item is modified or another factory is added (excluding manufacturing factories of medical devices in the form of software).

(4) When a person to whom the relevant manufacturing facilities, methods, etc. are transferred as a consequence of the division, merger, etc. of a company obtains permission for or certification of the modification of the manufactured item or files a notification of modification thereof following Paragraph (3), he or she shall submit the relevant application or notification to the Minister of Food and Drug Safety or the head of the Institute, along with a transfer or acquisition contract regarding the manufacturing facilities, methods, etc. of the relevant item. In such cases, when permission for or certification of modification of the relevant item is granted, conditions equivalent to those on the permission or certification for a transferor may be attached. <Amended on Jun. 14, 2018>

(5) When matters modified following Paragraph (3) pertain to the external appearance, packaging materials, packaging units, etc. of a manufactured item and are minor matters determined and publicly notified by the Minister of Food and Drug Safety, documents stating the details of the modification (including electronic documents) shall be submitted to the Minister of Food and Drug Safety or the head of the Institute, notwithstanding that Paragraph. In such cases, permission for or certification of modification or a notification of modification under Article 12 of the Act shall be deemed obtained or filed. <Amended on Jun. 14, 2018>

(6) In any of the following cases where any modification is made to matters permitted, certified, or notified, permission for or certification of modification or a notification of the modification under Article 12 of the Act shall be deemed obtained or filed: Provided, That in cases falling under Subparagraph 3, 4, or 6, the same shall apply only when any modification is made after an order of modification is issued by a certain time limit following Article 36 (2) of the Act: <Amended on Jan. 21, 2022>

1. Modification of the standards for the classification and designation of classes under Article 3 of the Act;
2. Modification of technical documents or clinical trial data under Article 6 (5) of the Act;
3. Follow-up measures according to a review of post-market surveillance of newly-developed medical devices, etc. under Article 8-2 (2) of the Act;
4. Re-evaluation under Article 9 of the Act;
5. Modification of standard specifications under Article 19 of the Act;
6. Measures taken following a report on side effects under Article 31 of the Act.

(7) When the Minister of Food and Drug Safety, the Commissioner of the Regional Office of Food and Drug Safety, or the head of the Institute grants permission for or the certification of modification or accepts a notification of modification following Paragraphs (1) through (6), he or she shall enter the modified matters in the relevant register. <Amended on Jun. 14, 2018>

(8) Details regarding the standards and procedures for the permission, certification, or notification of modification, the requirements for, scope of exemption of, and management of data, and other matters under Paragraphs (1) through (7) shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 27 (Compliance for Manufacturers) (1) Matters to be observed by Compliance obligations for medical device manufacturers following Article 13 (1) of the Act shall be as follows: <Amended on Dec. 4, 2020, Jan. 21, 2022>

1. Manufacturers shall manage the facilities of factories in a sanitary manner so as to not cause any harm to health and hygiene, and shall prevent cross-contamination or contamination, etc. from the outside;
2. Manufacturers shall not place objects likely to cause harm in working places, and shall prevent substances hazardous to public health from being discharged or released from working places;
3. Manufacturers shall prepare and keep documents about warehousing and release of raw materials and finished products, manufacturing processes, and quality management (including testing standards and methods, etc.) and shall thoroughly conduct manufacturing and quality inspections based on such documents;
4. Manufacturers shall prepare and keep the records of manufacturing and quality inspections under Subparagraph 3 by manufacturing unit and the records of handling customers' complaints, and shall retain such records for 5 years from the date of manufacturing (referring to a period corresponding to the product life cycle, where such life cycle exceeds 5 years);
5. When the safety and effectiveness of released medical devices are undermined or the quality thereof is poor, manufacturers shall take corrective measures, such as recall, without delay;
6. Manufacturers shall release sterile products after verifying that they have been packaged and sterilized in new containers;
7. Manufacturers shall release electronic or mechanical products after ensuring their electronic, mechanical, and electromagnetic safety;
8. Manufacturers shall release products to come in direct or indirect contact with the human body after ensuring their biological safety;
9. When manufacturers become aware of new data or information on the safety and effectiveness of permitted, certified, or notified medical devices (including cases of side effects following the use of the devices), they shall report it and take necessary safety measures as determined by the Minister of Food and Drug Safety;
10. Manufacturers shall maintain the standards for facilities and manufacturing and quality management systems under Attached Table 2;
11. Manufacturers shall distribute medical devices manufactured in compliance with the standards under Subparagraph 2 of Attached Table 2. In such cases, medical devices manufactured for the purpose of the recognition of compliance following Subparagraph 2 (f) of Attached Table 2 and recognized as compliant following that item shall be deemed manufactured after being recognized as compliant following that item;
12. Manufacturers shall conduct manufacturing and quality management or production management by applying the latest standard specifications determined by the Minister of Food and Drug Safety following Article 19 of the Act;
13. Manufacturers shall thoroughly inspect the hygiene of employees and provide them with the education and training necessary for the production of medical devices with excellent quality;
14. Manufacturers shall thoroughly conduct the affairs of post-market safety management, such as post-market surveillance, re-evaluation, management of medical devices subject to tracking management, and management of information regarding safety (including the management of reports on side effects);
15. When manufacturers purchase medical devices manufactured by their company from medical institutions, they shall observe the following:
    (a) They shall inspect whether such medical devices are in compliance with the standards for manufacturing and quality management systems for medical devices under Subparagraph 2 of Attached Table 2 and release them with certificates of inspection attached thereto only if they comply with such standards;
    (b) They shall prepare and keep the records of the content and results of inspections under item (a), the dates of issued certificates of inspection, etc., and shall retain such records for 2 years from the relevant date of release.
16. When manufacturers are requested to conduct inspections by medical device distributors or lessors following Subparagraph 1 (a) of Article 39, they shall observe the following:
    (a) They shall inspect whether medical devices are in compliance with the standards for manufacturing and quality management systems for medical devices under Subparagraph 2 of Attached Table 2 and issue certificates of inspection only if they comply with such standards;
    (b) They shall observe the matters determined and publicly notified by the Minister of Food and Drug Safety regarding the procedures and methods for issuing certificates of inspection, the period of reply, instructions about distribution or lease, etc.

(2) Manufacturers shall report the following matters to the Minister of Health and Welfare and the Minister of Food and Drug Safety following Article 13 (2) of the Act as determined and publicly notified by the Minister of Food and Drug Safety: <Amended on Apr. 13, 2020>

1. Results of producing and exporting medical devices for the pertinent year;
2. Reasons for and the amount and schedule of suspension of medical devices (limited to cases involving the suspension of the production of medical devices that have grave effects on public health where such devices is are publicly notified by the Minister of Food and Drug Safety after consultation with the Minister of Health and Welfare).

Article 28 (Notification of Business Closure) (1) When a manufacturer intends to file a notification of business closure or business suspension following Article 14 of the Act, they shall submit a notification in Attached Form 32 (including a notification in electronic form) to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of a factory, along with the following documents; and when a person who has suspended his or her business intends to file a notification of business resumption, he or she shall submit a notification in Attached Form 32 (including a notification in electronic form) to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the factory: <Amended on Apr. 13, 2020>

1. In case of business closure: A manufacturing business license and all the manufacturing licenses and certificates: Provided, That when the relevant licenses or certificates are lost, a written reason for the loss shall be submitted;
2. In case of business suspension: A manufacturing business license

(2) When a manufacturer intends to file a notification of business closure or business suspension following Article 14 of the Act along with a notification of business closure or business suspension following Article 8 (7) of the Value-Added Tax Act, he or she shall submit to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of a factory a notification in Attached Form 32 (including a notification in electronic form), along with the documents under the classifications of each subparagraph of Paragraph (1) and a notification of business suspension and business closure in Attached Form 9 of the Enforcement Rule of the Value-Added Tax Act. In such cases, the Commissioner of the Regional Office of Food and Drug Safety shall forward (including via an information and communications network; hereinafter, in this Article, the same shall apply) to the head of a tax office having jurisdiction over the location of a factory a notification of business suspension and business closure in Attached Form 9 of the Enforcement Rule of the Value-Added Tax Act. <Newly inserted on Apr. 13, 2020>

(3) Upon receipt of a notification of business closure under Paragraphs (1) and (2), the Commissioner of the Regional Office of Food and Drug Safety shall enter such details in the manufacturing business permission register; and upon receipt of a notification of business suspension or resumption, they shall enter such details in the manufacturing business permission register and a manufacturing business license, respectively. <Amended on Apr. 13, 2020>

(4) When the head of a tax office having jurisdiction over the location of a factory receives a notification of business closure or business suspension and forwards it to the head of the competent regional office of Food and Drug Safety following Article 13 (5) of the Enforcement Decree of the Value-Added Tax Act, a notification of business closure or business suspension under Paragraph (1) shall be deemed submitted. <Amended on Apr. 13, 2020>

Article 29 (Application for Import Business Permission) (1) A person who intends to obtain import business permission for medical devices following Article 15 (1) of the Act shall submit the application in Attached Form 1 (including an application in electronic form) to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of an import business, along with the documents referred to in the subparagraphs of Article 3 (1) (including electronic documents).

(2) Upon receipt of an application under Paragraph (1), the Commissioner of the Regional Office of Food and Drug Safety shall verify a corporation registration certificate (limited to a corporation) through administrative data matching under Article 36 (1) of the Electronic Government Act.

Article 30 (Application for Importing Permission) (1) A person who intends to obtain import permission for medical devices following Article 15 (2) of the Act shall submit an application in Attached Form 3 (including an application in electronic form) to the Minister of Food and Drug Safety, along with the following documents (including electronic documents):

1. Documents referred to in Article 5 (1) 2: Provided, That such documents may be omitted when it is evidenced that medical devices to be imported are the same products with the same origin of manufacture (referring to the same country of manufacture, manufacturing company, and factory), as medical devices already permitted, as determined by the Minister of Food and Drug Safety;
2. Documents evidencing that a factory of medical devices to be imported has the manufacturing and quality management systems under Article 15 (4) of the Act.

(2) A person who intends to obtain importing certification for medical devices following Article 15 (2) of the Act shall submit an application in Attached Form 5 (including an application in electronic form) to the head of the Institute, along with the documents referred to in the subparagraphs of Paragraph (1) (including electronic documents). In such cases, “permitted” in the proviso of Paragraph (1) 1 shall be deemed “certified.” <Amended on Jun. 14, 2018>

(3) A person who intends to file an importing notification for medical devices following Article 15 (2) of the Act shall submit a notification in Attached Form 7 (including a notification in electronic form) to the head of the Institute. <Amended on Jun. 14, 2018>

Article 31 (Standards for Facilities and Manufacturing and Quality Management Systems for Quality Inspections) (1) A person who intends to obtain import business permission or who intends to obtain import permission or importing certification or file an importing notification following the main clause of Article 15 (4) of the Act shall prepare the standards for the facilities and manufacturing and quality management systems as specified in Attached Table 4.

(2) “Cases prescribed by Ordinance of the Prime Minister, such as entrusting quality management testing” in the proviso of Article 15 (4) of the Act refers to when a person who intends to obtain import business permission, or who intends to obtain import permission or importing certification or file an importing notification entrusts quality management testing to any of the following persons. In such cases, such person need not be equipped with laboratories or testing facilities under Subparagraph 1 (c) of Attached Table 4: <Amended on May 1, 2017>

1. A medical device testing and inspection institution;
1-2. An institution conducting non-clinical studies;
2. A manufacturer whose compliance has been recognized following Subparagraph 2 (f) of Attached Table 2.

Article 32 (Exemption from Permission for Medical Device Import Businesses) (1) Medical devices that may be imported without obtaining import business permission, import permission, or importing certification or without filing an importing notification following Article 6 (10) of the Act applied *mutatis mutandis* according to Article 15 (6) of the Act shall be as follows. <Amended on Jun. 15, 2016, Jun. 14, 2018, Dec. 31, 2018>

1. A medical device subject to clinical trials for which approval of a clinical trial protocol is granted under the main clause of Article 10 (1) of the Act;
2. A separate medical device required for clinical trials for which approval of a clinical trial protocol need not be granted under the proviso of Article 10 (1) of the Act;
3. A separate medical device required for clinical trials regarding drugs, etc. for which approval of a clinical trial protocol shall be granted under Article 34 of the Pharmaceutical Affairs Act;
4. A medical device imported to obtain import permission or certification of medical devices or to file an importing notification thereof;
5. A medical device used for the purpose of research, such as product development;
5-2. A medical device not for distribution, which is imported to help consumers purchase a product, such as checking the actual appearance of the product;
5-3. A medical device imported to conduct testing and inspections under Article 27 of the Act;
6. A medical device determined and publicly notified by the Minister of Food and Drug Safety, such as a medical device for self-use or for relief operations, etc.;
7. Deleted. <Dec. 31, 2018>
8. A medical device determined and publicly notified by the Minister of Food and Drug Safety which is used in clinical laboratories and deemed suitable by the Minister based on the evaluations of quality management systems, inspection performance and competence, etc.

