ENFORCEMENT RULE OF THE ACT ON IN VITRO DIAGNOSTIC MEDICAL DEVICES

[Enforcement Date Dec. 31, 2020]
[Ordinance of the Prime Minister No.1662, Dec. 31, 2020, Amendment of Other Statutes]

Ministry of Food and Drug Safety (Innovative and Diagnostic Medical Devices Policy Division) 043-719-3785

Article 1 (Purpose) The purpose of this Rule is to prescribe the matters mandated by the Act on In Vitro Diagnostic Medical Devices and its Enforcement Decree and matters necessary for enforcing said Act and Decree.

Article 2 (Standards for the Classification and Designation of Classes) (1) In vitro diagnostic medical devices, following Article 3 (1) of the Act on In Vitro Diagnostic Medical Devices (hereinafter the "Act"), are categorized into four classes based on the level of safety management required. These are classes Ⅳ, Ⅲ, Ⅱ and Ⅰ, going from the highest to the lowest level of safety management required.

(2) When the Minister of Food and Drug Safety designates the grade of in vitro diagnostic medical devices following Article 3 (1) of the Act, the Minister shall do the following.

1. Designate an in vitro diagnostic medical device by item or item category
2. Consider the procedure and level of safety management according to the intended use of an in vitro diagnostic medical device
3. Consider the potential risks of using an in vitro diagnostic medical device to individual or public health
4. Consider the social impact and influence of an in vitro diagnostic medical device

(3) When the Minister of Food and Drug Safety deems it necessary to classify an in vitro diagnostic medical devices following Article 3 (1) of the Act, the Minister may request advice from a Committee of Experts on In Vitro Diagnostic Medical Devices under Article 21 of the Act.

(4) When the Minister of Food and Drug Safety classifies an in vitro diagnostic medical device following Article 3 (1) of the Act, the Minister shall publish the information on the website of the Ministry of Food and Drug Safety.

(5) The Minister of Food and Drug Safety may redesignate the class of an in vitro diagnostic medical device if there is an application from an interested party or if it is deemed necessary to do so. In this case, the provisions of Paragraphs (2) through (4) shall apply *mutatis mutandis* to the criteria and procedures for redesignation.

(6) Except as prescribed in Paragraphs (1) through (5), the details necessary for the classification, class designation, and redesignation of an in vitro diagnostic medical device shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 3 (Relationship with Other Statutes) According to Article 4 of the Act, except as prescribed in this Rule, the Enforcement Rule of the Medical Devices Act shall apply to in vitro diagnostic medical devices.

Article 4 (Procedures and Methods for Manufacturing Permission) (1) A person who intends to obtain a manufacturing permission under the main clause of Article 5 (1) of the Act shall submit the application in Attached Form 1 (including an application in electronic form) to the commissioner of a Regional Office of Food and Drug Safety (FDS) with jurisdiction over the location of a factory, along with the following documents (including electronic documents). In cases where at least two factories exist in different locations, such person may submit the application to the commissioner of a Regional Office of FDS with jurisdiction over either location.

1. Medical certificates proving that an applicant does not fall under the scope of Article 5 (2) 1 of the Act or a medical certificate of a specialist under the proviso of the same subparagraph issued less than 6 months before the date of application (excluding corporations)
2. Medical certificates proving that an applicant does not fall under Article 5 (2) 3 of the Act and a medical certificate issued less than six months before the date of application (excluding corporations)
3. Documents concerning a person in charge of quality (hereinafter "quality manager") following Article 5 (8) of the Act

(2) Upon the receipt of an application under Paragraph (1), the commissioner of a Regional Office of FDS shall check the certificate of corporate registration (limited to a corporation) through the joint use of administrative information under Article 36 (1) of the Electronic Government Act.

(3) When the commissioner of the Regional Office of FDS grants a manufacturing permission following the main clause of Article 5 (1) of the Act, the commissioner shall issue the permit in Attached Form 2 to the applicant and state the following matters in the manufacturing permission register.

1. Number and date of permission
2. Name and resident registration number of a person who has obtained the manufacturing permission (hereinafter "manufacturer") (in the case of a corporation, the name and resident registration number of its representative)
3. Name and address of the factory
4. Name, resident registration number, and classification of the qualifications of a quality manager

(4) Except as prescribed in Paragraphs (1) through (3), details necessary for the procedure and method for manufacturing permission shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 5 (In Vitro Diagnostic Medical Devices Subject to Manufacturing Permission, Manufacturing Certification, or Manufacturing Notification) (1) In vitro diagnostic medical devices subject to manufacturing certification or manufacturing notification for each item category following Article 5 (3) 1 of the Act are divided as follows.

1. Manufacturing certification by item category: in vitro diagnostic medical devices determined and notified by the Minister of Food and Drug Safety among Class II in vitro diagnostic medical devices
2. manufacturing notification by item category: in vitro diagnostic medical devices determined and notified by the Minister of Food and Drug Safety among Class I in vitro diagnostic medical devices.

(2) In vitro diagnostic medical devices subject to manufacturing permission, manufacturing certification, or manufacturing notification for each item following Article 5 (3) 2 of the Act are divided as follows.

1. Manufacturing permission by item: the in vitro diagnostic medical devices listed below
   A. Class III or Class IV in vitro diagnostic medical devices
   B. In vitro diagnostic medical devices that are essentially different from those already permitted, certified, or reported by item category or item in terms of structure, principle, performance, intended use, methods for use, etc., among Class I or Class II medical devices
   C. In vitro diagnostic medical devices other than those under Paragraph 1, Subparagraph 1; Item B in this subparagraph; and Subparagraph 2 in this paragraph among Class II in vitro diagnostic medical devices
2. Manufacturing certification by item: in vitro diagnostic medical devices, excluding in vitro diagnostic medical devices under Paragraph 1, Subparagraph 1 among Class II in vitro diagnostic medical devices, determined and notified by the Minister of Food and Drug Safety
3. Manufacturing notification by item: in vitro diagnostic medical devices excluding in vitro diagnostic medical devices under Paragraph 1, Subparagraph 2; and Item B in this paragraph among Class I in vitro diagnostic medical devices

Article 6 (Procedures and Methods of Manufacturing Permission) (1) A person who intends to obtain permission to manufacture an in vitro diagnostic medical device following Article 5 (3) of the Act shall submit the 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 certifying that facilities and manufacturing and quality management systems are in place following the main clause of Article 5 (5) of the Act
2. A copy of the contract for entrusting the manufacturing processes or testing for quality management following the proviso to Article 5 (5) of the Act, where such contract is concluded
3. Technical documents and data on clinical performance studies under Article 5 (6) of the Act. If there is a notice for the evaluation results (not exceeding 2 years from the date of notice) on technical documents and clinical performance studies following Article 9 (4) of the Enforcement Rule of the Medical Devices Act, the notice may be submitted instead.

