Regulation on the Permission, Notification, Review, Etc. of Medical Devices

[Enforcement: July 29, 2022] [Ministry of Food and Drug Safety Public Notification No. 2022-52, July 29, 2022, Partial Amendment]

Ministry of Food and Drug Safety (Medical Device Policy Division) +82-43-719-3766

Chapter 1. General Provisions

Article 1 (Purpose) The purpose of this Regulation is to ensure appropriate management of medical devices, such as, permission, etc., by setting forth details related to the following: permission/certification/notification of manufactured/imported medical devices; review of technical documents, etc. of medical devices; procedures for issuance of test certificate, etc.; methods and procedures for preliminary reviews; application method and procedure for permission of medical devices subject to exemption from distribution business notification and medical devices used for exhibition purposes; scope of allowable function improvement of medical devices; criteria and procedure for designation of orphan devices; and exemption of fees, etc. for application of manufacturing license/certification and permission of import submitted by resident companies in medical research and development in the High-Tech Medical Complex, pursuant to Articles 8 and 6-3 of the Medical Devices Act, Articles 5, 6, 7, 9, 25, 26, 27, 30, 33, 38, 41, 46 and 47 of Enforcement DateEnforcement Rule of the Medical Devices Act and Article 24 (3) of the Special Act on the Designation and Support of High-Tech Medical Complexes, and Article 5 (6) of the Enforcement Rule of the same Act.

Article 2 (Definitions) The meanings of the terms used herein are as below:

1. The term "same product item" means a group of products sharing the same country, the same name of manufacturer, and the same title of product item, which have the same intended use, the same instructions for use, the same manufacturing method, and the same raw materials (excluding instruments or machines) other than coloring agent or fragrances; however, there may be various models in the same product item that are different in colors, sizes, etc. or have modified or added components. Provided, that if the only difference regarding the manufacturing method involves the sterilization or packaging methods, the medical devices may still be considered part of a same product item.
2. The tern “single-use medical device” means a medical device intended to be used only once for one patient or to be used for one patient in one treatment procedure.
3. The term “composite medical device” means 2 or more medical devices working as one medical device with composite functions.
4. The term “medical devices packaged in a set” means 2 or more medical devices packaged as one unit.
5. The term “high-tech medical devices” means novel medical devices based on innovative science and technology, such as biotechnology, information technology, nanotechnology, robot technology, or medical technology, including hybrid medical devices.
6. The term “components” means the parts needed to constitute the main body of a medical device.
7. The term “test specifications” means test parameters, test standards, and methods established to verify the safety and performance of medical devices.
8. The term “product item” means an individual product belonging to the detailed product classification under the Enforcement Rule of the Medical Devices Act (hereinafter the “Enforcement Rule”) as per Attached Table No.1 and the Regulation on Medical Device Product Items and Class by Product Item (Public Notification of the Ministry of Food and Drug Safety): Provided, That if an item that does not fall under a detailed classification, it means an individual product classified in an intermediate classification.
9. The term “product category” means a low-level detailed product classification under Attached Table No.1 of the Enforcement Rule and the Regulation on Medical Device Product Items and Class by Product Item.
10. The term “novel product” means a medical device whose intended use, operating priciples, or raw materials (limited to medical supplies), etc., are not equivalent to a medical device that has already been permitted or certified.
11. The term “enhanced product” means a medical device that has an equivalent intended use, operating principles, and raw materials (limited to medical supplies) but does not have equivalent performance, test specifications, or instructions for use, etc., as medical devices already permitted or certified.
12. The term “equivalent product” means a medical device that has an equivalent intended use, mechanism of action, raw materials (limited to medical supplies), performance, test specifications, and instructions for use, etc. as medical devices already permitted or certified.
13. <Deleted.>
14. The term “use period or validity period” means an actual date, by which the performance and safety (sterilization for sterile devices) are maintained to ensure the proper function of a medical device as intended for use by its manufacturer.
15. The term “summary technical documentation” means standardized documents developed by the

IMDRF (International Medical Device Regulators Forum) to eliminate discrepancies in medical device regulations among countries. It is composed of the STED (Summary Technical Documentation) and related attachments.

16. The term “implantable medical device” means a medical device intended to be inserted and remain inside the human body for 30 days or more.
17. The term “by-stage review” means a review of the information necessary for permission, such as technical documents, etc., before submission of the application for manufacturing permission by classification at each stage of product development under Article 11 of the Medical Devices Act (hereinafter the “Act”) and Article 9 of the Enforcement Rule.
18. <Deleted.>
19. The term “pre-review” means the procedures for expeditiously confirming whether data are provided according to the data submission requirements before the official review of the application for permission as a product item and requesting data, etc., if necessary.
20. The term “medical device software” means software developed/manufactured for the purposes corresponding to Article 2 of the Act, including embedded software, stand-alone software, and mobile medical apps. It includes software that transmits data generated from a medical device to a server, etc. to perform storage/analysis and signal/image processing.
21. The term “embedded software” means software embedded/installed in a medical device or with a wired or wireless connection to control/operate the medical device, store/transmit data generated from the medical device, and process signals/images.
22. The term “stand-alone software” means an independent form of software operated in an equivalent environment to general-purpose computers, etc., without being bound to integrated hardware such as an electronic/mechanical device, and is used for purposes corresponding to Article 2 of the Act.
23. The term “medical mobile app” means software apps or web-based applications run on mobile devices and used as embedded software/stand-alone software or other similar functions.
24. The term “software upgrade” means the changes (including additions) in any of the following items to medical device software permitted, certified or notified for manufacture (import):
    A. Intended use or related main functions (the primary performance)
    B. Analytical algorithms (analytical methods), including analytical subject such as biosignals/medical images, or analytical techniques
    C. Development languages or operating environment of the medical device software
    D. Communication functions, etc. that affect cybersecurity.