(2) Matters regarding the import procedures, subject matters, issuance of a certificate, etc. of medical devices excluded from those subject to import business permission and import permission, certification, or notification following Paragraph (1) shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 33 (Compliance for Importers) (1) Compliance obligations for a medical device importer under Article 13 (1) of the Act applied *mutatis mutandis* according to Article 15 (6) of the Act shall be as follows: <Amended on Dec. 4, 2020, Jan. 21, 2022>

1. The importer shall manage the facilities of an import business in a sanitary manner so as to not cause any harm to health or hygiene and shall prevent cross-contamination or contamination, etc. from the outside;
2. The importer shall prepare and keep documents regarding the warehousing, release, and quality management of medical devices (including testing standards and methods, labeling, packaging, etc.) and management records on storage and shipment of accessories, and shall thoroughly conduct import and quality inspections based on such documents and records;
3. The importer shall prepare and keep the records of import and quality inspections under Subparagraph 2 by import unit and the records of handling customers' complaints, and shall retain such records for 5 years from the date of import (referring to a period corresponding to the product life cycle, where the product life cycle exceeds 5 years);
4. The importer shall release products only after verifying that the products have been sterilized;
5. The importer shall release electronic or mechanical products after ensuring their electronic, mechanical, and electromagnetic safety;
6. The importer shall release products to come in direct or indirect contact with the human body after ensuring their biological safety;
7. The importer shall prepare and keep a manual of product specifications by item including the following matters:
   (a) The name of a medical device (the product name, item name, and model name);
   (b) The name of a manufacturing company of an imported medical device and the country of manufacture thereof;
   (c) Self-quality-management-test specifications of the shapes, structures, and finished products;
   (d) Matters to be stated on the container, etc. of a medical device, as prescribed in Articles 20 through 23 of the Act;
   (e) The method for and order of installation (limited to medical devices for which installation management is required);
   (f) Matters regarding sterilization methods and standards, and assessment (limited to medical devices applied with sterile packaging);
   (g) The presenter and presentation date of a manual of product specifications (if revised, the reviser and date and cause of revision shall be stated);
8. The importer shall prepare and keep import management standards, including the following matters:
   (a) Matters regarding product management and testing and inspections;
   (b) Matters regarding an assessment of the results of testing and inspections and the handling of rejected products;
   (c) Matters regarding the management of testing and inspection facilities;
   (d) Methods for contacting the manufacturer of an imported medical device;
   (e) Matters regarding the conditions of manufacture and quality management by a manufacturer of an imported medical device;
   (f) The presenter and presentation date of import management standards (if revised, the reviser and date and cause of revision shall be stated).
9. The importer shall check whether an imported medical device has proper and correct labeling and packaging and prepare the records thereon;
10. The importer shall inspect product storage facilities and prepare the records thereon;
11. The importer shall ensure that a quality manager implements the following matters;
   (a) When complaints against the quality of released medical devices are filed, the quality manager shall prepare and

implement the relevant procedures to identify the causes thereof and take corrective measures and prepare and retain such records;

(b) The quality manager shall keep and use a manual of product specifications and import management standards for proper quality management of imported medical devices;

(c) The quality manager shall prepare work instructions based on documents under item (b) and inspect and check whether they are properly operated in compliance with the standards;

12. The importer shall take corrective measures, such as recall, without delay when the safety and effectiveness of released medical devices are undermined or the quality thereof is poor;

13. The importer shall formulate education plans to enable his or her employees to ensure the quality of imported medical devices, hold regular education and training sessions based on the plans, and prepare and retain records thereon;

14. When the importer becomes aware of new data or information on the safety and effectiveness of a medical device permitted, certified, or notified (including cases of side effects related to the use of the medical device), he or she shall report it and prepare the necessary safety measures as determined by the Minister of Food and Drug Safety;

15. For a factory of imported medical devices, the importer shall import and distribute medical devices manufactured in compliance with the standards specified in Subparagraph 3 of Attached Table 4. In such cases, medical devices imported for the purpose of the recognition of compliance under Subparagraph 3 of Attached Table 4 and recognized as compliant under that subparagraph shall be deemed imported after being recognized as compliant under that subparagraph;

16. The importer shall comply with the guidelines for export and import of medical devices publicly announced by the Minister of Trade, Industry and Energy under Article 12 of the Foreign Trade Act and regulations for management of imported medical devices determined by the Minister of Food and Drug Safety;

17. The importer shall apply the latest standard specifications determined by the Minister of Food and Drug Safety following Article 19 of the Act to maintain facilities and manufacturing and quality management systems, to import medical devices, and to conduct quality management or import management;

18. The importer shall thoroughly perform the affairs of post-market safety management, including post-market surveillance, re-evaluation, management of medical devices subject to tracking management, and management of safety information (including management of reports on side effects);

19. When the importer imports secondhand medical devices or purchases medical devices imported by his or her company from a medical institution, he or she shall observe the following:

(a) He or she shall inspect whether the medical devices are in compliance with the test specifications referred to in Subparagraph 7 (c) and release them with certificates of inspection attached thereto only where they are in compliance with such specifications;

(b) He or she shall prepare and keep the records of the details and results of inspections under item (a), the date of issuing certificates of inspection, etc. and retain such records for 2 years from the date of release;

20. Where the importer is requested to conduct an inspection by a medical device distributor or lessor under Subparagraph 1 (a) of Article 39, he or she shall observe the following:

(a) He or she shall inspect whether the medical devices are in compliance with the standards specified in Subparagraph 2 of Attached Table 2 and issue certificates of inspection only where they are in compliance with such standards;

(b) He or she shall comply with the matters determined and publicly notified by the Minister of Food and Drug Safety regarding the procedures and methods for issuing certificates of inspection, period of reply, instructions on distribution or lease, etc.

(2) An importer shall report to the Minister of Health and Welfare and the Minister of Food and Drug Safety the following matters as determined and publicly notified by the Minister of Food and Drug Safety under Article 13 (2) of the Act applied *mutatis mutandis* according to Article 15 (6) of the Act: Provided, That such report on matters under Subparagraph 1 need not be filed when a standard customs clearance forecast report has been filed in an electronic trade document under the Electronic Trade Facilitation Act: <Amended on Apr. 13, 2020>

1. Results of importing medical devices for the pertinent year;

2. Reasons for and the amount and schedule of suspension of medical devices (limited to cases of suspension of the production of medical devices that have grave effects on public health where such devices are publicly notified by the Minister of Food and Drug Safety after consultation with the Minister of Health and Welfare).

Article 34 (Application *Mutatis Mutandis*) Articles 3 (3), Article 4, article 5 (2) through (7), Article 6 (2) and (3), Article 7 (2) and (3), Article 9, Article 11 through 13, Article 16 through 19, Article 25, Article 26 (excluding Article 26 (1) 1), Article 28, and Article 64 shall apply *mutatis mutandis* to importers and import items. In such cases, “factory” shall be construed as “import business facility,” “manufacturing” as “import," “Paragraph (1)” in Article 5 (4) as “Article 30 (1),” “Article 27 (1)” in Article 12 (1) 9 as “Article 33 (1),” “import” in Article 12 (3) 2 as “manufacturing,” “Article 5 (1) 2” in Article 16 (2) as “Article 30 (1) 1,” and “Article 5 (1) 2” in Article 16 (3) as “Article 30 (1) 1”, respectively. <Amended Jul. 29, 2016, May 1, 2017>

Article 34-2 (Method for Supplying Orphan Medical Devices or Those in Urgent Need of Introduction) (1) When the Minister of Food and Drug Safety intends to supply orphan medical devices or those in urgent need of introduction under Article 15-2 (1), with the exception of its subparagraphs, of the Act (hereinafter “orphan medical devices or those in urgent need of introduction”), he or she shall conduct surveys on demand thereof from the relevant administrative agencies, medical institutions, health and medical service-related institutions, organizations and experts, patients, etc.

(2) When the Minister of Food and Drug Safety conducts surveys on demand under Paragraph (1), they shall establish quarterly, semi-annual, and annual plans to supply orphan medical devices or those in urgent need of introduction, including the following matters:

1. Matters regarding supply quantities;

2. Matters regarding supply prices;

3. Matters regarding supply targets;
4. Other matters deemed necessary by the Minister of Food and Drug Safety to supply orphan medical devices or those in urgent need of introduction.

(3) When the Minister of Food and Drug Safety intends to supply orphan medical devices or those in urgent need of introduction according to the supply plans under Paragraph (2), he or she shall conclude a supply contract with a supply target.

(4) Except as provided in Paragraphs (1) through (3), details necessary for methods for supplying orphan medical devices or those in urgent need of introduction shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on Jun. 12, 2019]

Article 34-3 (Entrustment of the Supply of Orphan Medical Devices or Those in Urgent Need of Introduction) (1) The Minister of Food and Drug Safety shall entrust the affairs related to the supply of orphan medical devices or those in urgent need of introduction and the provision of relevant information to the Institute under Article 15-2 (2) of the Act.

(2) The Institute entrusted with the affairs of orphan medical devices or those in urgent need of introduction under Paragraph (1) shall submit to the Minister of Food and Drug Safety a business operation plan, a fund operation plan, an update on business progress, fund execution details, etc. regarding the entrusted affairs as determined by the Minister of Food and Drug Safety.

[Newly inserted on Jun. 12, 2019]

Article 35 (Notification of Repair Businesses) (1) A person who intends to engage in the business of repairing medical devices under Article 16 (1) of the Act shall submit a notification for repair businesses in Attached Form 33 (including a notification in electronic form), along with the documents referred to in Article 3 (1) 1 and 2 (including electronic documents) to the Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, or a Self-Governing Province Governor (hereinafter the "Mayor/*Do* Governor") having jurisdiction over the location of a repair business. In such cases, the Mayor/Do Governor shall verify a corporation registration certificate (limited to a corporation) through the administrative data matching under Article 36 (1) of the Electronic Government Act. <Amended Apr. 13, 2020, Jun. 24, 2021>

(2) Upon acceptance of a repair business notification following Paragraph (1), the Mayor/Do Governor shall issue a certificate of notification in Attached Form 34 to a person who files such notification, and enter the following information in the repair business notification register: <Amended on Jun. 24, 2021>

1. The notification acceptance number and acceptance date;
2. Types of medical devices to be repaired;
3. The name and resident registration number of the repairer (in cases of a corporation, the name and resident registration number of its representative);
4. The name and location of the repair business (in cases of a corporation, the location of its principal office).

(3) When a repairer intends to modify the notified matters, he or she shall submit a notification for modification in Attached Form 35 (including a notification in electronic form) to the Mayor/*Do* Governor having jurisdiction over the repair business place, along with reasons for such modification, evidentiary documents therefor (including electronic documents), and the certificate of notification. In such cases, when the change of a location changes the competent notification-receiving authority, he or she shall submit the requirements to the Mayor/*Do* Governor having jurisdiction over the new location. <Amended on Jun. 24, 2021>

(4) Facilities and quality management systems to be secured by a person intending to file a notification of a repair business under the main clause of Article 16 (2) of the Act shall be as specified in Attached Table 5.

(5) When a repairer closes or suspends his or her business under Article 14 of the Act applied *mutatis mutandis* according to Article 16 (4) of the Act, he or she shall submit a notification in Attached Form 32 (including a notification in electronic form), along with the certificate of notification, to the Mayor/*Do* Governor having jurisdiction over the repair business place. When a person who has suspended their business files a notification for business resumption, he or she shall submit a notification in Attached Form 32 (including a notification in electronic form) to the Mayor/*Do* Governor having jurisdiction over the repair business place. <Amended Apr. 13, 2020, Jun. 24, 2021>

(6) Upon receipt of a notification under Paragraph (3) or (5), the Mayor/*Do* Governor shall enter the notification details in the relevant notification register and the certificate of notification, respectively. <Amended on Jun. 24, 2021>

(7) Article 28 (2) and (4) shall apply *mutatis mutandis* to a notification of business closure or business suspension under Paragraph (5). In such cases, "the Commissioner of the Regional Office of Food and Drug Safety" shall be construed as "the Mayor/*Do* Governor." <Amended on Apr. 13, 2020, Jun. 24, 2021>

Article 36 (Compliance for Repairers) Compliance obligations for repairers of medical devices under Article 13 of the Act applied *mutatis mutandis* according to Article 16 (4) of the Act shall be as follows: <Amended on Jun. 14, 2018>

1. They shall not repair a medical device by making alterations inconsistent with the details permitted, certified, or notified. This shall not apply to a minor repair for change under Article 46-2;
2. They shall state the trade name and address on the container or wrapper of a medical device where such device is repaired;
3. They shall notify a person who requests the repair of a medical device of the repair details in writing (in cases of a minor repair for change under Article 46-2, the details of such repair for change shall be included);
4. They shall maintain facilities and quality management systems under Article 35 (4).

Article 37 (Notification of Distribution Business or Leasing Business) (1) A person who intends to engage in the business of distributing or leasing medical devices under Article 17 (1) of the Act shall submit a notification in Attached Form 36 (including a notification in electronic form) to the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* (the head of a *Gu* refers to the head of an autonomous *Gu*; hereinafter the same shall apply) having jurisdiction over the distribution or leasing business place. In such cases, the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall verify a corporation registration certificate (limited to a corporation) through administrative data matching under Article 36 (1) of the Electronic Government Act. <Amended Apr. 13. 2020., Jun. 24., 2021>

(2) Upon acceptance of a notification of a medical device distribution or leasing business under Paragraph (1), the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall issue the certificate of notification in Attached Form 37 and enter the following information in the distribution or leasing business notification register: <Amended on Apr. 13, 2020>

1. The notification number and notification date;
2. The name and resident registration number of the medical device distributor or lessor (in cases of a corporation, the name and resident registration number of its representative);
3. The name and location of the business place.

(3) When a distributor or lessor modifies the matters notified following Paragraph (1), he or she shall submit a notification of modification in Attached Form 38 (including a notification in electronic form), along with the certificate of notification and documents verifying such modification, to the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* having jurisdiction over the distribution or leasing business place. In such cases, when the change of a location changes the competent notification-receiving authority, he or she shall submit the requirements to the Mayor/*Do* Governor having jurisdiction over the new location. <Amended on Apr. 13, 2020>

(4) When a distributor or lessor intends to file a notification of business closure or business suspension, he or she shall submit a notification in Attached Form 32 (including a notification in electronic form), along with the certificate of notification to the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* having jurisdiction over the distribution or leasing business place; and when a person who has suspended his or her business intends to file a notification of business resumption, he or she shall submit a notification in Attached Form 32 (including a notification in electronic form) to the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* having jurisdiction over the distribution or leasing business place. <Amended on Apr. 13, 2020>

(5) Upon receipt of a notification under Paragraph (3) or (4), the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall enter the notification details in the relevant notification register and the certificate of notification, respectively. <Amended on Apr. 13, 2020>

(6) Article 28 (2) and (4) shall apply *mutatis mutandis* to a notification of business suspension or business closure under Paragraph (4). In such cases, the "Commissioner of the Regional Office of Food and Drug Safety" shall be construed as the "Special Self-Governing Province Governor or the head of a *Si/Gun/Gu*." <Amended on Apr. 13, 2020>

Article 38 (Exemption from Distribution Business Notifications) Any of the following medical devices may be distributed without filing a notification under Article 17 (2) 4 of the Act:

1. Condoms;
2. Mobile phones, household electric appliances, etc., which have blood a feature of glucose monitoring or blood glucose monitoring devices used in combination therewith;
3. Other medical devices publicly notified by the Minister of Food and Drug Safety considering the degree of harm and safety.