(2) When the Minister of Food and Drug Safety grants a manufacturing permission following Article 5 (3) of the Act, the Minister shall issue the permit in Attached Form 4 to the applicant and state the following matters in the manufacturing permission register.

1. License number and date
2. Name of the in vitro diagnostic medical device (product name, item name, and model name)

(3) The details necessary for the scope of document submission and preparation criteria of attached documents under each subparagraph of Paragraph (1) shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 7 (Integrated Handling of Applications for Manufacturing Permission and New Health Technology Assessment, etc.) (1) When the Minister of Food and Drug Safety receives an application for a new health technology assessment, an application for identifying whether a device is a health care benefit item or nonbenefit item, or other applications under the Rules on New Health Technology Assessment and the Rules on Standards for Health Care Benefits Covered by National Health Insurance, along with an application for manufacturing permission filed under Article 6 (1), the Minister shall, without delay, forward the applications 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 shall take the necessary measures to share the attached documents of the application for manufacturing permission filed under subparagraphs of Article 6 (1) with the Minister of Health and Welfare or the President of the Health Insurance Review and Assessment Service.

(2) If deemed necessary for the efficient processing of applications for manufacturing permission under Article 6 (1), the Minister of Food and Drug Safety may present their opinion on the new health technology assessment under the Rules on New Health Technology Assessment or the identification of whether a device is a health care benefit item or nonbenefit item under the Rules on Standards for Health Care Benefits Covered by National Health Insurance to the Minister of Health and Welfare or the President of the Health Insurance Review and Assessment Service.

(3) When the Minister of Food and Drug Safety receives the results of the new health technology assessment or the confirmation on whether a device is a health care benefit item or nonbenefit item from the Minister of Health and Welfare or the President of the Health Insurance Review and Assessment Service under the Rules on New Health Technology Assessment and the Rules on Standards for Health Care Benefits Covered by National Health Insurance, the Minister of Food and Drug Safety, without delay, shall inform the applicant of the results. If deemed necessary for the processing of the application for manufacturing permission under Article 6 (1), the Minister of Food and Drug Safety may refer to the results of the new health technology assessment and the confirmation whether a device is a health care benefit item or nonbenefit item.

Article 8 (Procedures and Methods for Manufacturing Certification) (1) A person who intends to obtain manufacturing certification of an in vitro diagnostic medical device under Article 5 (3) of the Act shall submit the application in Attached Form 5 (including an application in electronic form) to the National Institute of Medical Device Safety Information (hereinafter the "Institute") established under Article 42 of the Medical Devices Act, along with the documents referred to in the subparagraphs of Article 6 (1) (including electronic documents).

(2) When the Institute issues a manufacturing certificate following Article 5 (3) of the Act, the certificate in Attached Form 6 shall be issued to the applicant and state the following matters in the manufacturing certification register.

1. Certification number and date
2. Name of the in vitro diagnostic medical device (product name, item name, and model name)

Article 9 (Procedures and Methods for Manufacturing Notification) (1) A person who intends to file a manufacturing notification of an in vitro diagnostic medical device under Article 5 (3) of the Act shall submit the notification form in Attached Form 7 (including a notification in electronic form) to Institute along with the documents referred to in Article 6 (1) 2 (including electronic documents).

(2) When the Institute accepts the manufacturing notification following Article 5 (3) of the Act, the notification certificate in Attached Form 8 shall be issued to the notification filer and state the following matters in the manufacturing notification register.

1. Report number and date
2. Name of the in vitro diagnostic medical device (product name, item name, and model name)

Article 10 (Standards for Facilities and Manufacturing and Quality Management System) (1) The standards for facilities and manufacturing and quality management systems under the main clause of Article 5 (5) of the Act shall be specified in the following subparagraphs.

1. Facility standards
   A. To have a facility where the whole manufacturing process of the product is completed
   B. To have a laboratory or testing facility where quality control tests and inspections on products can be conducted independently
   C. To have a storage room or storage facility where raw materials, materials, or products can be safely and hygienically stored, as determined and notified by the Minister of Food and Drug Safety
   D. To have facilities, tools, or equipment determined and notified by the Minister of Food and Drug Safety for the manufacture, management, testing, and inspection of products.
2. Standards for manufacturing and quality management systems
   A. To document and implement a quality management system for manufacturing and quality control
   B. To document the tasks, responsibilities, and authority of each member of an organization and follow the documents
   C. To document and keep results and records about the implementation of manufacturing and quality control
   D. To conduct internal and external inspections to maintain the conformity of manufacturing and quality control systems
   E. To meet standards similar to those prescribed in Items A through D, established and notified by the Minister of Food and Drug Safety for manufacturing and quality control

(2) Matters necessary for details and methods of operation of standards for facilities, manufacturing and quality management systems under Paragraph (1) shall be determined and notified by the Minister of Food and Drug Safety.

(3) If a manufacturer receives the permission for, registers, or reports his or her business along with manufacturing businesses of medical devices under Article 6 of the Medical Devices Act, pharmaceuticals or quasi drugs under Article 31 of the Pharmaceutical Affairs Act, foods or food additives under Article 21 of the Enforcement Decree of the Food Sanitation Act, health functional foods under Article 5 of the Health Functional Foods Act, or cosmetics under Article 3 of the Cosmetics Act, manufacturing facilities and equipment may be used to manufacture medical devices, pharmaceuticals, quasi drugs, food, food additives, health functional foods, or cosmetics when there is no risk of contamination between medical devices, pharmaceuticals, quasi drugs, food, food additives, health functional foods, or cosmetics and in vitro diagnostic medical devices.

Article 11 (Exemption from the Provision of Facilities and Manufacturing and Quality Control Systems) (1) A manufacturer may not be equipped with facilities, tools, or equipment under any of the following subparagraphs following the proviso to Article 5 (5) of the Act.

1. When entrusting a test for quality control (only when entrusted to a medical device testing and inspection agency under Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry, or to a person determined and notified by the Minister of Food and Drug Safety among persons who have facilities and manufacturing and quality management systems under Article 5 (5) of the Act or Article 6 (4) of the Medical Devices Act): laboratories, facilities, tools and equipment for testing
2. When entrusting the manufacturing process: Facilities, tools, and equipment related to the entrusted process

(2) When a manufacturer entrusts a test for quality control or manufacturing process following the proviso to Article 5 (5) of the Act, the consignor or trustee shall faithfully fulfill their responsibilities and obligations under the entrustment as determined and notified by the Minister of Food and Drug Safety.

Article 12 (Quality Manager) (1) The qualification standards for quality managers are as follows.