Chapter 2 Permission/Certification/Notification of Medical Device Product Items and Product Categories

Article 3 (Application for the Permission/Certification/Notification of Medical Devices, Etc.) (1) Medical devices subject to certification or notification of manufacture/import by product category shall be classified as per Attached Table No.1, and 1 or more representative product in the same product item shall be selected for the application: Provided, That if an applied-for product whose structure / mechanism of action / performance / intended use and method of use, etc., are essentially not equivalent and clinical investigation data are required to be submitted under Article 9 (2) 6 of the Enforcement Rule, it shall be subject to an application for permission as a separate product item.

(2) A person seeking to obtain permission/certification or to fiile a notification by product items belonging to the same product item shall submit one application for all product items.

(3) The product item title of a composite medical device shall be recorded as that of the medical device that performs its primary function. In the case each device in the combination belongs to a different class, the class of the device of highest risk shall be recorded: Provided, That in case of the disassembly of a combined medical device, each medical device in the combination shall require separate permission, certification or notification.

(4) Medical devices packaged in a set shall be permitted, certified, or notified as a product item according to the following subparagraphs:

1. The title of the product item shall be recorded as the medical device packaged in a set that meets the primary intended use or performs the primary function.
2. In the case that each device packaged in a set belongs to a different class, the class of the device of highest risk shall be recorded.
3. For product permission, certification or notification, the code number, name (product name, title of product item, and model name) and class of each device included in a set shall be recorded.

(5) A person seeking separate product permissions/certifications for each device in medical devices packaged as a set that has already been permitted or certified under paragraph (4) may be exempted from submitting technical documents and clinical investigation data, etc., (hereinafter “technical documents, etc.”) or a report of the review of technical documents, etc.

(6) For product item permissions/certifications or notifications for export purposes only, the documents provided by the following subparagraphs of Article 5 (1) of the Enforcement Rule (the documents in Article 5 (1) 3 in case of a notification a product item) may be exempted.

(7) If a person intends to sell in the Republic of Korea product items permitted, certified or notified following paragraph (6), he/she shall obtain a separate manufacture/import permission/certification or

notification of manufacture/import: Provided, That the foregoing shall not apply where an export contract is concluded and a sale is made to “a trader” under subparagraph 3 of Article 2 of the “Foreign Trade Act, “a trader” under Article 2, Subparagraph 2 of the Electronic Trade Facilitation Act or a medical device vendor under Article 17 of the Act.

(8) For products whose classifications require more time to determine, such as newly developed medical devices, etc., product permission/certification may be obtained or a product notification may be accepted using an intermediate classification or a separately specified product item title and code number. In this case, the classification standard following Article 2 of the Enforcement Rule shall be applied for classification.

(9) For medical devices in class 2 that were permitted and certified more than 3 times as equivalent products, the Minister of Food and Drug Safety may publicly announce on the home page of the Ministry of Food and Drug Safety its intended use, mechanism of action, raw materials, performance, test specification, instructions for use, etc. In the case of addition, amendment, or exclusion of the same matters, a public announcement shall also be made.

(10) For the products being publicly announced following paragraph (9) (hereinafter “publicly announced equivalent product”), a test report on safety and performance that proves conformity to publicly announced equivalent products shall be submitted instead of the documents following Article 5 (1) 2 of the Enforcement Rule. In such case, the test report shall be limited to those that have been issued by a testing and inspection agency of medical devices (hereinafter “testing and inspection agency”) designated by the Minister of Food and Drug Safety as set forth in Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry.

(11) A person seeking to confirm that their product is the same as an already permitted or certified product item (hereinafter “same product”) shall apply to the Minister of Food and Drug Safety for such confirmation with evidence that the requirements in the following subparagraphs are fulfilled. The Minister of Food and Drug Safety shall then notify the result of the review within 10 days.

1. The applicant device shall have the same intended use, operating priciples, raw materials, performance, test specifications and method of use, etc. as a medical device already permitted or certified
2. The applicant device shall be manufactured at the same factory (for imported medical devices, the same country of manufacture, the same manufacturer, and the same factory).
3. The applicant device shall be manufactured according to the method of design/development/production used by the subcontracted manufacturer (applicable only to the medical devices manufactured in Korea).