Article 39 (Method for Ensuring Quality of Medical Devices by Distributor or Lessor) The method for ensuring the quality of medical devices under Article 18 (1) of the Act and Subparagraph 1 of Article 10-2 of the Enforcement Decree of the Medical Devices Act (hereinafter the "Decree") shall be as follows: <Amended on Jun. 15, 2016>

1. When a distributor or lessor purchases medical devices from a medical institution, he or she shall comply with the following matters:
   (a) The distributor or lessor shall request the manufacturer or importer of the relevant medical devices for inspections or request a medical device testing and inspection institution for inspections;
   (b) The distributor or lessor shall distribute or lease only the medical devices that have received certificates of inspection issued following Article 27 (1) 15 (a) or 33 (1) 19 (a) according to the results of the inspections under item (a);
   (c) When the distributor or lessor receives any instructions regarding distribution or lease following Article 27 (1) 16 (b) or 33 (1) 20 (b) according to the results of the inspections under item (a), he or she shall comply with such instructions.
2. A distributor or lessor shall prepare the records of the details and results of an inspection under each item of Subparagraph 1, the issuer and issuance date of a certificate of inspection, instructions regarding distribution or lease, etc. and retain such records for 2 years from the date of distribution;
3. A distributor or lessor shall prepare and keep the records regarding the handling of defective medical devices and retain such records for 1 year from the date of the record;
4. A distributor or lessor shall comply with the standards for distribution quality management of medical devices specified in Attached Table 6: Provided, That this shall not apply when the business is exempted from distribution business notification requirements under Article 17 (2) of the Act.

Article 40 (Matters Regarding Maintenance of Order in Distribution by Distributor or Lessor) Matters regarding the maintenance of order in distribution in relation to the safety of medical devices, etc. under Article 18 (1) of the Act and Subparagraph 1 of Article 10-2 of the Decree shall be as follows:

1. A distributor or lessor shall not purchase medical devices from persons other than manufacturers, importers, and distributors: Provided, That purchases from a medical institution shall be excluded;

2. A distributor or lessor shall not use any of the following names or labels for the name, etc. of a business place and shall not use them together with the label of the business place;
(a) A name or label likely to be misunderstood as a business place of a manufacturer or an importer;
(b) The name of a medical institution under Article 3 of the Medical Service Act or any name similar thereto.
3. A distributor or lessor shall not distribute or lease any of the following medical devices and shall not store or display them for the purpose of distribution or lease:
(a) Medical devices with no certificates of inspection attached under Subparagraph 1 (b) of Article 39;
(b) Medical devices contaminated or damaged or those subject to an order of collection or destruction issued by the Minister of Food and Drug Safety or the Commissioner of the Regional Office of Food and Drug Safety;
(c) Medical devices whose use-by dates or expiration dates passed.
4. A distributor or lessor shall not distribute medical devices for which permission or certification has not been obtained or a notification has not been filed and shall not store or display them for the purpose of distribution.

Article 41 (Exemption from Certificates of Inspection of Secondhand Medical Devices) Medical devices determined and publicly notified by the Minister of Food and Drug Safety, such as medical devices with low potential risk, may be distributed with no certificate of inspection attached, notwithstanding Articles 27 (1) 15 and 33 (1) 19, Subparagraph 1 (b) of Article 39, and Subparagraph 3 (a) of Article 40.

Article 42 (Labeling on Container) The container or wrapper of a medical device need not be labeled following the proviso of Article 20, with the exception of its subparagraphs, of the Act, in any of the following cases: <Amended on Jun. 15, 2016>
1. When the area of the container or wrapper is too small, or the container or wrapper cannot contain all the matters referred to in the subparagraphs of Article 20 of the Act, and therefore, such matters are stated on an outside container, outside package, or package insert: Provided, That even in such cases, the model name or the trade name of a manufacturer or importer shall be stated on the container or wrapper of a medical device;
2. When a medical device for export has been labeled according to the standards of the export destination country.

Article 43 (Labeling on Package Inserts) (1) "Matters prescribed by Ordinance of the Prime Minister" in Article 22 (1) 4 of the Act refers to the following:
1. The matters prescribed in Subparagraphs 1 through 3 and 5 through 7 of Article 20 of the Act;
2. The intended use of a product;
3. Keeping or storage methods;
4. The trade names and addresses of a person requesting manufacture (referring to the person who entrusts) and a manufacturer (referring to the person to whom it is entrusted) when a domestic manufacturer entrusts the entire manufacturing processes;
5. A model name and the name of a manufacturing business labeled on a minimum unit package, for devices individually packaged for single use;
6. Information regarding appropriate procedures for reuse, such as cleaning, disinfection, packaging, re-sterilization methods, and the limit on the number of times of reuse, in cases of medical devices reusable after sterilization;
7. Matters regarding the characteristics, types, intensity, diffusion, etc. of radiation, in cases of medical devices emitting radiation for the purpose of medical treatment;
8. The date of the preparation of package inserts;
9. Other matters regarding technical information, such as characteristics of medical devices.

(2) The following shall be stated in the package insert of a medical device for clinical trials, notwithstanding Paragraph (1):
1. The label “For Clinical Trials”;
2. The product name and model name;
3. The manufacturing number and manufacturing date (which may be replaced with the use-by date, if any);
4. Keeping and storage methods;
5. The trade name of a manufacturer or an importer (in cases of entrusted manufacturing or import, including the origin of manufacture and country name);
6. The label “Not Permitted for Use for Purposes Other than Clinical Trials”.

(3) When the matters prescribed in Paragraph (1) 1 through 5 are stated on a container, wrapper, or package, the package insert may not include such labeling.

Article 44 (Labeling Methods) (1) Following Article 23 of the Act, the container, wrapper, outside container, package, or package insert of a medical device shall be labeled according to the following methods: <Amended on Jun 24, 2021>
1. A label shall be provided in Korean alphabet hangeul, and a label in Chinese characters or other foreign languages in the same font size as that of Hangeul may be added: Provided, That a label need not be provided in hangeul in the following cases:
(a) Providing a label on a medical device for export in the language of an export destination country;
(b) Stating the items which were written in foreign languages in the process of medical device permission, certification, or notification in the same foreign language.
2. Font size, line height, and other labeling methods determined and publicly notified by the Minister of Food and Drug Safety shall be followed.

(2) When the name of a product, the trade name of a manufacturer or importer, or other matters are stated on the container, outer package, or package of a medical device, braille may be used in conjunction with the labeling methods under Paragraph (1).

Article 45 (Scope of Medical Device Advertisements) (1) The scope of advertisements prohibited under Article 24 (2) and (3) of the Act shall be any of the following advertisements specified in Attached Table 7:

1. Advertisements under Subparagraph 2 of Article 2 of the Act on Fair Labeling and Advertising;
2. Advertisements through methods such as solicitation of purchase and product presentation and demonstration by a medical device handler (including workers, etc. employed by the medical device handler).

[Wholly Amended on Jun. 24, 2021]

Article 45-2 (Objection to Results of Redeliberation by a Voluntary Deliberation Agency) A person who intends to file an objection to the results of the re-deliberation by a voluntary deliberation agency (referring to an institution or organization that has reported to the Minister of Food and Drug Safety following Article 25-2 (1); hereinafter the same shall apply) under Article 25 (5) of the Act and Article 10-4 (4) of the Decree shall submit an application for objection to the results of re-deliberation on medical device advertisements in Attached Form 38-2 to the Minister of Food and Drug Safety, along with the following documents:

1. Purport and reasons for objection;
2. Content of an application for deliberation on the advertisement of medical devices;
3. A copy of the notice of the results of deliberation or re-deliberation on the advertisement of medical devices;
4. Other references verifying the factuality, etc. of an application for deliberation on the advertisement.

[Newly inserted on Jun. 24, 2021]

Article 45-3 (Notification and Monitoring of Voluntary Deliberation Agency) (1) A person who intends to notify deliberation on the advertisement of medical devices under Article 25-2 (1) of the Act and Article 10-5 (4) of the Decree shall submit an application for the notification of a voluntary deliberation agency for the advertisement of medical devices to the Minister of Food and Drug Safety, along with the following documents. In such cases, the Minister of Food and Drug Safety shall verify the corporation registration certificate (limited to a corporation) through administrative data matching under Article 36 (1) of the Electronic Government Act: <Amended on Jan. 21, 2022>

1. Status of a department and full-time workers that are exclusively responsible for relevant affairs under Article 10-5 (3) 1 of the Decree;
2. Status of computerized equipment and an office under Article 10-5 (3) 2 of the Decree;
3. A copy of the articles of association of the institution or organization;
4. A copy of the registration of a consumer organization made with the Fair Trade Commission under Article 29 of the Framework Act On Consumers (limited to cases under Article 25-2 (1) 2).

(2) A voluntary deliberation agency shall monitor whether an advertisement of medical devices that it has reviewed complies with Article 24 (2) or (3) under Article 25-4, and submit the results thereof to the Minister of Food and Drug Safety for each quarter within 30 days from the end of the pertinent quarter.

[Newly inserted on Jun. 24, 2021]

Article 45-4 (Medical Devices Subject to Sealing) (1) “Medical devices prescribed by Ordinance of the Prime Minister” in Article 25-5, with the exception of its subparagraphs, of the Act refers to any of the following medical devices:

1. Medical devices that are subject to tracking management are to be inserted into the human body for at least 1 year, and have sterile packaging;
2. The following medical devices that are likely to be contaminated or spoiled when distributed while being open:
   (a) Disposable syringes (limited to those with sterile packaging);
   (b) Disposable needles (limited to those with sterile packaging);
   (c) Sutures;
   (d) Wound dressings (limited to those with sterile packaging);
   (e) Contact lenses;
   (f) Other medical devices with sterile packaging, which are publicly notified by the Minister of Food and Drug Safety that such devices need to be enveloped during distribution.

(2) The seal under Article 25-5 shall ensure that a container or package cannot be opened without removing the seal thereon and is difficult to return to its original condition after being opened.

[Newly inserted on Jan. 21, 2022]

Article 46 (Approval for Display of Medical Devices for the Purpose of Exhibition) (1) A person who intends to display medical devices for the purpose of exhibition under the proviso of Article 26 (1) of the Act shall obtain approval therefor from the Commissioner of the Regional Office of Food and Drug Safety in advance.

(2) A person who intends to display medical devices approved under Paragraph (1) shall not engage in acts other than those determined and publicly notified by the Minister of Food and Drug Safety, such as the simple operation of devices to explain the utilization methods, etc. and attachment or keeping of promotional materials regarding the notified details.

(3) When medical devices approved under Paragraph (1) fall under any of the following cases, the Commissioner of the Regional Office of Food and Drug Safety shall revoke such approval, and may take measures including the enveloping or sealing of the relevant medical devices or the suspension of the display thereof:
1. When medical devices are displayed or used differently from what have been approved;
2. When acts other than those permitted under Paragraph (2) are performed;
3. When other acts likely to cause harm to public health are performed.

(4) After the certified medical devices under Paragraph (1) are used following their certification, the relevant medical devices may be used as medical devices under Subparagraph 4 of Article 10, Article 32 (1) 5-2 and 5-3 as determined and publicly noticed by the Minister of Food and Drug Safety. <Newly inserted on Jun. 24, 2021>

(5) Details regarding methods and procedures for filing an application for approval under Paragraph (1), approval standards, and other matters shall be determined and publicly notified by the Minister of Food and Drug Safety. <Amended on Jun. 24, 2021>

Article 46-2 (Minor Repair for Change of Medical Devices) A medical device repairer may make repairs to change any of the following appearances within the extent not to affect the safety and effectiveness of the medical devices under the proviso of Article 26 (3) of the Act:
1. Repairs to change the colors, materials, etc. of outer packages aimed at protecting the medical devices from external shock;
2. Repairs to change the shapes, structures, etc. of external appearances, such as holders, handles, or wheels, not directly related to the performance of medical devices.

[Newly inserted on Jun. 14, 2018]

Article 47 (Scope of Permission to Alter or Remodel Medical Devices) Medical devices that manufacturers and importers may alter or remodel under Article 26 (4) 1 of the Act shall be as follows. In such cases, such medical devices shall be altered or remodeled to the extent not to change the unique characteristics but to improve the performance thereof:
1. Radiation-generating devices for diagnosis under Article 37 of the Medical Service Act;
2. Special medical equipment under Article 38 of the Medical Service Act;
3. Other medical devices determined and publicly notified by the Minister of Food and Drug Safety, whose safety and effectiveness are not affected by alteration or remodeling.

Article 48 (Designation of Quality Management Review Institution) (1) A person who intends to apply for the designation of an institution as a quality management review institution under Article 28 (2) of the Act shall submit an application for the designation as a medical device quality management review institution in Attached Form 39 (including an application in electronic form) to the Minister of Food and Drug Safety, along with the following documents (including electronic documents):
1. The current status of a quality management review institution in terms of its organization and personnel (referring to documents evidencing personnel's qualifications and work experience);
2. Documents regarding management and operational standards for quality review affairs;
3. Documents regarding the scope of quality review affairs.

(2) When a quality management review institution is designated based on the results of the examination of documents submitted under Paragraph (1) and the fact-finding surveys on quality review capabilities, the Minister of Food and Drug Safety shall issue a certificate of designation as a medical device quality management review institution in Attached Form 40.

(3) In cases of modification of any of the following matters, a quality management review institution designated under Paragraph (2) shall submit an application for modification of the designated matters of a medical device quality management review institution in Attached Form 41 (including an application in electronic form), along with the certificate of designation as a medical device quality management review institution and data verifying the modified matters (including electronic documents), to the Minister of Food and Drug Safety within 30 days from the date reasons for such modification occur:
1. The representative of the quality management review institution;
2. The name and location of the quality management review institution;
3. The scope of quality review affairs.