1. A person with a clinical laboratory scientist's license under the Act on Medical Technologists

2. A person with qualifications as a biomedical engineer or quality management engineer under the National Technical Qualifications Act
3. A person with the qualifications of a medical device RA (Regulatory Affairs) expert recognized by the Minister of Food and Drug Safety following Article 19 (1) of the Framework Act on Qualifications
4. A person who has earned a bachelor's degree (including a person recognized by law as having an educational background equal to or greater than that. Hereinafter, the same shall apply in this Article.) from a school under the subparagraphs of Article 2 of the Higher Education Act (excluding a junior college under Subparagraph 4 of that Article; hereafter "university, college, etc.") and who has majored in the field of natural science, engineering, or medicine under Attached Table 1 of the Regulations on the Establishment and Operation of Universities and Colleges (hereafter "field related to in vitro diagnostic medical devices")
5. A person who has obtained a bachelor's degree in a field other than those related to in vitro diagnostic medical devices from a university, college, etc., and has obtained a master's degree or higher in a field related to in vitro diagnostic medical devices from a graduate school under Article 29 of the Higher Education Act after obtaining a bachelor's degree
6. A person who has obtained a bachelor's degree in a field other than those related to in vitro diagnostic medical devices from a university, college, etc., and has at least 1 year of experience in quality control at a medical device or in vitro diagnostic medical device manufacturing/import company after obtaining the bachelor's degree
7. A person who has obtained a degree in a field related to in vitro diagnostic medical devices from a junior college under subparagraph 4 of Article 2 of the Higher Education Act (including a person recognized by law as having an educational background equal to or greater than that. Hereinafter, the same shall apply in this Article.) and has engaged in quality management for at least one year in a company that manufactures or imports medical devices or in vitro diagnostic medical devices after obtaining the degree
8. A person who has obtained a degree in a field not related to in vitro diagnostic medical devices from a junior college under Subparagraph 4 of Article 2 of the Higher Education Act and has engaged in quality management for at least 3 years (2 years, in the case of a graduate of a junior college with a term of 3 years under Article 48 (1) of the Higher Education Act) in a company that manufactures or imports medical devices or in vitro diagnostic medical devices
9. 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 equal or higher educational background by law, but excluding a person falling under Subparagraph 10) who has engaged in quality management for at least 5 years in a company that manufactures or imports medical devices or in vitro diagnostic medical devices after graduating the high school or high technical school
10. A graduate of a high school geared toward industrial demand in a field related to in vitro diagnostic medical devices under Article 90 (1) 10 of the Enforcement Decree of the Elementary and Secondary Education Act who has engaged in quality management for at least 3 years in a company that manufactures or imports medical devices or in vitro diagnostic medical devices after graduating high school
11. A person who has engaged in quality management for at least 6 years in a company that manufactures or imports medical devices or in vitro diagnostic medical devices

(2) According to Article 5 (8) of the Act, a manufacturer shall have at least one quality manager for each factory. When two or more quality managers are assigned to one factory, the duties shall be divided, and the limits of the responsibilities of each quality manager shall be specified.

(3) According to Article 5 (8) of the Act, a quality manager shall not take on any other task other than those under Article 6-2 (1) of the Medical Devices Act: *Provided*, that the same shall not apply in any of the following subparagraphs:

1. When a manufacturer obtains the import business license following Article 11 (1) of the Act (hereinafter "importer"), and a quality manager handles affairs for both the manufacturing and import businesses
2. When a manufacturer or importer is engaged in both manufacturing and import businesses under the Medical Devices Act, and a quality manager handles the affairs under this Act and the Medical Devices Act
3. When they handle affairs not affecting the duties of a quality manager and determined and notified by the Minister of Food and Drug Safety.

Article 13 (Approval of Clinical Performance Study Protocols) (1) A person who intends to obtain approval for a clinical performance study protocol according to Article 7 (1) of the Act shall submit the application for approval of a clinical performance study protocol in Attached Form 9 (including an application in electronic form and the following documents [including electronic documents]) to the Ministry of Food and Drug Safety or an institutional review board for clinical performance studies under Article 8 (2) of the Act (hereinafter "the review board").

1. A clinical performance study protocol according to the clauses other than each subparagraph of Article 7 (1) of the Act (hereinafter "clinical performance study protocol"). In the case of companion diagnostic medical devices under Article 6 (1) of the Act, this may be replaced by the submission of a clinical trial protocol under Article 24 (1) 10 of the Regulation on Safety of Pharmaceuticals, etc., or a clinical trial protocol approval certificate under Article 24 (7) of the same Rule.
2. Data evidencing that an in vitro diagnostic medical device for clinical performance study is manufactured in compliance with the standards of facilities and manufacturing and quality control systems under Article 10 (1)
3. Data according to the following categories

A. In case the in vitro diagnostic medical devices are reagents, contrast agents or calibrators:

1) Information on the origin or development process and the principle and method of detection and measurement
2) Information on the purpose of use
3) Information on raw materials and manufacturing methods
4) Information on the storage method and usage period or expiration date
5) The following data to verify performance
A. Data on analytical performance tests
B. Information on quality control tests
C. Data on storage of reference materials and samples, etc.
6) Information on handler safety
7) Comparison with previously approved products
8) Information on domestic and international usage status

B. In case the in vitro diagnostic medical devices are equipment, machines, devices, or software:
1) Information on the origin, discovery, or development progress
2) Information on the purpose of use
3) Information on the principles of operation
4) The following data to confirm the performance and safety of a product and test specifications and their grounds and actual measurement data. If there are no test specifications locally and abroad, data on the test specifications set by an applicant, their grounds, and actual measurements to confirm the performance and safety of a product shall be submitted.
A. Information on electrical and mechanical safety
B. Radiation safety data
C. Safety information on electromagnetic fields
D. Performance data
5) Comparison with previously approved products
6) Information on domestic and international usage status

(2) The matters to be included in the clinical performance study protocol are as follows.
1. Matters concerning the purpose and background of the clinical performance study
2. Matters concerning the duration and method of the clinical performance study
3. Matters concerning the name and location of a clinical performance study institution under Article 8 (1) of the Act (hereinafter “clinical performance study institution”)
4. Matters concerning the manager, person in charge, and researcher of the clinical performance study
5. Matters concerning in vitro diagnostic medical devices for the clinical performance study
6. Matters concerning the selection of subjects and consent for the clinical performance study, etc.
7. Matters concerning compensation, medical treatment, and safety measures for the subjects of the clinical performance study
8. Other matters deemed necessary for the clinical performance study, determined and publicly notified by the Minister of Food and Drug Safety

(3) If deemed necessary for the approval of the clinical performance study protocol under Article 7 (1) of the Act, the Minister of Food and Drug Safety or a review board may request the cooperation, in the form of opinions or data, of in vitro diagnostic medical device-relevant institutions, organizations, or experts.