(4) Matters to be observed by a quality management review institution under Article 28 (4) of the Act shall be as follows:
1. The institution shall retain for 5 years the records on quality review, such as copies of compliance certificates and all review data regarding the issuance of compliance certificates;
2. The institution shall report on the results of the quality review as determined by the Minister of Food and Drug Safety;
3. The institution shall comply with the management and operational standards for medical device quality management review institutions, which are determined and publicly notified by the Minister of Food and Drug Safety;
4. The institution shall maintain the requirements for the designation as a quality management review institution under Article 28 (3) of the Act;
5. The institution shall comply with other matters determined and publicly notified by the Minister of Food and Drug Safety, such as matters to be stated by a quality management review institution when issuing compliance certificates.

(5) The Minister of Food and Drug Safety may conduct a regular or occasional investigation into a quality management review institution.

(6) Except as provided in Paragraphs (1) through (5), details necessary for the procedures and methods for designating a quality management review institution, operation thereof, etc. shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 49 (Standards for the Designation and Management of Medical Devices Subject to Tracking Management) (1) Medical devices subject to tracking management under the subparagraphs of Article 29 (1) of the Act shall be as follows:
1. The following medical devices to be inserted into the human body for at least 1 year:
   (a) Implantable cardiac pacemakers;
   (b) Implantable cardiac pacemaker electrodes;
   (c) Composite artificial heart valves;

(d) Biological artificial heart valves;
(e) Non-biological artificial heart valves;
(f) Implantable cardioverter-defibrillators (ICDs);
(g) Electrically-powered implantable infusion pumps;
(h) Other medical devices determined and publicly notified by the Minister of Food and Drug Safety as necessary to track the locations of such devices.

2. The following medical devices for life support used in any place other than a medical institution:
(a) Home care ventilators (limited to regular wearing);
(b) Other medical devices determined and publicly notified by the Minister of Food and Drug Safety as necessary to track the locations of such devices.

(2) When the Minister of Food and Drug Safety permits the manufacture, import, etc. of medical devices subject to tracking management under Paragraph (1), he or she shall state in the license the phrase "Medical Device Subject to Tracking Management."

Article 50 (Matters regarding Records on Medical Devices Subject to Tracking Management) (1) Manufacturers, importers, distributors, lessors, and repairers who handle medical devices under Article 30 (1) of the Act (hereinafter "handlers") and the founders of medical institutions that handle medical devices subject to tracking management, and medical doctors, oriental medical doctors, dentists, etc. who work at medical institutions (hereinafter "users") shall prepare records of the following matters:

1. Records of handlers:
(a) The quantity and date of manufacture or import (limited to manufacturers or importers) by product name (by item name, in the absence of the product name), by model name, and by manufacture unit;
(b) The quantity and date of distribution or lease; the trade name and address of a distributor or lessor or the founder of a medical institution (excluding repairers) by product name (by item name, in the absence of the product name), by model name, and by manufacture unit;
(c) The date of repair and the trade name and address of a requester (limited to repairers) by product name (by item name, in the absence of the product name), by model name, and by manufacture unit;
(d) Other matters necessary to prevent harm to health and hygiene;

2. Records of users:
(a) The name, address, birth date, and gender of a patient who uses a medical device subject to tracking management;
(b) The name and manufacturing number of a medical device subject to tracking management, and those in lieu thereof;
(c) The date of use of a medical device subject to tracking management;
(d) The name and location of a medical institution that uses a medical device subject to tracking management;
(e) Other matters necessary to prevent harm to health and hygiene.

(2) Handlers or users of medical devices subject to tracking management shall submit records and data related to the medical devices subject to tracking management to the Minister of Food and Drug Safety according to the following classifications. In such cases, such handlers or users may submit such records and data using a computer program determined by the Minister of Food and Drug Safety: <Newly inserted on Jun. 15, 2016, Jun. 24, 2021>

1. Handlers: Handlers shall prepare records and data related to medical devices subject to tracking management every month and submit such records and data by the end of the following month as determined and publicly notified by the Minister of Food and Drug Safety;

2. Users:
(a) In cases of business closure of a medical institution, users shall submit the entire record of use when filing a notification of business closure;
(b) In cases of medical devices subject to tracking management publicly notified by the Minister of Food and Drug Safety that may cause death or are gravely life-threatening, users shall submit data for each half year by the end of the following month of the end of the pertinent half year;
(c) Upon receipt of a request by the Minister of Food and Drug Safety to submit records and data related to medical devices subject to tracking management, users shall submit such records and data within 10 days from the date of receipt of such request.

(3) When handlers and users of medical devices subject to tracking management prepare records under Paragraph (1), they shall maintain confidentiality.

(4) Records of medical devices subject to tracking management under Paragraph (1) shall be retained until the time determined by the following subparagraphs:

1. When a medical device subject to tracking management is no longer used because of the death, etc. of a patient who has used such medical device;
2. When the reasons to retain the previous records of a non-single-use medical device subject to tracking management cease to exist as the information thereon under Paragraph (1) 2 (a) or (c) is newly recorded;
3. When the reasons to retain the relevant records cease to exist, as tracking management is no longer necessary or any other reason occurs.

(5) The Minister of Food and Drug Safety may create and operate unique device identification (UDI) codes to be attached to or labeled on the containers, outer packages, or packages of medical devices subject to tracking management for efficient management of medical devices subject to tracking management.

(6) Details regarding records by handlers or users of medical devices subject to tracking management under Paragraphs (1) and (2) and the submission of such records shall be determined and publicly notified by the Minister of Food and Drug Safety. <Newly inserted on Jun. 24, 2021>

Article 51 (Reporting on Side Effects) (1) A person who intends to file a report on the side effects of a medical device under Article 31 (1) of the Act shall do so as prescribed in the following subparagraphs and retain the relevant data for two years:

1. Within 7 days, when a medical device causes death or life-threatening side effects. In such cases, the details thereof shall be additionally reported within eight days from the date of the first report;
2. Within 15 days, when the following side effects are caused or adverse events occur:
   (a) When admission to a hospital or the extension of an admission period is required;
   (b) When recovery is impossible or a serious disability or impaired function occurs;
   (c) When congenital malformations or abnormalities are caused.

(2) The Minister of Food and Drug Safety shall notify the founder of a medical institution of the side effects, a recall plan, etc. under Article 31 (4) of the Act by means of visit, mail, telephone, email, fax, etc.

(3) The founder of a medical institution who has notified patients of the side effects, recall plan, etc. under Article 31 (5) of the Act shall prepare a written confirmation of notice to the patients in Attached Form 42 and submit it to the Minister of Food and Drug Safety. <Amended on Jun. 14, 2018>

(4) Except as provided in Paragraphs (1) through (3), details regarding the reporting and management of side effects shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 52 (Standards and Procedures for the Recall of Harmful Medical Devices) (1) With respect to any medical device that has caused, or is likely to cause, harm to the human body among the medical devices repaired, distributed, or leased (hereinafter “medical device subject to recall”), the relevant medical device repairer, distributor, or lessor shall immediately cease repairing, distributing, or leasing such medical device following Article 31 (2) of the Act and notify such fact to the manufacturer or importer of such medical device (hereinafter “person responsible for recall”).

(2) Following Article 31 (2) of the Act, with respect to medical devices that a person responsible for recall has distributed or leased after manufacturing or importing such devices, such person responsible for recall shall verify whether any medical device suspected to be subject to recall or any medical device notified under Paragraph (1) falls under any of the following:

1. A medical device of which use causes grave irreversible side effects or death, or a medical device that is likely to cause such side effects or death;
2. A medical device of which use causes reversible temporary or medical side effects, or a medical device that is likely to cause such side effects;
3. A medical device which, when used, rarely causes side effects, but is problematic in terms of safety and effectiveness for failing to satisfy the standard specifications referred to in Article 19 of the Act.

(3) With respect to any medical device found to be falling under any subparagraph of Paragraph (2) based on the results of verification under Paragraph (2), a person responsible for recall shall take measures, such as immediately ceasing the distribution of the relevant medical device, and submit a recall plan in Attached Form 43 (including a plan in electronic form) to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the person responsible for recall business within 5 days from the date of verification under Paragraph (2). In such cases, the person responsible for recall may submit a recall plan using a computer program determined by the Minister of Food and Drug Safety. <Amended on Dec. 31, 2018, Dec. 23, 2019>

1. Deleted. <Dec. 31, 2018>
2. Deleted. <Dec. 31, 2018>

(4) Notwithstanding Paragraph (3), with respect to any medical device falling under Paragraph (2) 3, when a person responsible for recall finds it impracticable to submit a recall plan within 5 days, he or she may request the Commissioner of the Regional Office of Food and Drug Safety to extend the submission period by up to 10 days only once, specifying the reasons for such request. <Newly inserted on Dec. 31, 2018>

(5) When a person responsible for recall submits a recall plan under Paragraph (3), he or she shall attach the following documents thereto (including documents in electronic form): <Amended on Dec. 31, 2018, Jun. 12., 2019, Dec. 23, 2019>

1. A copy of the records on the manufacturing or import of the relevant item, the records on the distribution amount and date by distributor, the records on the lease amount and date by lessor, etc.;
2. A notice of a recall plan to be notified under Article 53 (3);
3. Deleted. <Dec. 31, 2018>
4. When a medical device subject to recall falls under Paragraph (2) 1, the name and location of a medical institution that has used the relevant medical device and information on its founder including his or her name.

(6) When a person responsible for recall prepares a recall plan under Paragraph (3), he or she shall determine the scheduled date for the completion of the recall according to the following classifications: Provided, That when it is deemed impracticable to perform the recall within such date, the period of recall may be determined in excess of the period classified as follows, stating the reasons therefor: <Amended on Dec. 31, 2018>

1. A medical device falling under Paragraph (2) 1: Within 15 days from the start date of the recall;
2. A medical device falling under Paragraph (2) 2 or 3: Within 30 days from the start date of the recall.

(7) When any recall plan submitted under Paragraphs (3) through (5) is deemed insufficient, the Commissioner of the Regional Office of Food and Drug Safety may order the relevant person responsible for recall to supplement such recall plan. <Amended on Dec. 31, 2018>

(8) Except as provided in Paragraphs (1) through (7), details regarding the evaluation of the degree of harm of medical devices, the preparation and supplement of recall plans, etc. shall be determined and publicly notified by the Minister of Food and Drug Safety. <Newly inserted on Dec. 31, 2018>

Article 53 (Publication of Recall Plans) (1) Upon receipt of an order to publish a recall plan from the Commissioner of the Regional Office of Food and Drug Safety following Article 31 (3) of the Act, a person responsible for recall shall publish such recall plan according to the following classifications:

1. Medical devices falling under Article 52 (2) 1: Public announcement of the recall plan through broadcasting defined in Subparagraph 1 of Article 2 of the Broadcasting Act; daily newspapers (referring to all the copies of the relevant newspapers printed and distributed for a day] that are distributed nationwide and registered under Article 9 (1) of the Act on the Promotion of Newspapers, Etc.; or mass media at least equivalent thereto (including such media as may be recognized by the Minister of Food and Drug Safety considering the intended uses, utilization methods, etc. of medical devices subject to recall);
2. Medical devices falling under Article 52 (2) 2: Public announcement of the recall plan in medical journals or medical engineering journals or media at least equivalent thereto;
3. Medical devices falling under Article 52 (2) 3: Public announcement of the recall plan on the website of a person responsible for recall or media at least equivalent thereto.

(2) The Commissioner of the Regional Office of Food and Drug Safety may post the trade name of a person responsible for recall; the name, manufacturing number, date of manufacturing, use-by date, and expiration date of a product; and the reason for recall on the website of the regional office of food and drug safety.

(3) A person responsible for recall shall notify a recall plan to a repairer, distributer, lessor, or founder of a medical institution that handles medical devices subject to recall (hereinafter “handler of medical devices subject to recall”) via visit, mail, telephone, telegram, email, fax, public announcement through media, etc. and retain data evidencing such notice for two years from the date of the completion of recall.

(4) A handler of medical devices subject to recall notified of a recall plan under Paragraph (3) shall take measures, such as returning a medical device subject to recall, and prepare a written confirmation of recall in Attached Form 44 and send it to the person responsible for the recall of such medical device subject to recall.

⑤ Deleted. <Jun. 14, 2018>

(6) The Minister of Food and Drug Safety may establish and operate a computer program that provides information on medical devices subject to recall, etc. and recommend that a handler of medical devices subject to recall, etc. install such program.

(7) Except as provided in Paragraphs (1) through (6), details regarding the method and period for the publication of recall plans, notice of such plans, etc. shall be determined and publicly notified by the Minister of Food and Drug Safety. <Newly inserted on Dec. 31, 2018>

[Paragraph (5) of this Article shall be effective until May 10, 2016, following Article 2 of the Addenda to the Ordinance of the Prime Minister No. 1181 promulgated on Jul. 29, 2015.]

Article 54 (Destruction of Medical Devices Subject to Recall) (1) A person responsible for recall shall destroy a medical device that has been recalled or returned or take other measures to prevent harm, and prepare a recall evaluation report in Attached Form 45 (including a report in electronic form) with respect thereto. <Amended on Dec. 23, 2019>

(2) When a person responsible for recall destroys a medical device subject to recall following Paragraph (1), he or she shall submit an application for destruction in Attached Form 46 (including an application in electronic form), along with the following documents (including documents in electronic form) to the competent Mayor/*Do* Governor; destroy the relevant medical device according to the environment-related statutes and regulations in the presence of the relevant public officials of the competent Special Metropolitan City, Metropolitan City, Do, and Special Self-Governing Province (hereinafter “City/Do”); and prepare the written confirmation of destruction in Attached Form 47 (including a written confirmation in electronic form) and retain it for two years: <Amended on Dec. 23, 2019, Apr. 13, 2020, Dec. 31, 2020, Jun. 24, 2021>

1. A copy of a recall plan in Attached Form 43;
2. A copy of written confirmation of recall in Attached Form 44.

(3) Upon completion of a recall, a person responsible for the recall shall submit the recall completion report in Attached Form 48 (including a report in electronic form), along with the following documents (including documents in electronic form) to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the person responsible for recall. In such cases, the person responsible for recall may submit the relevant recall completion report using a computer program determined by the Minister of Food and Drug Safety <Amended on Dec. 23, 2019>

1. A copy of written confirmation of recall in Attached Form 44;
2. A copy of a recall evaluation report in Attached Form 45;
3. A copy of a written confirmation of destruction in Attached Form 47 (limited to where a medical device has been destroyed).