(4) When the Minister of Food and Drug Safety or a review board approves a clinical performance study protocol following Article 7 (1) of the Act, the written approval of the clinical performance study protocol in Attached Form 10 shall be issued to the applicant.

(5) A person who intends to modify a clinical performance study protocol approved under Article 7 (1) of the Act shall submit the application for the approval of the modification of the clinical performance study protocol in Attached Form 11 (including applications in electronic documents) along with a written approval of a clinical performance study protocol and documents proving the modification thereof (including electronic documents) to the Minister of Food and Drug Safety or a review board.

(6) When the Minister of Food and Drug Safety or a review board approves the modification of a clinical performance study protocol following Article 7 (1) of the Act, the modification shall be added to a written approval of a clinical performance study protocol, and the written approval shall be given to the applicant.

(7) Except as prescribed in Paragraphs ① through ⑥, the details necessary for the procedure and method of approval or modification approval of a clinical performance study protocol shall be determined and notified by the Minister of Food and Drug Safety.

Article 14 (Standards for In Vitro Diagnostic Medical Devices for Clinical Performance Study) The term “standards prescribed by Ordinance of the Prime Minister” in the first clause of Article 7 (2) of the Act means standards for facilities and manufacturing and quality management systems under Article 10 (1).

Article 15 (Restriction of Human Subjects of a Clinical Performance Study) (1) In the main clause of Article 7 (3) 2 of the Act, “collective facility prescribed by Ordinance of the Prime Minister, such as a social welfare facility” means any of the following collective facilities.

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 the case of mental medical institutions)
4. 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
5. Mother-and-child family welfare facilities (limited to facilities that support basic living and self-support living), father-and-child family welfare facilities (limited to facilities that support basic living and self-support living), unmarried mother-and-child family welfare facilities (limited to facilities that support basic living), and temporary supporting welfare facilities under Article 19 of the Single-Parent Family Support Act
6. 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
7. Protection facilities for victims of sexual violence under Article 12 of the Sexual Violence Prevention and Victims Protection Act
8. Shelters for victims of domestic violence under Article 7 of the Act on the Prevention of Domestic Violence and Protection, etc., of Victims
9. Facilities established by a person who had obtained permission for a rehabilitation service following Article 67 of the Act on Probation (limited to those with committal facilities)
10. 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
11. Juvenile reformatories and Juvenile Classification Review Boards under the Act on the Treatment of Protected Juveniles, etc.
12. Detention facilities under Article 52 (2) of the Immigration Act

(2) A person who is admitted into one of the collective facilities prescribed in the Paragraph (1) (hereinafter “inmate” in this paragraph) under the proviso of Article 7 (3) 2 of the Act may be selected as a subject of a clinical performance study if the following criteria are met.

1. Illnesses or diseases break out only among inmates
2. The necessity of a clinical performance study for the illnesses or diseases of inmates is recognized
3. Compensation, medical treatment, and safety measures for inmates are fully prepared
4. It is inevitable that inmates are selected as subjects because of the nature of the clinical performance study

Article 16 (Specimen Provider’s Written Consent) (1) A person who intends to use the remaining specimens (hereinafter “leftover specimens” in this Article) for diagnosis or treatment following the main clause of Article 7 (3) 4 of the Act shall obtain written consent that includes following matters from the specimen providers.

1. Matters concerning the preservation, management, use, and disposal of leftover specimens
2. Matters concerning the protection and processing of personal information, such as anonymization of leftover specimens
3. Matters concerning the scope of clinical performance study institutions in which leftover specimens are provided
4. Matters concerning the method of withdrawal of consent and the disposal of leftover specimens upon such withdrawal

(2) A person who intends to obtain written consent under Paragraph (1) shall fully explain the matters under each subparagraph of the same paragraph to a specimen provider before obtaining such written consent.

(3) When anonymizing the personal information of specimen providers following the main clause of Article 7 (3) 5 of the Act, the following methods shall be followed.

1. Keep the personal identification information of specimen providers and leftover specimens separate.
2. Anonymize the personal identification information of specimen providers.
3. Conduct security measures for records and information on specimen providers and leftover specimens.

Article 17 (Standards for Clinical Performance Study Implementation and Management) (1) The “standards for implementation and management of a clinical performance study as prescribed by Ordinance of the Prime Minister” in Article 7 (3) 6 of the Act are the following.

1. A clinical performance study shall be conducted in a safe and scientific manner according to the clinical performance study protocol approved or modified by the Minister of Food and Drug Safety or a review board pursuant to Article 7 (1) of the Act and shall be conducted within 2 years from the date of approval.
2. Clearly document the authority and responsibilities of all members participating in a clinical performance study, including the sponsor of a clinical performance study, the head of a clinical performance study institution, the manager of a clinical performance study, the person in charge of a clinical performance study, the manager of an in vitro diagnostic medical device for a clinical performance study, and the subjects of a clinical performance study.
3. When conducting a clinical performance study, prepare compensation procedures, treatment plans, and other comprehensive safety measures for possible damages to clinical performance study subjects, and fully explain them to the clinical performance study subjects.
4. Report adverse effects or serious and unexpected abnormalities that occur during a clinical performance study to the Minister of Food and Drug Safety or a review board without delay, and prepare countermeasures.
5. Submit the report on the status of the clinical performance study in attached Form 12 to the Minister of Food and Drug

Safety or a review board by the end of February each year, and when the clinical trial is completed, submit the report in attached Form 13 within 20 days from the date of completion.

6. When completing a clinical performance study, the clinical performance study protocol, records, and data on the implementation and operation of the clinical performance study shall be retained for 3 years from the end of the clinical performance study.
7. Observe other standards determined and notified by the Minister of Food and Drug Safety similar to those prescribed in Subparagraphs 1 through 6 for the safe and scientific implementation of a clinical performance study.

(2) Matters necessary for the details of the clinical performance study implementation and management standards, methods of operation, etc., under paragraph (1) shall be determined and notified by the Minister of Food and Drug Safety.

Article 18 (Modification or Cancellation of a Clinical Performance Study) (1) The Minister of Food and Drug Safety may request cooperation from institutions, organizations, or experts related to in vitro diagnostic medical devices to provide opinions or data if the Minister intends to modify or cancel a clinical performance study following Article 7 (4) of the Act or to take other necessary measures.

(2) The Minister of Food and Drug Safety shall notify the person who has obtained approval of a clinical performance study protocol and a review board in writing if the Minister modifies or cancels a clinical performance study pursuant to Article 7 (4) of the Act or to take other necessary measures.

Article 19 (Standards for Designation of Clinical Performance Study Institutions) (1) Clinical performance study Institutions shall be equipped with facilities, professionals, and organizations according to the following categories.

1. Facilities: Laboratory and testing facilities for a clinical performance study, storage facilities for specimens, storage facilities for in vitro diagnostic medical devices, and storage facilities for records and data related to a clinical performance study
2. Professionals: Personnel following Article 9 (1) 1 through 3 of the Act, managers of in vitro diagnostic medical devices, and persons in charge of storing records and data
3. Organizations: A review board and organization specializing in a clinical performance study

(2) Matters necessary for the details and operation method of facilities, professionals, and organizations of clinical performance study institutions under Paragraph (1) shall be determined and notified by the Minister of Food and Drug Safety.

Article 20 (Procedures and Methods for Designating Clinical Performance Study Institutions) (1) A person who intends for their institution to be designated as a clinical performance study Institution according to Article 8 (1) of the Act shall submit the application for designation of in vitro diagnostic medical device clinical performance study institution in Attached Form 14 (including an application in electronic form) to the Minister of Food and Drug Safety along with the following documents (including electronic documents).

1. A document proving that an institution falls under each subparagraph of Article 8 (1) of the Act
2. A document proving that an institution conforms with the designation criteria under each subparagraph of Article 19 (1).
3. Administrative regulations for clinical performance studies
4. Documents on the composition and operation of a review board
5. If the institution has experience conducting clinical performance studies (including clinical and nonclinical studies) in the past 2 years, documents proving this experience

(2) The Minister of Food and Drug Safety may conduct an on-the-spot inspection or request cooperation from relevant administrative agencies, public institutions, corporations, organizations, or experts if deemed necessary for the designation of a clinical performance study institution following Article 8 (1) of the Act.

(3) When the Minister of Food and Drug Safety designates a clinical performance study institution following Article 8 (1) of the Act, the Minister shall issue the certificate of designation as a clinical performance study institution in Attached Form 15 to the applicant and post the designation on the Ministry of Food and Drug Safety's website.

(4) When a clinical performance study institution approved following Article 8 (1) of the Act intends to modify designated matters, it shall submit the application for modification of designation of clinical performance study institution in Attached Form 16 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 of clinical performance study institution and documents verifying modified matters (including electronic documents).

(5) Except as prescribed in Paragraphs (1) through (4), details necessary for the procedure and method for the designation and modified designation of a clinical performance study institution shall be determined and notified by the Minister of Food and Drug Safety.

Article 21 (Establishment and Operation of a Review Board) (1) A review board shall be composed of not less than 5 and not more than 30 members, including one chairperson.

(2) The chairperson of a review board shall be elected from among the members, and the members of a review board shall be appointed or nominated by the head of a clinical performance study institution from among those with abundant knowledge and experience in clinical performance studies (including clinical trials and nonclinical studies). At least one member who does not major in medicine, dentistry, oriental medicine, pharmacy, nursing, or clinical pathology and has no interest in the clinical performance study institution shall be included (at least 2 for a review board composed of 10 or more members).

(3) The term of members of a review board shall be 2 years.

(4) The meeting of a review board shall require the attendance of a majority of the registered members, and shall be resolved with the approval of a majority of the attending members.

(5) "Other matters prescribed by Ordinance of the Prime Minister" in Article 8 (2) 4 of the Act refers to matters related to the countermeasures for adverse effects or serious and unexpected abnormalities, etc., that occur during a clinical performance study.

(6) Except as prescribed in paragraphs (1) through (5), the details necessary for the establishment, operation, etc., of a review board shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 22 (Clinical Performance Study Institution's Compliance) (1) When a clinical performance study institution conducts a clinical performance study following Article 8 (3) of the Act, the following matters shall be observed.

1. Prepare and issue a clinical performance study report to a sponsor of a clinical performance study within 3 months from the study's date of completion.
2. Report the results of a clinical performance study to the Minister of Food and Drug Safety within 3 months from date of completion of the clinical performance study.
3. Keep records and documents on a clinical performance study for 3 years from the study's date of completion.

(2) Details necessary for the procedures and methods for the compliance of a clinical performance study institution under each subparagraph of Paragraph (1) shall be determined and notified by the Minister of Food and Drug Safety.

Article 23 (Training for Persons Engaging in Clinical Performance Studies) (1) Training for persons engaging in clinical performance studies following Article 9 (1) of the Act (hereinafter "clinical performance study training") shall be conducted according to the following categories.

1. Training topics:
   A. Matters concerning the improvement of business expertise
   B. Matters concerning laws and regulations on in vitro diagnostic medical devices
   C. Matters concerning occupational ethics
   D. Matters concerning domestic and international trends in clinical performance studies (including clinical trials and nonclinical studies)
   E. Other matters deemed necessary for clinical performance study training, which are determined and publicly notified by the Minister of Food and Drug Safety
2. Training hours: More than 8 hours yearly
3. Training method: Physical or virtual

(2) Clinical performance study trainings shall be conducted by institutions or organizations designated by the Minister of Food and Drug Safety among medical device- or in vitro diagnostic medical device-related institutions or organizations equipped with facilities, manpower, and equipment necessary for training.

(3) Except as prescribed in Paragraphs (1) and (2), details necessary for the methods and procedures for clinical performance study training and operation of training institutions, etc., shall be determined and notified by the Minister of Food and Drug Safety.

Article 24 (Permission for Modification) (1) "Major matters prescribed by Ordinance of the Prime Minister" in the first clause of Article 10 (1) of the Act are matters according to the following subparagraphs.

1. In the case of permission for manufacturing business following Article 5 (1) of the Act:
   A. Changes in the location of a factory or addition of a new factory
   B. Changes in representative
   C. Changes in quality manager
2. In the case of manufacturing permission, manufacturing certification, or manufacturing notification following Article 5 (3) of the Act:
   A. Changes in the location of a factory or addition of a new factory for the product
   B. Changes in the shape and structure, raw materials, performance, purpose, and usage of in vitro diagnostic medical devices as determined and notified by the Minister of Food and Drug Safety (changes in raw materials only apply to manufacturing permission and manufacturing certification).

(2) A person who intends to make any modification on matters of Subparagraph 1 of Paragraph 1 under the first clause of Article 10 (1) of the Act shall submit the application for permission for modification in Attached Form 17 (including an application in electronic form) to the commissioner of the Regional Office of FDS along with the documents proving the modification (including electronic documents) within 30 days from the date of the changes. In this case, Article 4 (3) shall apply *mutatis mutandis* to the issuance of a permit for manufactuing business and preparation of a manufacturing permission register.

(3) A person who intends to obtain a modification permission, modification certification, or modification notification on matters of Subparagraph 2 of Paragraph 1 under the first clause of Article 10 (1) of the Act shall submit an application for a modification permission to the Minister of Food and Drug Safety, or the application for modification application or modification notification to the Institute in Attached Form 18 (including an application or notification in electronic form) along with the documents proving the modification (including electronic documents) within 30 days from the date of the changes. In this case, Article 6 (2) applies *mutatis mutandis* to the issuance of a permit and keeping a manufacturing permission register, Article 8 (2) to the issuance of a certificate and keeping a manufacturing certificate register, and Article 9 (2) to the issuance of a report acknowledgment and keeping a manufacturing notification register, respectively.