(4) Upon receipt of a recall completion report under Paragraph (3), the Commissioner of the Regional Office of Food and Drug Safety shall take measures according to the following classifications:

1. When it is deemed that the recall of a medical device subject has been properly conducted according to the recall plan, the completion of the recall shall be confirmed and notified in writing to the person responsible for recall;
2. When it is deemed that the recall has not been effectively conducted, the person responsible for recall shall be ordered to take additional measures necessary for the recall.

(5) When the destruction under Paragraph (2) is completed, the Mayor/*Do* Governor shall notify such fact to the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the person responsible for recall. <Amended on Jun. 24, 2021>

(6) Except as provided in Paragraphs (1) through (5), details regarding measures such as destruction, preparation of recall evaluation reports, reporting on completion of a recall, measures to be taken, etc. shall be determined and publicly notified by the Minister of Food and Drug Safety. <Newly inserted on Dec. 31, 2018>

Article 54-2 (Reporting on Details of Supply of Medical Devices) A person who intends to report the details of the supply of medical devices following Article 31-2 (1) of the Act shall submit the report on the details of the supply of medical devices in Attached Form 48-2 (including electronic documents) to the Minister of Food and Drug Safety using an integrated medical device information system following Article 31-3 (1) of the Act (hereinafter "integrated medical device information system"), by the end of the month following the month when the relevant medical devices are supplied.

[Newly inserted on Oct. 22, 2019]

[The previous Article 54-2 was renumbered as Article 54-3 on Oct. 22, 2019]

[Enforcement Date] The amended provisions of Article 54-2 shall enter into force on the date according to the following classifications:

1. Class IV medical devices: July 1, 2020;
2. Class III medical devices: July 1, 2021;
3. Class II medical devices: July 1, 2022;
4. Class I medical devices: July 1, 2023.

Article 54-3 (Operation of Integrated Medical Device Information System) (1) The information to be registered (including registration of modifications; hereinafter the same shall apply) by medical device manufacturers and importers in the integrated medical device information system following Article 31-3 (2) of the Act (hereinafter "medical device information, etc.") shall be as follows.

1. Information on UDI codes of medical devices;
2. Information on medical device products (including information on medical device permission, certification, or notification);
3. Information on medical device manufacturers and importers (including the foreign origins of manufacture).

(2) The standards to be observed by medical device manufacturers and importers in registering and managing medical device information, etc. following Article 31-3 (3) of the Act (hereinafter "standards for management of integrated medical device information") shall be as specified in Attached Table 7-2.

(3) The Minister of Food and Drug Safety may require the head of the integrated medical device information center to conduct the following affairs:

1. Educating medical device manufacturers and importers regarding the registration of medical device information, etc. and the methods for using the integrated medical device information system, etc.;
2. Providing information on the permission, certification, and notification of medical devices, precautions for the use of medical devices, etc.

(4) Details necessary for the operation and management of the integrated medical device information system, including the target and scope of medical device information, etc. under Paragraph (1) and the methods for providing medical device information, etc. shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on Dec. 31, 2018]

[Renumbered from the previous Article 54-2; the previous Article 54-3 has been renumbered as Article 54-4 on Oct. 22, 2019]

Article 54-4 (Standards, Targets, and Procedures for Reporting Foreign Substances) (1) The scope of foreign substances to be reported to the Minister of Food and Drug Safety by a medical device handler following Article 31-5 (1) of the Act (hereinafter "foreign substances") shall be as follows:

1. A substance that is not a normal material used for medical devices, such as metal, plastic, or debris generated during manufacturing processes and that may cause direct or indirect harm or damage to the human body during the use of the medical devices;
2. A substance related to living things such as insects and their eggs, parasites and their eggs, and animal carcasses that may cause direct or indirect harm or damage to the human body during the use of medical devices;
3. Other substances determined and publicly notified by the Minister of Food and Drug Safety to prevent harm caused by the use of medical devices among the substances equivalent to those falling under Subparagraph 1 or 2.

(2) Medical device handlers who intend to report the discovery of foreign substances following Article 31-5 (1) of the Act shall submit a foreign substance discovery report in Attached Form 48-3 (including a report in electronic form), along with evidentiary data to the Minister of Food and Drug Safety. <Amended on Oct. 22, 2019>

(3) Upon receipt of a report on the discovery of foreign substances following Paragraph (2), the Minister of Food and Drug Safety shall notify the details thereof to the Commissioner of the Regional Office of Food and Drug Safety without delay.

(4) Upon receipt of notice under Paragraph (3), the Commissioner of the Regional Office of Food and Drug Safety shall conduct an investigation into the cause of inclusion of the foreign substances without delay following Article 31-5 (2) of the Act. In such cases, the Commissioner of the Regional Office of Food and Drug Safety may request necessary cooperation from the relevant central administrative agencies, local governments, public institutions, corporations, organizations, experts, etc. to investigate the cause of inclusion of the foreign substances.

(5) Upon completion of an investigation into the cause of inclusion of foreign substances following Paragraph (4), the Commissioner of the Regional Office of Food and Drug Safety shall take the following measures without delay in comprehensive consideration of the results of the relevant investigation, the stability of medical devices, the need to prevent harm, etc.: <Amended on Jan. 21, 2022>

1. An order to conduct an inspection following Article 33 of the Act;
2. An order of recall, destruction, or any other treatment or the publication thereof following Article 34 of the Act;
3. An order of necessary measures such as suspension of use or repair following Article 35 of the Act.

(6) Except as provided in Paragraphs (1) through (5), details necessary for the procedures and methods for reporting the discovery of foreign substances and for an investigation into the inclusion of foreign substances, and relevant measures shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on Jun. 12, 2019]

[Renumbered from the previous Article 54-3 on Oct. 22, 2019]

Article 55 (Collection) (1) When collecting medical devices following Article 32 (1) 2 of the Act, a certificate of collection in Attached Form 49 shall be issued to a person subject to collection.

(2) When a specialized inspection of any medical device collected under Paragraph (1) is required, a request for a specialized inspection may be made to a medical device testing and inspection institution or an institution conducting non-clinical studies. <Amended on May 1, 2017>

Article 56 (Medical Device Surveillance Officer Identification) An identification proving the identity of a relevant public official under Article 32 (2) of the Act (including cases applicable *mutatis mutandis* under the latter part of Article 34 (2) of the Act) shall be as prepared in Attached Form 50.

Article 56-2 (Procedures for On-Site Inspections and Suspension of Import) (1) When the Minister of Food and Drug Safety intends to conduct an on-site inspection following Article 32-2 (1), with the exception of its subparagraphs, of the Act (hereinafter "on-site inspection"), he or she shall notify the details of the on-site inspection in writing (including electronic documents) to the medical device manufacturer, the medical device importer, the manager of an overseas factory, or the government of an exporting country 20 days prior to the execution of the on-site inspection.

(2) Upon completion of an on-site inspection under Article 32-2 (2) of the Act (including where an on-site inspection is refused), the Minister of Food and Drug Safety shall notify the results of the inspection and provide opinions on the necessary measures to the Commissioner of the Regional Office of Food and Drug Safety within 30 days from the completion date of the on-site inspection.

(3) The Commissioner of the Regional Office of Food and Drug Safety notified of the results of an on-site inspection under Paragraph (2) may take the following measures following Article 32-2 (2) of the Act. In such cases, with respect to the relevant measure taken, the Commissioner of the Regional Office of Food and Drug Safety shall notify the matters pertaining to the details of, reasons for, and date of such measure, etc. in writing (including electronic documents) to the medical device manufacturer, the medical device importer, the manager of an overseas factory, or the government of an exporting country: <Amended on Jan. 21, 2022>

1. Suspension of import;
2. An order of recall, destruction, or any other measure or the publication thereof following Article 34 of the Act;
3. An order of necessary measures, such as suspension of use or repair, following Article 35 of the Act.

(4) When any measure is canceled following Article 32-2 (3) of the Act, such as suspension of import, the Commissioner of the Regional Office of Food and Drug Safety shall notify the matters pertaining to the details of, reasons for, and date of the cancellation, etc. in writing (including electronic documents) to the medical device manufacturer, the medical device importer, the manager of an overseas factory, or the government of an exporting country.

[Newly inserted on Jun. 12, 2019]

Article 57 (Orders for Recall, Destruction, and Publication) (1) Following Article 34 (3) of the Act, upon verification as to whether a medical device under the subparagraphs of Article 34 (1) of the Act falls under any subparagraph of Article 52 (2), the Commissioner of the Regional Office of Food and Drug Safety, the Special Self-Governing Province Governor, or the head of a *Si/Gun/Gu* may order a person responsible for recall to recall or destroy the relevant medical device or to perform other treatments, and to publish such fact. <Amended on Dec. 31, 2018, Apr. 13, 2020, Jan. 21, 2022>

(2) Articles 52 (3) through (8), Article 53, and Article 54 shall apply *mutatis mutandis* to the methods for recall, destruction, or publication under Paragraph (1). <Amended on Dec. 31, 2018, Jan. 21, 2022>

[Title amended on Jan. 21, 2022]

Article 58 (Standards for Administrative Dispositions) (1) The standards for administrative dispositions under Article 36 of the Act shall be as specified in Attached Table 8.

(2) The standards for administrative dispositions under Article 37 of the Act shall be as specified in Attached Table 9.

Article 59 (Qualifications and Scope of Duties of Medical Device Surveillance Officers) (1) Medical device surveillance officers under Article 40 of the Act shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Commissioner of the Regional Office of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* from among any of the following public officials under the authority thereof: <Amended on Jun. 24, 2021>

1. A person who has graduated from a junior college or a university or college with a degree in medicine, pharmacy, dentistry, oriental medicine, veterinary medicine, medical engineering, or natural science or engineering or a person who has qualifications at least equivalent thereto;
2. A person who has at least 1 year of work experience in health care administration.

(2) The scope of duties of medical device surveillance officers shall be as follows: <Amended on May 1, 2017, Dec. 31, 2018, Jun. 24, 2021>

1. In cases of medical device surveillance officers belonging to the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, or a regional office of food and drug safety, the following duties: Provided, That when it is necessary to conduct a national survey, systematic survey, etc., the duties referred to in Subaparagraphs 2 and 3 may be performed:

(a) Follow-up surveillance of medical device manufacturers and importers and collection and inspection of medical devices;
(b) Follow-up surveillance of institutions reviewing technical documents, clinical trial institutions, institutions conducting non-clinical studies, quality management review institutions, and other places handling medical devices in the process of conducting business affairs; and collection and inspection of medical devices (limited to medical device surveillance officers belonging to the Ministry of Food and Drug Safety or a regional office of food and drug safety);

2. Deleted. <Jun. 24, 2021>
3. In cases of medical device surveillance officers belonging to a *Si/Gun/Gu*, follow-up surveillance of medical device distributors and lessors, the founders of medical institutions under the Medical Service Act, and the founders of veterinary hospitals under the Veterinarians Act.

Article 59-2 (Qualifications of Customer Medical Device Surveillance Officers) (1) The Commissioner of the Regional Office of Food and Drug Safety, Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, the Special Self-Governing Province Governor, the Special Self-Governing City Mayor, or the head of a *Si/Gun/Gu* may commission any of the following persons as a consumer medical device surveillance officer following Article 40-2 (1) of the Act: <Amended on Apr. 13, 2020, Jun. 24, 2021>

1. A person falling under any subparagraph of Article 59 (1);
2. A person with at least 1 year of work experience at a company or institution related to medical devices;
3. A person who has completed an education program determined and publicly notified by the Minister of Food and Drug Safety;
4. From among the members or employees of associations or organizations related to medical devices, a person recommended by the head of the relevant association or organization;
5. From among the executive officers and employees of consumer organizations registered under Article 29 of the Framework Act on Consumers, a person recommended by the head of the relevant organization.

(2) A consumer medical device surveillance officer commissioned under Paragraph (1) (hereinafter “consumer medical device surveillance officer”) shall serve for two years and may be recommissioned for another term of two years.

(3) “Matters prescribed by Ordinance of the Prime Minister” in Article 40-2 (2) 3 of the Act refers to the following:

1. Assisting relevant public officials in destroying, enveloping, or sealing goods following Article 34 (2) of the Act;
2. Reporting and providing information on violators of statutes and regulations related to medical devices;
3. Others affairs such as public campaigns for the safe management of medical devices.

(4) Upon commission of a consumer medical device surveillance officer under Paragraph (1), the Commissioner of the Regional Office of Food and Drug Safety, the Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, the Special Self-Governing Province Governor, the Special Self-Governing City Mayor, or head of a *Si/Gun/Gu* shall provide education on the statutes and regulations, etc. related to medical devices at least once a year to such commissioned consumer medical device surveillance officer following Article 40-2 (4) of the Act. <Amended on Apr. 13, 2020, Jun. 24, 2021>

(5) A written approval for unaccompanied access to a distribution or leasing business place by a consumer medical device surveillance officer and an identification indicating his or her status under Article 40-2 (7) of the Act shall be as prepared in Attached Forms 50-2 and 50-3, respectively.

(6) Except as provided in Paragraphs (1) through (5), details regarding the operation of consumer medical device surveillance officers shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on Jun. 15, 2016]

Article 59-3 (Designation of Medical Device Safety Information Monitoring Centers) (1) A person who intends to obtain designation as a monitoring center (hereinafter “monitoring center”) on medical device safety information under Article 43 (1) 7 (hereinafter “medical device safety information”) for an institution following Article 43 (3) shall submit an application for designation as a monitoring center in Attached Form 50-4 (including an application in electronic form) to the Minister of Food and Drug Safety, along with documents (including electronic documents) regarding the following matters:

1. A business progress plan of a monitoring center;
2. Budget for a business progress plan of a monitoring center;
3. Facilities and personnel required for a business progress plan of a monitoring center;
4. Performance regarding collection and analysis of medical device safety information within the last 3 years (only when applicable);
5. Other matters similar to documents under Subparagraphs 1 through 4 which are deemed necessary by the Minister of Food and Drug Safety.