(4) A person who intends to report modification following Article 10 (2) of the Act shall report all such modification to the

Minister of Food and Drug Safety or the Institute within 10 days from the end of each quarter. In this case, a copy of records on modified matters prepared and retained following Article 10 (2) of the Act shall be submitted to the Minister of Food and Drug Safety or the Institute.

(5) Except as prescribed in Paragraphs (1) through (4), the details necessary for the procedure and method of modification permission, modification certification, modification reports, and modification notification shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 25 (Procedures and Methods of import Permission) A person who intends to obtain import permission following the first clause of Article 11 (1) of the Act shall submit the application in Attached Form 1 (including an electronic application) to the commissioner of the Regional Food and Drug Administration having jurisdiction over the location of the import company. In this case, the provisions of each subparagraph of Article 4 (1) and Article 4 (2) through (4) shall apply *mutatis mutandis* to the public notice on the details of attached documents, checking of documents through joint use of administrative information, issuance of a permit, preparation of a permission register, and procedures and methods for permission, and the permit shall be issued through Attached Form 2.

Article 26 (Procedures and Methods for import Permission) (1) A person who intends to obtain import permission for in vitro diagnostic medical devices following Article 11 (2) of the Act shall submit the 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). Documents under Subparagraph 3 may be omitted when it is evidenced that in vitro diagnostic 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 in vitro diagnostic medical devices already permitted, as determined by the Minister of Food and Drug Safety.

1. Documents evidencing that facilities and manufacturing and quality management systems are in place following the main clause of Article 11 (4) of the Act
2. When entrusting a test for quality control following the proviso to Article 11 (4) of the Act, a copy of the entrustment contract
3. Technical documents and data on clinical performance studies under Article 5 (6) of the Act as applied *mutatis mutandis* following Article 11 (5) of the Act. If there is a notice of the review results on technical documents and clinical performance studies following Article 9 (4) of the Enforcement Rule of the Medical Devices Act (not exceeding 2 years from the date of issuance), it may be submitted in place of the review results.

(2) A person who intends to obtain import certification for in vitro diagnostic medical devices following Article 11 (2) of the Act shall submit the application in Attached Form 5 (including an application in electronic form) to the Institute along with the documents (including electronic documents) described in Paragraph (1). In this case, partial proviso other than each subparagraph of Paragraph (1) shall apply *mutatis mutandis* to the omission of the submission of documents under Subparagraph 3 of Paragraph (1).

(3) A person who intends to report the import of in vitro diagnostic medical devices following Article 11 (2) of the Act shall submit the notification in Attached Form 7 (including a notification in electronic form) to the Institute along with the documents (including electronic documents) described in Subparagraph 2 of Paragraph (1).

(4) The provisions of the following subparagraphs shall apply *mutatis mutandis* to import permission, import certification, or import notification under Paragraphs (1) through (3):

1. Public notice on the details of the issuance of a permit, preparation of an import permission register, scope of submission of the attached documents, the guidelines for preparing attached documents, etc., related to the import permission: Article 6 (2) and (3). In this case, the permit shall be issued through Attached Form 4.
2. Issuance of certificates and preparation of an import certification register related to import certification: Article 8 (2). In this case, the certificate is issued through Attached Form 6.
3. Issuance of a declaration certificate and preparation of an import declaration register related to import declaration: Article 9 (2). In this case, the declaration certificate is issued through Attached Form 8.

Article 27 (Standards for Facilities and Manufacturing and Quality Management Systems for Quality Inspections) (1) Articles 10 (1) and (2) shall apply *mutatis mutandis* to the details and operating methods of standards for facilities and manufacturing and quality control systems under the main clause of Article 11 (4) of the Act.

(2) If an importer entrusts testing for quality control to any of the following persons following the proviso to Article 11 (4) of the Act, the importer need not be equipped with laboratories, facilities, tools, and equipment for testing.

1. Medical device testing and inspection institutions under Article 6 (2) 4 of the Act on Testing And Inspection in the Food and Drug Industry
2. Among those who have facilities and manufacturing and quality control systems under Article 5 (5) of the Act or Article 6 (4) of the Medical Devices Act, those determined and notified by the Minister of Food and Drug Safety

(3) When an importer entrusts testing for quality control following the proviso to Article 11 (4) of the Act, the consignor or consignee shall faithfully fulfill their responsibilities and obligations as determined and notified by the Minister of Food and Drug Safety.

Article 28 (Applying *Mutatis Mutandis*) (1) Article 5 shall apply *mutatis mutandis* to the classification of in vitro diagnostic medical devices subject to import permission, import certification, or import declaration following Articles 5 (3) and (11) of the Act as applied *mutatis mutandis* pursuant to Article 11 (5) of the Act.

(2) Article 12 shall apply *mutatis mutandis* to the qualification standards, assignment standards, and standards for concurrent

duties, etc., of quality managers to be hired by importers following Article 5 (8) of the Act as applied *mutatis mutandis* following Article 11 (5) of the Act.

(3) Article 24 shall apply *mutatis mutandis* to the subject, procedure, method, and reporting deadline, etc., of modification permission, modification certification, modification report or notification under Article 10 of the Act as applied *mutatis mutandis* following Article 11 (5) of the Act.

Article 29 (Subjects for Certification of In Vitro Diagnostic Test in Clinical Laboratories) The term "a test determined by Ordinance of the Prime Minister" in the first clause of Article 12 (1) of the Act refers to any of the following tests.

1. Next generation sequencing
2. Among in vitro diagnostic tests for serum, plasma, chromosomes, DNA (Deoxyribonucleic acid), RNA (Ribonucleic acid), protein, etc., those determined and notified by the Minister of Food and Drug Safety

Article 30 (Procedures and methods for Certification of In Vitro Diagnostic Test in Clinical Laboratories) (1) A person who intends to obtain certification of in vitro diagnostic tests in clinical laboratories following Article 12 (1) of the Act shall submit the application in Attached Form 19 (including an application in electronic form) to the Minister of Food and Drug Safety along with the following documents (including electronic documents).

1. Documents proving compliance with the in vitro diagnostic test certification standards of a clinical laboratory following Article 32
2. Administrative regulations for in vitro diagnostic tests
3. If the applicant has experience conducting clinical laboratory in vitro diagnostic tests in the past 2 years, documents proving this experience

(2) The Minister of Food and Drug Safety may conduct an on-the-spot inspection or request cooperation from in vitro diagnostic test-related institutions, organizations, and experts, etc., to provide opinions or data if deemed necessary for the certification of in vitro diagnostic tests in a clinical laboratory following Article 12 (1) of the Act.

(3) When the Minister of Food and Drug Safety certifies an in vitro diagnostic test in a clinical laboratory following Article 12 (1) of the Act, the Minister shall issue the clinical laboratory in vitro diagnostic test certificate in Attached Form 20.

(4) When a person who has obtained in vitro diagnostic test certification following Article 12 (1) of the Act intends to obtain certification of modification, the person shall submit the application in Attached Form 21 (including an application in electronic form) to the Minister of Food and Drug Safety along with the documents evidencing the modification (including electronic documents) within 30 days from the date of the changes. In this case, Paragraphs (2) and (3) shall apply *mutatis mutandis* to the procedure and method of modification certification.

(5) Except as prescribed in Paragraphs (1) through (4), details necessary for the procedure and method of in vitro diagnostic test certification or modification certification of a clinical laboratory shall be determined and notified by the Minister of Food and Drug Safety.

Article 31 (Validity Period of In Vitro Diagnostic Test Certifications in Clinical Laboratories) (1) The validity period of in vitro diagnostic test certification of a clinical laboratory under Article 12 (1) of the Act shall be 3 years, and the validity period begins from the date of certification.

(2) When a person who has obtained a clinical laboratory in vitro diagnostic test certification under Article 12 (1) of the Act intends to continue testing following Article 29 after the expiration of the certification, the person may reapply for an in vitro diagnostic test certification under Article 30, 3 months before the expiration of the certification.

(3) When the Minister of Food and Drug Safety receives an application for an in vitro diagnostic test certification of a clinical laboratory following Paragraph (2), the Minister shall notify the applicant of the result before the in vitro diagnostic test certification previously issued expires.

(4) When the Minister of Food and Drug Safety recertifies the in vitro diagnostic test of a clinical laboratory following Paragraphs (2) and (3), the validity period of the certification shall begin the day after the expiration date of the previous certification.

Article 32 (Standards for the Certification of In Vitro Diagnostic Tests in Clinical Laboratories) (1) In Article 12 (2) of the Act, the term "the certification standards prescribed by Ordinance of the Prime Minister" refers to the standards specified in the following subparagraphs.

1. To have the following facilities:
   A. Test laboratories or inspection laboratories
   B. Storage facilities for specimen
   C. Storage facilities for in vitro diagnostic medical devices
   D. Other facilities similar to those prescribed in Items A through C and determined and publicly notified by the Minister of Food and Drug Safety for in vitro diagnostic tests
2. To have following equipment or tools:
   A. Next generation sequencer (only applicable to inspections under Article 29, Subparagraph 1)
   B. Polymerase chain reactor (only applicable to the inspection under subparagraph 2 of Article 29)
   C. Centrifuge
   D. Refrigerator or freezer
   E. Image recorder
   F. Other equipment or tools similar to those prescribed in Itmes A through E and determined and publicly notified by the

Minister of Food and Drug Safety for in vitro diagnostic tests

3. To have following personnel:
   A. In vitro diagnostic test manager
   B. Person in charge of in vitro diagnostic tests or researchers
   C. In vitro diagnostic medical device managers
   D. In vitro diagnostic test records and data manager
4. To establish a quality control system that includes the following items:
   A. Documentation of quality management systems for in vitro diagnostic test quality management
   B. Documentation of duties, responsibilities, authority, etc., of personnel related to in vitro diagnostic tests
   C. A system for preparing and retaining results and records of in vitro diagnostic tests
   D. A regular internal inspection system for in vitro diagnostic test systems

(2) Details and methods of operation of the in vitro diagnostic test certification standards for a clinical laboratory under paragraph (1) shall be determined and notified by the Minister of Food and Drug Safety.

Article 33 (Compliance) A person who has obtained a clinical laboratory in vitro diagnostic test certification following Article 12 (1) of the Act shall observe the following matters following Paragraph (4) of the same Article.

1. Submit the performance of the previous year's in vitro diagnostic tests under Article 29 to the Minister of Food and Drug Safety by January 31 of each year.
2. Keep documents and records related to in vitro diagnostic tests under Article 29 for 3 years from the date the in vitro diagnostic tests are completed.
3. If a serious abnormality occurs during an in vitro diagnostic test under Article 29, report it to the Minister of Food and Drug Safety.
4. Maintain the certification criteria for clinical laboratory in vitro diagnostic tests under Article 32.

Article 34 (Assessment and Evaluation of Inspection Capabilities) The Minister of Food and Drug Safety shall annually assess and evaluate the inspection capabilities of a person who has certification in an in vitro diagnostic test of a clinical laboratory following Article 12 (5) of the Act. If the Minister of Food and Drug Safety deems that there are serious or urgent reasons to assess and evaluate these inspection capabilities, they may be frequently assessed and evaluated.

Article 35 (Consignment of the In Vitro Diagnostic Test Certification of Clinical Laboratories) (1) Where entrusting in vitro diagnostic test certification following Article 12 (7) of the Act, the Minister of Food and Drug Safety shall publicly seek and select an entrusted agency. However, if the Minister of Food and Drug Safety deems it particularly necessary for more efficient work, the Minister may designate and entrust the certification work to an agency privately.

(2) When the Minister of Food and Drug Safety entrusts in vitro diagnostic test certification following Article 12 (7) of the Act, the Minister shall post entrusted agencies and entrusted work on the website of the Ministry of Food and Drug Safety.

Article 36 (Descriptions Allowed to be Left Out When Labeling) Some of the descriptions prescribed in subparagraphs of Article 13 of the Act (hereinafter "description" in this Article) on the container or wrapper of an in vitro diagnostic medical device may be left out according to the partial proviso of the same Article in the following cases.

1. In case the container or wrapper of an in vitro diagnostic medical device is small, and all the descriptions cannot be included in the label, and description items that are not labeled on the container or wrapper are written in an external container, packaging, or package insert. However, the name and address of the manufacturer or importer under Subparagraph 1 of Article 20 of the Medical Devices Act and the model name of a product under Subparagraph 3 of the same Article shall be written on a container or wrapper of an in vitro diagnostic medical device.
2. In case the container or wrapper is used for an in vitro diagnostic medical device for export, descriptions shall be labeled according to the standards of the country importing the in vitro diagnostic medical device

Article 37 (Labeling on Package Inserts) "Matters determined by Ordinance of the Prime Minister" in Article 15 (1) 4 of the Act refers to matters according to the following categories.