(2) Upon receipt of an application under Paragraph (1), the Minister of Food and Drug Safety shall verify a license for opening a medical institution through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That when an applicant does not consent to the verification of the license for opening a medical institution, such applicant shall attach a copy thereof.

(3) When deemed necessary for designation as a monitoring center under Article 43 (3) by the Minister of Food and Drug Safety, he or she may conduct a fact-finding survey on the facility and personnel of such center.

(4) When deemed necessary for effective operation of monitoring centers under Article 43 (3) by the Minister of Food and Drug Safety, he or she may designate monitoring centers by distributing them across regions or districts as determined by the Minister of Food and Drug Safety.

(5) When the Minister of Food and Drug Safety designates a monitoring center under Article 43 (3), he or she shall issue the applicant with a certificate of designation as a monitoring center in Attached Form 50-5.

(6) Except as provided in Paragraphs (1) through (5), details necessary for procedures and methods for designation as a monitoring center shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on Dec. 4, 2020]

Article 59-4 (Business Scope and Operation of Monitoring Centers) (1) The scope of business of a monitoring center shall be as follows:

1. Collection of side effects or safety information regarding medical devices;
2. Analysis and research on side effects of medical devices;
3. Exchange and cooperation with other medical institutions regarding medical device safety information;
4. Education and campaigns regarding medical device safety information;
5. Business similar to the matters under Subparagraphs 1 through 4 which is deemed necessary by the Minister of Food and Drug Safety.

(2) A monitoring center shall report through the Institute every year to the Minister of Food and Drug Safety on matters regarding a business operation plan, budget plan, results of business and budget execution, etc., as determined by the Minister of Food and Drug Safety.

(3) A monitoring center shall notify the Institute every month of matters on side effects or safety information as determined by the Minister of Food and Drug Safety for supporting medical device safety information businesses: Provided, That in cases of matters regarding information with grave effects on public health, etc., the monitoring center shall report such matters to the Minister of Food and Drug Safety and the Institute without delay.

(4) When deemed necessary for securement of appropriate business operations or budget operations of a monitoring center by the Minister of Food and Drug Safety, he or she may order relevant measures, including the complementation or improvement of the relevant monitoring center.

(5) When deemed necessary for facilitation of the operation of a monitoring center by the Minister of Food and Drug Safety, he or she shall fully or partially support operational expenses of such center within a set budget.

(6) Except as provided in Paragraphs (1) through (5), details necessary for the business, operation, and supervision of a monitoring center shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on Dec. 4, 2020]

Article 60 (Procedures and Methods for Revoking Manufacturing Permission of Medical Devices) The procedures, methods, etc. for revocation under Article 43-2 of the Act shall be governed by the Administrative Procedures Act.

[Title amended on Jan. 21, 2022]

Article 61 (Guidance and Supervision for the Institute) The Minister of Food and Drug Safety shall provide guidance and supervision to the Institute on the following matters at least once a year following Article 43-3 (4) of the Act: <Amended on Jun 14, 2018>

1. Whether the affairs related to certification or notification entrusted to the Institute following Article 44 (2) of the Act have been appropriately performed;
2. Whether the operational budget has been appropriately compiled and executed;
3. Other matters deemed necessary by the Minister of Food and Drug Safety.

[Title amended on Jun. 14, 2018]

Article 61-2 (Qualifications, Scope of Duties, and Identifications of Investigators of Causal Relationship) (1) An investigator of causal relationship under Article 43-5 (1) of the Act (hereinafter “investigator of causal relationship”) shall be appointed or commissioned from among any of the following persons:

1. An employee of the Institute responsible for investigating and identifying the causal relationship between medical devices and the side effects;
2. A public health doctor defined in Article 2 of the Act on Special Measures for Health and Medical Services in Agricultural and Fishing Villages, Etc.;
3. A medical doctor, dentist, oriental medical doctor, or nurse referred to in Article 2 (1) of the Medical Service Act;
4. Other persons with abundant expertise and experience in fields related to medical devices.

(2) The head of the Institute may pay allowances and travel expenses to a commissioned investigator of causal relationship within a set budget.

(3) An investigator of causal relationship may investigate and identify the causal relationship between medical devices and the side effects in any of the following cases:

1. When side effects falling under Article 51 (1) 1 or 2 have occurred or are suspected of having occurred during the use of medical devices;
2. When unintended syndromes, symptoms, or diseases have occurred in large numbers to patients who have used the medical devices at a specific region or in a specific period of time;
3. Other cases where the Minister of Food and Drug Safety deems it necessary to investigate and identify the causal relationship between medical devices and the side effects.

(4) An identification indicating the authority of an investigator of causal relationship referred to in the latter part of Article 43-5 (3) of the Act shall be as prepared in Attached Form 50-4.

(5) “Relevant documents” in the latter part of Article 43-5 (3) of the Act refers to documents including the following matters:

1. The purpose, duration, scope, and contents of the investigation;
2. The name and position of a person responsible for the investigation;
3. The list of submitted data;
4. The statutes and regulations serving as a legal basis for the investigation;

5. The details of administrative dispositions, penalties, etc. for the refusal, obstruction, evasion, etc. of the investigation and statutes and regulations used as a legal basis therefor;
6. Except as provided in Subparagraphs 1 through 5, matters deemed necessary by the Minister of Food and Drug Safety for the relevant investigation.

[Newly inserted on Jun. 14, 2018]

Article 62 (Medical Devices Excluded from Validity Periods) The validity period of manufacturing permission, etc. under the main clause of Article 49 (1) (hereinafter "manufacturing permission, etc.") does not apply to any of the following medical devices following the proviso of Article 49 (1):

1. Medical devices for export produced or imported only for the export;
2. Medical devices that have obtained conditional manufacturing permission or for which a conditional manufacturing notification has been filed under Article 7 of the Act (including cases applicable *mutatis mutandis* under Article 15 (6) of the Act).

[Wholly amended on Dec. 4, 2020]

Article 62-2 (Renewal of Manufacturing Permission) Standards for manufacturing permission, etc. under Article 49 (3) of the Act shall be as follows:

1. Any serious problem shall not exist regarding safety or effectiveness of medical devices;
2. Data necessary for renewal of manufacturing permission, etc. shall be faithfully submitted;
3. Production or import performance data shall exist regarding the relevant medical device;
4. Statues and regulations related to medical devices shall be faithfully observed;
5. Other standards similar to the ones under Subparagraphs 1 through 4 determined and publicly notified by the Minister of Food and Drug Safety shall be satisfied.

(2) A person who intends to have manufacturing permission, etc. renewed under Article 49 (3) of the Act shall submit an application for the renewal of manufacturing (import) permission in Attached Form 51, an application for renewal of manufacturing (import) certification in Attached Form 51-2, or an application for notification of the renewal of manufacturing (import) notification in Attached Form 51-3 (including an application in electronic form) to the Minister of Food and Drug Safety [limited to manufacturing (import) renewal; hereinafter the same shall apply] or to the Institute [limited to manufacturing (import) certification or notification renewal; hereinafter the same shall apply], along with the following documents (including electronic documents):

1. Original copy of a manufacturing (import) license or manufacturing (import) certificate of the relevant medical device;
2. Data evidencing that safety and effectiveness of the relevant medical device has been maintained over the previous validity period;
3. Data regarding production or import performance of the relevant medical device for the previous validity period;
4. Other cases similar to data under Subparagraphs 1 through 3, which are deemed necessary by the Minister of Food and Drug Safety for the renewal of manufacturing permission, etc.

(3) When deemed necessary for renewal of a manufacturing permission, etc. under Article 49 (3) of the Act, the Minister of Food and Drug Safety or the Institute may conduct a fact-finding survey on a manufacturer or importer or request a related institution, organization, specialist, etc. to provide data or opinion.

(4) When the Minister of Food and Drug Safety or the Institute renews manufacturing permission, etc. under Article 49 (3) of the Act, he or she shall issue a new manufacturing (import) license in Attached Form 4 or a new manufacturing (import) certificate in Attached Form 6 and notify the applicant of the renewal of manufacturing (import) notification in writing. In such cases, the validity period of the renewed manufacturing permission, etc. shall start from the day following the end of the previous validity period.

(5) When deemed necessary for renewal of manufacturing permission, etc. under Article 49 (3) of the Act, the Minister of Food and Drug Safety or Institute may notify in advance the manufacturer or importer of the fact that the manufacturing permission, etc. cannot be renewed after the expiration of the validity period and matters regarding renewal procedure.

(6) "Unavoidable causes prescribed by Ordinance of the Prime Minister" under the proviso of Article 49 (6) of the Act refers to the following cases: <Amended on Jan. 21, 2022>

1. When it is deemed impossible to proceed with normal manufacturing operations because raw materials for manufacturing of medical devices were not provided;
2. When it is deemed impossible to proceed with normal import processes because of suspension of medical device export in the exporting country or political or economic situation thereof;
3. When demand for orphan medical devices applied to a small number of patients, etc. is deemed non-existent;
4. Other causes similar to those under Subparagraphs 1 through 3 which are determined and publicly notified by the Minister of Food and Drug Safety.

(7) Except as provided in Paragraphs (1) through (6), details necessary for the procedures and methods for the renewal of manufacturing permission, etc. shall be determined and publicly notified by the Minister of Food and Drug Safety.

[Newly inserted on Dec. 4, 2020]

Article 63 (Re-Issuance of Licenses) (1) A medical device manufacturer, importer, repairer, distributor, or lessor who intends to be reissued a license, certificate, or certification of notification for reasons recognized by the Minister of Food and Drug Safety, including when the license, certificate, or certification of notification is lost, becomes unusable, or becomes subject to any modification, such manufacturer, importer, repairer, distributor, or lessor shall submit an application in Attached Form 52 (including an application in electronic form), along with the relevant license, certificate, or certification of notification (excluding when the license, certificate, or certificate of notification is lost) to a person according to the following classifications: <Amended on Jun. 14, 2018, Jun. 24, 2021>

1. For a medical device manufacturer or importer:
   (a) The manufacturing or import business license: The Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the relevant manufacturing or import business place;
   (b) The manufacturing or import license: The Minister of Food and Drug Safety;
   (c) The manufacturing or import certificate and the certificate of manufacturing or import notification: The head of the Institute;
2. Deleted. <Jun. 24, 2021>
3. For a medical device repairer, distributor, or lessor: The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* having jurisdiction over the location of the relevant repair, distribution, or leasing business place.

(2) When reissuing a license, certificate, or certificate of notification following Paragraph (1), the Minister of Food and Drug Safety, Commissioner of the Regional Office of Food and Drug Safety, the head of the Institute, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall enter the reasons for re-issuance in the relevant register. <Amended on Jun. 14, 2018, Jun. 24, 2021>

(3) Any person who intends to be confirmed or proved regarding matters permitted, certified, or notified under Article 6 or 15 of the Act shall submit an application in Attached Form 53 (including an application in electronic form; for a foreign-language application, the translation thereof) to the Minister of Food and Drug Safety, the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the relevant manufacturing or import business place, or the head of the Institute. <Amended on Jun. 14, 2018>

Article 64 (Cooperation in Provision of Data) Any person who has applied for manufacturing permission or manufacturing certification or has filed a manufacturing notification under Articles 5 through 7 may request that the Minister of Food and Drug Safety or the head of the Institute provide specialized institutions or organizations entrusted with the relevant affairs under Article 55 of the Medical Service Act with documents including the relevant applications for manufacturing permission or notifications, and data stating the current status of the procedures for manufacturing licenses, etc. In such cases, the Minister of Food and Drug Safety or the head of the Institute who receives such request may provide the relevant documents and data to such specialized institutions or organizations. <Amended on Jun. 14, 2018>

Article 65 (Fees) (1) Fees under Article 50 of the Act shall be as specified in Attached Table 10: Provided, That when any matter permitted, certified, or notified is modified, a person who has filed an application or notification shall be exempted from fees if such person is not responsible for the modification, including when the need for modification arises due to the change of location following the reorganization of administrative districts.

(2) The fees under Paragraph (1) may be paid according to the following classifications: <Amended on Jun. 15, 2016, Jun. 14, 2018>

1. Payment to a State agency: Using electronic money, electronic payment, etc. via the information and communications network (hereafter, in this Paragraph, “electronic money, etc.”) or revenue stamps (in cases of business affairs under the authority of the Minister of Food and Drug Safety, cash or payment receipts verifying cash payment);
2. Payment to a local government: Electronic money, etc. or revenue stamps of the relevant local government;
3. Payment to the Institute: Electronic money, etc.

(3) When the person who has paid fees under Paragraphs 1 and 2 withdraws the application for permission, certification, etc. within the period determined and publicly notified by the Minister of Food and Drug Safety, the Minister of Food and Drug Safety may return the entire or part of such fees as determined and publicly notified by the Minister of Food and Drug Safety. <Newly inserted on Apr. 13, 2020>

Article 66 (Re-Examination of Regulation) The Minister of Food and Drug Safety shall examine the appropriateness of the following matters every 3 years, counting from each base date specified in the following (referring to the period that ends on the day before the base date of every third year), and shall take measures, such as making improvements:

1. A notification of a medical device repair business, a notification of modification thereof, or a notification of business closure or suspension under Article 35: January 1, 2014;
2. A notification of a medical device distribution or lease business, a notification of modification thereof, or a notification of business closure or suspension under Article 37: January 1, 2014.