1. For in vitro diagnostic medical devices for clinical performance study: the following items
   A. Name and address of the manufacturer (including the manufacturer entrusted in the case of consignment) or importer
   B. For imported products, name of exporting country, name and address of the manufacturer
   C. Product name and model name
   D. Storage method
   E. The description "For clinical performance study"
   F. The description "Cannot be used for purposes other than clinical performance study"
2. For in vitro diagnostic medical devices other than those in Subparagraph 1: the following items
   A. Matters under each subparagraph of Article 13 of the Act (excluding Subparagraphs 4 and 8 of Article 20 of the Medical Devices Act among matters under Subparagraph 1 of the same Article)
   B. In case the manufacturer entrusts all manufacturing processes, name and address of the consignee and consignor
   C. Matters concerning technical information, such as characteristics and structure of in vitro diagnostic medical devices
   D. For in vitro diagnostic medical devices that emit radiation, matters concerning the characteristics, types, etc., of the radiation
   E. The year and month of preparation of package inserts

Article 38 (Certificate Indicating the Authority of Public Officials) The certificate indicating the authority of public officials

pursuant to Article 16 (2) of the Act is in attached Form 22.

Article 39 (Standards for Administrative Dispositions) (1) The standards for administrative disposition against manufacturers or importers following Article 18 (1) of the Act are as shown in Attached Table 1.

(2) Standards for the administrative disposition against clinical performance study institutions following Article 19 (1) of the Act are as shown in Attached Table 2.

Article 40 (Technical Support) (1) When the Institute conducts a support project following Article 22 (1) of the Act (hereinafter "support project" in this Article), matters related to details and plan, etc., of the support project shall be posted on the Institute's website every year. However, in light of the nature and characteristics of a support project, if urgent or intensive support is required, matters on the support project may be frequently posted.

(2) The Institute may request cooperation from in vitro diagnostic medical device-related institutions, organizations, and experts to provide opinions or data if deemed necessary for the efficient implementation of a support project.

(3) If the Institute deems it necessary to discuss important matters related to the implementation of a support project, such as planning, inspection, and evaluation, the Institute may form and operate a support project consultative body composed of relevant public officials, executives or employees of the Institute, and medical device experts.

(4) Except as prescribed in Paragraphs (1) through (3), details necessary for the procedures and methods of a support project and the formation and operation of a support project consultative body shall be determined and notified by the Minister of Food and Drug Safety.

ADDENDA <Act No. 1614, May 1, 2020>

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

Article 2 (Amendment of Other Acts and Subordinate Statutes) (1) Some parts of the Enforcement Rule of the Medical Devices Act are amended as follows.

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

The proviso to Article 20 (1) 3 and Article 20 (3) 3 are deleted.

Items (C) and (D) of Subparagraph 1 in Attached Table 1 are deleted, and "according to Items A through D" in Item E of the same subparagraph shall be changed into "according to Item 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) The Ministry of Food and Drug Safety and its affiliated organizations' rules for requesting tests and inspections are revised as follows.

In Subparagraph 1 of Article 3, "quasi drugs and medical devices under the Medical Devices Act" shall be changed into "quasi drugs and medical devices under the Medical Devices Act and in vitro diagnostic medical devices under the Act on In Vitro Diagnostic Medical Devices."

Article 3 (Relationship with Other Statutes) If the Enforcement Rule of the Medical Devices Act or its provisions are cited in other statutes at the time of enforcement of this Rule, this Rule or the relevant provisions of this Rule shall be deemed to be cited.

ADDENDA <Act No. 1662, Dec. 31, 2020> (Enforcement Rule of Medical Devices Act)

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

Article 2 omitted

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. For reviewing clinical performance study: KRW 1,495,000 2. For reviewing technical documents: KRW 719,000 3. Others: KRW 158,000	1. For reviewing clinical performance study: KRW 1,662,000 2. For reviewing technical documents: KRW 799,000 3. Others: KRW 176,000

The fee column at the back of Attached Form 5 shall be as follows.

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

The fee column at the back of Attached Form 7 shall be as follows.

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

The fee column in front of Attached Form 18 shall be as follows.

Fee	
e-Government	Visit/Mail
1. Permission for modification For reviewing clinical performance study KRW 1,009,000 For reviewing technical documents KRW 551,000 Others: KRW 121,000 2. Certification for modification: KRW 82,000 3. Report for modification: KRW 39,000	1. Permission for modification For reviewing clinical performance study KRW 1,112,000 For reviewing technical documents: KRW 612,000 Others: KRW 135,000 2. Certification v: KRW 93,000 3. Report for modification: KRW 43,000

Article 4 omitted

Attached Tables / Forms

[Attached Table 1] Standards for Administrative Disposition against Manufacturers or Importers (related to Article 39 (1))
[Attached Table 2] Standards for Administrative Disposition for Clinical Performance Study Institutions (related to Article 39 (2))
[Attached Form 1] Application for Permission of In Vitro Diagnostic Medical Device Manufacturing (Import) Business
[Attached Form 2] In Vitro Diagnostic Medical Device Manufacturing (Import) Business Permit
[Attached Form 3] Application for Permission of In Vitro Diagnostic Medical Device Manufacturing (Import)
[Attached Form 4] In Vitro Diagnostic Medical Device Manufacturing (Import) Permit
[Attached Form 5] Application for Certification of In Vitro Diagnostic Medical Device Manufacturing (Import)
[Attached Form 6] Certificate of In Vitro Diagnostic Medical Device Manufacturing (Import)
[Attached Form 7] Notification of In Vitro Diagnostic Medical Device Manufacturing (Import)
[Attached Form 8] Certificate of Report of In Vitro Diagnostic Medical Device Manufacturing (Import)
[Attached Form 9] Application for Approval of In Vitro Diagnostic Medical Device Clinical Performance Study Protocol
[Attached Form 10] In Vitro Diagnostic Medical Device Clinical Performance Study Protocol Approval Letter
[Attached Form 11] Application for Approval of the Modification of In Vitro Diagnostic Medical Device Clinical Performance Study Protocol
[Attached Form 12] Report on the Status of Conducting In Vitro Diagnostic Medical Device Clinical Performance Studies
[Attached Form 13] Completion Report of In Vitro Diagnostic Medical Device Clinical Performance Studies
[Attached Form 14] Application for Designation of In Vitro Diagnostic Medical Device Clinical Performance Study Institution
[Attached Form 15] Designation of In Vitro Diagnostic Medical Device Clinical Performance Study Institution
[Attached Form 16] Application for Modification of Designation of In Vitro Diagnostic Medical Device Clinical Performance Study Institution
[Attached Form 17] Application for Permission for Modification of In Vitro Diagnostic Medical Device Manufacturing (Import) Business
[Attached Form 18] Application for Permission, Certification, or Notification for Modification of In Vitro Diagnostic Medical Devices
[Attached Form 19] Application for Certification of In Vitro Diagnostic Tests in Clinical Laboratories
[Attached Form 20] Certificate of In Vitro Diagnostic Test in Clinical Laboratories
[Attached Form 21] Application for Certification of Modification of In Vitro Diagnostic Tests in Clinical Laboratories
[Attached Form 22] Certificate of In Vitro Diagnostic Medical Device Supervisor