ADDENDA <Act No. 1181, Jul. 29, 2015>

Article 1 (Enforcement Date) This Rule shall enter into force on July 29, 2015: Provided, That the amended provisions according to the following classifications shall enter into force on the dates specified in the relevant subparagraphs:

1. The amended provisions pertaining to the manufacturing and quality management systems in Articles 5, 6, 8, 16, 17, 26, 27, 30, 31, and 33, Attached Tables 2 through 4, and Attached Forms 3, 5, and 29 through 31: January 29, 2016;
2. In the amended provisions of the proviso of Article 9 (2), the provisions providing for the exclusion of medical devices determined and publicly notified by the Minister of Food and Drug Safety as medical devices requiring the submission of data regarding clinical trials: January 1, 2016;
3. The amended provisions of Subparagraph 2 of Attached Table 1: February 1, 2016;

4. Among the amended provisions of Article 9 (3), with the exception of its subparagraphs, the provisions providing for the submission to the head of an institution for reviewing technical documents: January 1, 2017.

Article 2 (Effective Period) The amended provisions of Articles 50 (2) and 53 (5) shall be effective until May 10, 2016.

Article 3 (Applicability of Cooperation in Provision of Data) The amended provisions of Article 64 (including cases applicable *mutatis mutandis* under Article 34) shall also apply to a person who applies for manufacturing or import permission or files a manufacturing or importing notification before this Rule enters into force.

Article 4 (Special Cases Concerning Manufacture of In Vitro Diagnostic Drugs and Recognition of Compliance with Quality Management Standards) With respect to in vitro diagnostic drugs under Article 6 of the Addenda to the Enforcement Rule of the Medical Devices Act (Ordinance of the Prime Minister No. 1081), any person who has obtained permission for manufacture, distribution, or import of items or has filed a notification for manufacture, distribution, or import of items following Article 4 or 5 of the Rule on Safety of Drugs, etc. as of the enforcement date specified in Subparagraph 1 of Article 1 of that Addenda, shall be deemed to have obtained recognition for compliance with standards under the amended provisions of Attached Table 2 by the dates according to the following classifications:

1. Class II in vitro diagnostic devices: November 10, 2016;
2. Class III and Class IV in vitro diagnostic devices: November 10, 2015.

Article 5 (General Transitional Measures) Any disposition, procedure, or other acts carried out under the previous provisions before this Rule enters into force shall be deemed carried out under the corresponding provisions of this Rule.

Article 6 (Transitional Measures Concerning Application of Standards for Administrative Dispositions) The previous provisions shall apply to administrative dispositions for violations committed before this Rule enters into force.

Article 7 (Transitional Measures Concerning Introduction of Standards for Distribution Quality Management) Any person who has filed a notification of a distribution or lease business as of the enforcement date specified in Subparagraph 2 of Article 1 of the Addenda to the Enforcement Rule of the Medical Devices Act (Ordinance of the Prime Minister No. 1081) shall comply with the standards prescribed in the amended provisions of Attached Table 6 by December 31, 2015.

Article 8 (Transitional Measures Concerning Forms) (1) Any manufacturer or importer under Article 3 of the Addenda to the Medical Devices Act (Act No. 12392) (hereafter in this Article “manufacturer or importer under the previous provisions”), at the time the Enforcement Rule of the Medical Devices Act (Ordinance of the Prime Minister No. 1093) enters into force, may continue to use a manufacturing or import business license issued under the previous provisions until they are reissued the relevant license under Paragraph (2).

(2) Any manufacturer or importer under the previous provisions shall be reissued a manufacturing or import business license following the amended provisions of Attached Form 2 from the Commissioner of the Regional Office of Food and Drug Safety having jurisdiction over the location of the relevant manufacturing or import business place within 3 months from July 29, 2016.

Article 9 (Relationship with Other Statutes) (1) When any of the previous provisions of the Enforcement Rule of the Medical Devices Act is cited by other statutes and regulations at the time this Rule enters into force, and when this Rule includes a corresponding provision, such corresponding provision shall be deemed cited in lieu of the previous provision of this Rule.

(2) When any in vitro diagnostic reagent or in vitro diagnostic drug under the Rule on Safety of Drugs, Etc. is cited by other statutes and regulations at the time the Enforcement Rule of the Medical Devices Act (Ordinance of the Prime Minister No. 1081) enters into force, an in vitro diagnostic medical device referred to in this Rule shall be deemed cited in lieu thereof.

ADDENDA <Act No. 1284, Jun. 15, 2016>

This Rule shall enter into force on the date of its promulgation.

ADDENDA <Act No. 1307, Jul. 29, 2016>

This Rule shall enter into force on the date of its promulgation.

ADDENDA <Act No. 1354, Jan. 4, 2017>

This Rule shall enter into force on the date of its promulgation.

ADDENDA <Act No. 1389, May 1, 2017>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of promulgation.

Article 2 (Applicability to Amounts of Fees) Among the amended provisions of Attached Table 10 and Attached Forms 3, 5, 7, 8, 30, and 31, the provisions pertaining to the amounts of fees shall begin to apply when an application, notification, or request for review is filed after this Rule enters into force.

Article 3 (Transitional Measures Concerning Designation as Institutions Conducting Non-Clinical Studies) A person conducting non-clinical studies under Article 27 of the Act among the institutions designated as medical device testing and inspection institutions referred to in Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry, at the time this Rule enters into force, shall be deemed designated as an institution conducting non-clinical studies under the amended provisions of Article 24-2: Provided, That such institution shall obtain designation as an institution conducting non-clinical studies under the amended provisions of Article 24-2 within 2 years from the date this Rule enters into force.

ADDENDA <Act No. 1469, Jun. 14, 2018>

Article 1 (Enforcement Date) This Rule shall enter into force on June 14, 2018: Provided, That the amended provisions of Articles 10, Article 14 (4) through (9), Articles 32, 51, and 53, Article 63 (1), with the exception of its subparagraphs, and Attached Forms 11-2 and 12 shall enter into force on the date of its promulgation; and the amended provisions of Articles 36 and 46-2 shall enter into force on September 14, 2018.

Article 2 (Transitional Measures Concerning Minor Repair of Medical Devices) Notwithstanding the amended provisions of the proviso of Subparagraph 1 of Article 36, the previous provisions shall apply when a medical device repairer performs a minor repair of medical devices under the amended provisions of Article 46-2 before this Rule enters into force.

ADDENDA <Act No. 1512, Dec. 31, 2018>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of its promulgation: Provided, That the amended provisions of Articles 52 through 54 and 57 shall enter into force 3 months after the date of its promulgation; and the amended provisions of Article 54-2 and Subparagraph 29-2 of II of Attached Table 8 shall enter into force on the date specified in Article 2 (1) 3 of the Addenda.

Article 2 (Enforcement Date of the Medical Devices Act) (1) The “date prescribed by Ordinance of the Prime Minister” in the main clause of Article 1 of the Addenda to the Medical Devices Act (Act No. 14330) refers to the dates according to the following classifications: <Amended on Oct. 22, 2019>

1. The amended provisions of the former part of Article 16 (4) and Article 31-4 of the Medical Devices Act (Act No. 14330): The date of promulgation;
2. The amended provisions of Articles 2 (4), Article 36 (1) 9-2, and Article 3-2 of the Medical Devices Act (Act No. 14330): July 1, 2019;
3. The amended provisions of Articles 20, Article 31-3, Article 36 (1) 17-3, and Article 56 (1) 2-3 of the Medical Devices Act (Act No. 14330):
   (a) For Class IV medical devices: July 1, 2019;
   (b) For Class III medical devices: July 1, 2020;
   (c) For Class II medical devices: July 1, 2021;
   (d) For Class I medical devices: July 1, 2022;
4. The amended provisions of Articles 31-2, Article 36 (1) 17-2, and Article 56 (1) 2-2 of the Medical Devices Act (Act No. 14330): The dates according to the following classifications:
   (a) Class IV medical devices: July 1, 2020;
   (b) Class III medical devices: July 1, 2021;
   (c) Class II medical devices: July 1, 2022;
   (d) Class I medical devices: July 1, 2023.

(2) Notwithstanding Paragraph (1) 3, the date the amended provisions of Subparagraph 9 of Article 20 and Article 22 of the Medical Devices Act (Act No. 15279) enter into force following the proviso of Article 1 of the Addenda to that Act shall be July 1, 2019.

Article 3 (Applicability to Recall Procedures of Harmful Medical Devices) The amended provisions of Articles 52 and 57 shall begin to apply when any medical device is verified as a medical device subject to recall under any Subparagraph of Article 52 (2) after this Rule enters into force.

Article 4 (Applicability to Registration of Integrated Medical Device Information) The amended provisions of Article 54-2 shall begin to apply when any medical device manufacturer or importer supplies medical devices after this Rule enters into force.

Article 5 (Transitional Measures Concerning Standards for Administrative Dispositions) Notwithstanding the amended provisions of Attached Table 8, the previous provisions shall apply to any violation committed before this Rule enters into force.

ADDENDA <Act No. 1542, Jun, 12, 2019>

This Rule shall enter into force on June 12, 2019: Provided, That the amended provisions of Article 9 (2) 4 and Subparagraph 3 of Article 22 shall enter into force on the date of its promulgation.

ADDENDA <Act No. 1567, Oct. 22, 2019>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of its promulgation: Provided, That the amended provisions of Article 54-2, Subparagraph 29-2 of II. Individual Standards of Attached Table 8, and Attached Form 48-2 shall enter into force on the dates according to the following classifications, and the amended provisions of Attached Form 7 shall enter into force 1 year after the date of its promulgation.

1. Class IV medical devices: July 1, 2020;
2. Class III medical devices: July 1, 2021;
3. Class II medical devices: July 1, 2022;
4. Class I medical devices: July 1, 2023.

Article 2 (Applicability to Entering Resident Registration Numbers in Manufacturing Business Permission Register) The amended provisions of Article 3 (3) 4 (including cases applicable *mutatis mutandis* under Article 34) shall also apply to the permission register or notification register for persons who have obtained manufacturing business permission or have filed an import business notification before this Rule enters into force.

Article 3 (Applicability to Reporting Details of Supply of Medical Devices) The amended provisions of Article 54-2 shall begin to apply to medical devices supplied in the month following the 1 in which the amended provisions of the proviso of Article 1 of the Addenda enter into force.

Article 4 (Transitional Measures Concerning Application of Standards for Administrative Dispositions) Notwithstanding the amended provisions of Subparagraph 9 (g) of II. Individual Standards of Attached Table 8 and Subparagraph 12 (f) of the Individual Standards, the previous provisions shall apply when the standards for administrative dispositions against violations committed before this Rule enters into force are applied.

ADDENDA <Act No. 1580, Dec. 23, 2019>

This Rule shall enter into force on the date of its promulgation.

ADDENDA <Act No. 1607, Apr. 13, 2020>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of its promulgation: Provided, That the amended provisions of Article 27 (2), Article 33 (2), and Subparagraph 9-2 of II. Individual Standards of Attached Table 8 shall enter into force 1 year and 6 months after the date of its promulgation, and the amended provisions of Article 65 (3) shall enter into force 6 months after the date of its promulgation.

Article 2 (Applicability to Reports on Production or Import Suspension) The amended provisions of Article 27 (2) 2 and Article 33 (2) 2 shall begin to apply when the production or import of medical device is suspended after the relevant amended provisions enter into force following the proviso of Article 1 of the Addenda.

Article 3 (Applicability to the Return of Fees) The amended provisions of Article 65 (3) shall begin to apply to the fees paid after the relevant amended provisions enter into force following the proviso of Article 1 of the Addenda.

Article 4 (Transitional Measures Concerning Period for Handling Notification of Modification of Medical Device Repair Businesses) Notwithstanding the amended provisions of Attached Form 35, the previous provisions shall apply when the procedure of notification on modification of medical device repair business is underway.

ADDENDA <Act No. 1614, May 1, 2020> (Enforcement Rule of the Act On In Vitro Diagnostic Medical Devices)

Article 1 (Enforcement Date) This Act shall enter into force on May 1, 2020.

Article 2 (Amendment of Other Statues and Regulations) (1) Part of the Enforcement Rule of The Medical Devices Act shall be amended as follows:

Article 11 (2) 1 (d) is deleted.

The provisos to Article 20 (1) 3 and Paragraph (3) 3 of the same Article are deleted.

Subparagraphs 1 (c) and (d) in attached Table 1 are deleted, and "according to Items (a)A through (d)" in the Item (e) shall be changed into "according to Items (a) and (b)."

The proviso to Subparagraph 3 in the box on attached documents in attached Form 19 is deleted.

The proviso to Subparagraph 3 in the box on attached documents in attached Form 20 is deleted.

② Omitted

Article 3 omitted

ADDENDA <Act No. 1617, May 29, 2020> (Rules on Supporting and Managing Innovative Medical Devices)

Article 1 (Enforcement Date) This Rule shall enter into force on the date of promulgation.

Article 2 (Amendment of Other Statues and Regulations) Part of the Enforcement Rule of The Medical Devices Act shall be amended as follows.

Columns for attached documents of the former part of Attached Form 30 shall be as follows:

Attached Documents	1. Medical device software designated as an innovative medical device (referring to independently developed and manufactured software) under Article 21 (2) of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices: The following documents under the subparagraphs of Article 11 of the Rules on Supporting and Managing Innovative Medical Devices: (a) Document verifying the modified matters; (b) Technical documents and clinical trial data under Article 6 (5) of the Medical Devices Act (limited to modified matters determined and publicly notified by the Minister of Food and Drug Safety that affect the safety and effectiveness of medical device software designated as an innovative medical device); (c) Data evidencing the standards for facilities and manufacturing and quality management systems under Article 15 of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices are satisfied (limited to modification of the factory or business facility determined and publicly notified by the Minister of Food and Drug Safety). 2. Medical devices not falling under Subparagraph 1: The following documents under the subparagraphs of Article 26 (3) of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices: (a) Document verifying the modified matters; (b) Documents under Article 5 (1) 2 of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices when a major matter that affects the safety or effectiveness of the medical device, such as the design, chemical components, energy source, manufacturing process, etc. is modified; (c) A copy of a contract for entrustment (limited to when the manufacturing processes or testing for quality management are entrusted; including electronic documents) and data evidencing the standards for the facilities and manufacturing and quality management systems under Attached Form 2 of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices are satisfied, when the location of the factory of the relevant item is modified or other factories are added;

Columns for attached documents of the former part of Attached Form 30 shall be as follows:

Attached Documents	1. Medical device software designated as an innovative medical device (referring to independently developed and manufactured software) under Article 21 (2) of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices: The following documents under the subparagraphs of Article 11 of the Rules on Supporting and Managing Innovative Medical Devices: (a) Document verifying the modified matters; (b) Technical documents and clinical trial data under Article 6 (5) of the Medical Devices Act (limited to modified matters determined and publicly notified by the Minister of Food and Drug Safety that affect the safety and effectiveness of medical device software designated as an innovative medical device); (c) Data evidencing the standards for facilities and manufacturing and quality management systems under Article 15 of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices are satisfied (limited to modification of the factory or business facility determined and publicly notified by the Minister of Food and Drug Safety) 2. Medical devices not falling under Subparagraph 1: The following documents under the subparagraphs of Article 26 (3) of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices: (a) Document verifying the modified matters; (b) Documents under Article 5 (1) 2 of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices when a major matter that affects the safety or effectiveness of the medical device, such as the design, chemical components, energy source, manufacturing process, etc. is modified; (c) A copy of a contract for entrustment (limited to when the manufacturing processes or testing for quality management are entrusted; including electronic documents) and data evidencing the standards for the facilities and manufacturing and quality management systems under Attached Form 2 of the Enforcement Rule of the Act on Nurturing Medical Device Industry and Supporting Innovative Medical Devices are satisfied, when the location of the factory of the relevant item is modified or other factories are added;

ADDENDA <Act No. 1658, Dec. 4, 2020>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of its promulgation: Provided, That the amended provisions of Article 27 (1) 9, Article 33 (1) 14, and Attached Table 8 shall enter into force 1 month after the date of its promulgation.

Article 2 (Applicability to Compliance for Manufacturers or Importers) The amended provisions of Article 27 (1) 9 and Article 33 (1) 14 shall begin to apply to the data or information (including cases of side effects following the use of the medical device) of which manufacturers or importers become aware after the relevant amended provisions enter into force following the proviso of Article 1 of the Addenda.

ADDENDA <Act No. 1662, Dec. 31, 2020>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of promulgation.

Article 2 (Transitional Measures Concerning Fees) Notwithstanding the amended provisions of Attached Form 10, the previous provisions shall apply to the fees for the application for medical device manufacturing or import permission or modification thereof, or the request for review of technical documents, etc. before this Rule enters into force.

Article 3 (Amendment of Other Statutes) Parts of the Enforcement Rule of the Act on In Vitro Diagnostic Medical Devices shall be amended as follows.

The fee column at the back of Attached Form 3 shall be as follows:

Fee	
e-Government	Visit/Mail
1. Subject of the review of data regarding clinical performance studies: KRW 1,495,000; 2. Subject of the review of technical documents: KRW 719,000 3. Other cases: KRW 158,000.	1. Subject of the review of data regarding clinical performance studies: KRW 1,662,000; 2. Subject of the review of technical documents: KRW 799,000; 3. Other cases: KRW 176,000.

The fee column at the back of attached Form 5 shall be as follows:

Fee	
e-Government	Visit/Mail
130,000 KRW	145,000 KRW

The fee column at the back of attached Form 7 shall be as follows:

Fee	
e-Government	Visit/Mail
85,000 KRW	96,000 KRW

The fee column in front of attached Form 18 shall be as follows:

Fee	
e-Government	Visit/Mail
1. Modification Permission For reviewing clinical performance study: 1,009,000 KRW For reviewing technical documents: 551,000 KRW Others: 121,000 KRW 2. Modification Certification: 82,000 KRW 3. Modification notification: KRW 39,000.	1. Modification Permission - Subject of the review of data regarding clinical performance studies: KRW 1,122,000; For reviewing technical documents: 612,000 KRW Others: 135,000 KRW 2. Modification Certification: 93,000 KRW 3. Modification notification: KRW 39,000.

Article 4 (Transitional Measures Concerning Amendment of Other Statues and Regulations) Notwithstanding the amended provisions of Attached Forms 3, 5, 7, and 18 of the Enforcement Rule of the Act On In Vitro Diagnostic Medical Devices, the previous provisions shall apply to the fees for an application for permission and certification or a notification of in vitro diagnostic medical device manufacture and import filed before this Rule enters into force.

ADDENDA <Act No. 1709, Jun. 24, 2021>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of its promulgation: Provided, That the following amended provisions shall enter into force on the dates according to the following classification:

1. Amended provisions of Articles 45, 45-2, 45-3, Attached Forms 38-2, 38-3, and Subparagraph 8 of Attached Table 8 I and Attached Table 10: June 24, 2021;
2. Amended provision of Article 50 (2) 2 (b): 1 year after promulgation.

Article 2 (Applicability to Medical Devices for the Purpose of Exhibition) The amended provisions of Article 46 (4) shall begin to apply to medical devices certified as medical devices for exhibition purposes before this Rule enters into force.

Article 3 (Applicability to Medical Devices Subject to Tracking Management) The amended provision of Article 50 (2) 2 (b) shall begin to apply when medical institutions use medical devices subject to tracking management determined and publicly notified by the Minister of Food and Drug Safety after the enforcement date following Subparagraph 2 of Article 1 of the Addenda.

ADDENDA <Act No. 1786, Jan. 21, 2022>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of its promulgation: Provided, That the following amended provisions shall enter into force on the dates according to the following classifications:

1. Amended provisions of Articles 14, 15, 45-4, Subparagraphs 3-2, 3-3, 8 (d), 9 (g), 12 (f), 20-2, 26-2 of Attached Table 8 II, Subparagraph 5 of Attached Table 9 II, and Attached Form 11: January 21, 2022;
2. Amended provisions of Articles 18, 18-2 through 18-5, 27, 33, 54-4, 56-2, 57, Subparagraph 5, Subparagraphs 5-2 through 5-8 of Attached Table 8 II, Subparagraph 7 of Attached Table 10, Attached Form 16, Attached Forms 16-2 through 16-4, and Attached Form 17: February 18, 2022.

Article 2 (Applicability to Sealing of Medical Devices) The amended provision of Article 45-4 shall begin to apply to the medical devices manufactured or imported after the enforcement date following Subparagraph 1 of Article 1 of the Addenda.

ADDENDA <Act No. 1819, Jul. 20, 2022>

Article 1 (Enforcement Date) This Rule shall enter into force on the date of its promulgation: Provided, That the following amended provisions shall enter into force on the dates according to the following classifications:

1. Class II, III, IV medical devices: July 21, 2022;
2. Class I medical devices: July 1, 2023.

Article 2 (Applicability to Standards for Administrative Dispositions) The amended provisions of the latter part of Subparagraph 2 (a) of Attached Table 8 I and the latter part of Subparagraph 3 of Attached Table 9 I shall begin to apply to the first violation conducted after this Rule enters into force.

Attached Tables / Forms

[Attached Table 1] Standards and Procedures for Medical Device Classification and the Designation of Classes (In Relation to Article 2
[Attached Table 2] Standards for Facilities and Manufacturing and Quality Management Systems [In Relation to Act 8 (1)]
[Attached Table 3] Standards for Medical Device Clinical Trial Management (In Connection with Article 24 (1))
[Attached Table 4] Standards for Facilities and Manufacturing and Quality Management Systems of Import Businesses (In Relation to Article 31 (1))
[Attached Table 5] Standards for Facilities and Quality Management Systems of Repair Businesses [In Relation to Article 35 (4)]
[Attached Table 6] Distribution Quality Management Standards for Medical Devices [in Relation to Subparagraph 4 Article 39]
[Attached Table 7] Scope of Prohibited Advertisements (In Relation to Article 45 (1))
[Attached Table 7-2] Standards for Management of Integrated Medical Device Information [in Relation to Article 54-3 (2)]
[Attached Table 8] Standards for Administrative Dispositions [In Relation to Article 58 (1)]
[Attached Table 9] Standards for Administrative Dispositions [in Relation to Article 58 (2)]
[Attached Table 10] Fees [in Relation to Article 65 (1)]
[Attached Form 1] Application for Permission of Medical Device Manufacturing (Import) Business
[Attached Form 2] License for Medical Device Manufacturing (Import) Business
[Attached Form 3] Application for Permission of Medical Device Manufacturing (Import)
[Attached Form 4] License for Medical Device Manufacturing (Import)
[Attached Form 5] Application for Certification of Medical Device Manufacturing (Import)
[Attached Form 6] Certificate of Medical Device Manufacturing (Import)
[Attached Form 7] Notification of Medical Device Manufacturing (Import)
[Attached Form 8] Request for Review of Medical Device Technical Documents, Etc.
[Attached Form 9] Notification of Review Results of Medical Device Technical Documents, Etc.
[Attached Form 10] Notification on Non-Working as Quality Manager
[Attached Form 11] Application for Designation as Institutions Offering Education for Medical Device Quality Managers
[Attached Form 11-2] Application for Modification of Designation as Institutions Offering Education for Medical Device Quality Managers
[Attached Form 12] Certificate of Designation as Institutions Offering Education for Medical Device Quality Managers
[Attached Form 12-2] Application for Designation as Institutions for Reviewing Technical Documents on Medical Devices
[Attached Form 12-3] Certificate of Designation as Institutions for Reviewing Technical Documents on Medical Devices
[Attached Form 12-4] Application for Modification of Designated Matters of Institutions for Reviewing Technical Documents on Medical Devices
[Attached Form 13] Certificate of Conditional Permission for Medical Device Manufacturing (Import) Business
[Attached Form 14] Certificate of Conditional Permission for Medical Device Manufacturing (Import)
[Attached Form 15] Certificate of Conditional Medical Device Manufacturing (Import)
[Attached Form 16] Application for Approval of a Medical Device Post-Marketing Surveillance (PMS) Plan (or Modification Thereof)
[Attached Form 16-2] Approval of Medical Device Post-Marketing Surveillance Plan (PMS)
[Attached Form 16-3] Periodic Report on Medical Device Post-Marketing Surveillance (PMS)

[Attached Form 16-4] Request for Review of Medical Device Post-Marketing Surveillance (PMS) Results
[Attached Form 17] Notification of Results of Medical Device Post-Marketing Surveillance Review
[Attached Form 18] Application for Re-Evaluation of Medical Devices
[Attached Form 19] Application for Approval of Medical Device Clinical Trial Protocol
[Attached Form 20] Application for Approval of Modification of Medical Device Clinical Trial Protocol
[Attached Form 21] Certificate of Approval of Medical Device Clinical Trial Protocol
[Attached Form 22] Application for Designation as Medical Device Clinical Trial Institutions
[Attached Form 23] Certificate of Designation as Medical Device Clinical Trial Institutions
[Attached Form 24] Application for Modification of Designation as Medical Device Clinical Trial Institutions
[Attached Form 25] Report on Status of Medical Device Clinical Trial
[Attached Form 26] Report on Termination of Medical Device Clinical Trial
[Attached Form 26-2] Application for Designation as Institutions Conducting Non-Clinical Studies
[Attached Form 26-3] Certificate of Designation as Institution Conductings Non-Clinical Studies
[Attached Form 26-4] Application for Modification of Designation as Institutions Conducting Non-Clinical Studies
[Attached Form 27] Application for Preliminary Examination for Medical Devices
[Attached Form 28] Notification of Results of Preliminary Examination for Medical Devices
[Attached Form 29] Application for Approval of Modification of Medical Device Manufacturing (Import) Business Permission
[Attached Form 30] Application for Approval of Modification of Medical Device Permission
[Attached Form 31] Application for Certification of Modification of Medical Device Certification
[Attached Form 32] Notification of Closure or Suspension of Medical Device Business
[Attached Form 33] Notification of Medical Device Repair Business
[Attached Form 34] Certificate of Notification of Medical Device Repair Business
[Attached Form 35] Notification of Modification of Medical Device Repair Business Notification
[Attached Form 36] Notification of Medical Device Distribution Business or Lease Business
[Attached Form 37] Certificate of Notification of Medical Device Distribution (Lease) Business
[Attached Form 38] Notification of Modification of Medical Device Distribution (Lease) Business
[Attached Form 38-2] Objection to Results of Medical Device Advertisement Re-Evaluation
[Attached Form 38-3] Notification by Voluntary Deliberation Agency for Medical Device Advertisements
[Attached Form 39] Application for Designation as Medical Device Quality Management Review Institution
[Attached Form 40] Certificate of Designation as Medical Device Quality Management Review Institution
[Attached Form 41] Application for Modification of Designation as Medical Device Quality Management Review Institution
[Attached Form 42] Confirmation of Notice to Patients
[Attached Form 43] Recall Plan
[Attached Form 44] Confirmation of Destruction
[Attached Form 45] Recall Evaluation Report
[Attached Form 46] Application for Destruction
[Attached Form 47] Confirmation of Destruction
[Attached Form 48] Recall Completion Report
[Attached Form 48-2] Report on Details of the Medical Device Supply
[Attached Form 48-3] Report on Discovery of Foreign Substances
[Attached Form 49] Certificate of Collection of Medical Devices
[Attached Form 50] Medical Device Surveillance Officer Identification
[Attached Form 50-2] Approval for Unaccompanied Access to Distribution (Lease) Business by Consumer Medical Device Surveillance Officer
[Attached Form 50-3] Consumer Medical Device Surveillance Officer Identification
[Attached Form 50-4] Application for Designation as Medical Device Safety Information Monitoring Centers
[Attached Form 50-5] Certificate of Designation as Medical Device Safety Information Monitoring Centers
[Attached Form 50-6] Identification as Investigator of Causal Relationship
[Attached Form 51] Application for Renewal of Medical Device Manufacturing (Import) Permission
[Attached Form 51-2] Application for Renewal of Medical Device Manufacturing (Import) Certification
[Attached Form 51-3] Application for Renewal of Medical Device Manufacturing (Import) Notification
[Attached Form 52] Request for the Re-Issuance of Medical Devices License/Certificates

[Attached Form 53] Request for Issuance of Medical Device Certificates in English
[Attached Form 54] Application for Re-Classification of Medical Devices
[Attached Form 55] Expedited Report of Adverse Device Effects (ADE)
[Attached Form 56] Report on Medical Device Adverse Reactions