(12) In the case that a medical research and development organization located in a high-tech medical complex applies for permission/certification for the manufacture of a medical device, it shall be exempt from all fees under Attached Table No. 10 of the Enforcement Rule, in accordance with Article 4 (6) of the Enforcement Rule of the Special Act on the Designation and Support of High-Tech Medical Complexes, which shall apply *mutatis mutandis* according to Article 5 (6) of the Enforcement Rule of the same Act.

(13) In the case that a resident medical research and development organization located in a high-tech medical complex applies for an import license under Article 24 (2) of the Special Act on the Designation and Support of High-Tech Medical Complexes, it shall be exempted from fees.

(14) A person that seeks to apply for manufacturing permission for high-tech medical devices, etc., may apply for the review of technical documents, etc., under Article 9 of the Enforcement Rule at each stage of product development.

(15) A person seeking permission, certification or notification under Article 6 (2) of the Act may apply for a briefing session, etc., to the Minister of Food and Drug Safety in advance.

Article 4 (Handling, Etc., of Manufacture/Import Notifications) (1) A person that seeks to file the manufacturing or import notification of a medical device shall complete the registration of the manufacturing (import) notification and submit it to the Director of the National Institute of Medical Device Safety Information (hereinafter “a written notification”) through the electronic government service system of the Institute. The notification shall then be considered accepted: Provided, any of the following subparagraphs shall not be regarded as notification accepted.

1. Where the written notification medical device is subject to permission/certification following Article 4 of the Enforcement Rule
2. Where the notified product is not a medical device
3. Where the notified medical device uses or contains raw materials that fall under any of the subparagraphs of Article 5

(2) Notwithstanding paragraph (1), any notification submitted simultaneously with an application for the permission of a medical device manufacturing (importing) business shall be regarded as accepted when permission is granted.

Article 5 (Medical Devices Using Raw Materials with Safety/Efficacy Concerns, Etc.) The medical devices in the following subparagraphs cannot obtain permission/certification or be notified under Article 6-3 (1) and Article 15 (6) of the Act:

1. Medical devices to which the Minamata Convention on Mercury applies (except dental amalgams)
2. Medical devices using or containing asbestos

3. Medical devices in the following Items containing phthalates such as DEHP (di-(2- ethylhexyl) –phthalate), DBP (Dibutyl phthalate) or BBP (Benzyl butyl phthalate), etc.:
   A. An infusion set
   B. Blood circuit for an artificial kidney
4. Powdered surgical gloves and medical gloves

Article 6 (Preparation of an Application and Notification, Etc., for Permission/Certification of Manufacture/Import) (1) An application for manufacturing (import) permission/certification of medical devices (hereinafter referred to as “application for permission/certification”) or a notification shall be appropriately prepared as evidenced by the attachments, as set forth in this Regulation, and shall be documented as per Articles 8 through 18.
(2) For medical devices for export only, the application for permission/certification or notification shall bear the statement “For export purposes only” in the Remarks column.
(3) For medical devices subject to certification/notification by product category, the application for certification or notification shall have the “Product category” box checked.
(4) For used medical devices, the application for import permission/certification or notification shall bear the statement “Used medical device” in the Remarks
(5) For equivalent products, the application for permission/certification shall bear the statement “Equivalent product (permission number of the reference product)” in the Remarks column.
(6) For publicly announced equivalent products, the application for permission/certification shall bear the statement “Publicly announced equivalent product (public announcement number, product item title, and code number)” in the Remarks column.
(7) For implantable medical devices, the application for permission/certification shall bear the statement “Implantable medical device” in the Remarks column.
(8) For resident medical research and development organizations in high-tech medical complexes, applications for permission/certification as per paragraph (1) may be prepared in English following the Special Act on the Designation and Support of High-Tech Medical Complexes, Article 24 (3).
(9) For medical devices compounded with, or in combination of drugs or quasi drugs, the application for permission shall bear the statement “product items compounded with, or in combination of drugs (quasi drugs)” in the Remarks column.
(10) For newly developed medical devices, the application for permission shall bear the statement “Newly developed medical devices” in the Remarks column.
(11) For same products, the application for permission/certification shall bear the statement “Same product (permission/certification number of the same product)” in the Remarks column.

Article 7 <Deleted.>

Chapter 3. Specific Information Requirements in Medical Device Permission/Certification Applications and notifications, Etc.

Article 8 (Name) (1) The name of a medical device shall be recorded according to one of the following subparagraphs: Provided That, for the certification/notification of product categories, the statement “and the same product item” shall be added next to the model name of the applied-for representative product.
1. When the product name is recorded, the “manufacturer (importer) name / product name,” “product item title,” and “model name” shall each be recorded. The manufacturer (importer) name may be omitted, and 2 or more product names may be recorded.
2. When a product name is not recorded, the “manufacturer (importer) name,” “product item title,” and “model name” shall be recorded.

(2) A product name shall not be the same as that of a medical device already permitted, certified or notified. Any of the cases in the following subparagraphs shall be exceptions from the foregoing provision:
1. When the applicant device has the same intended use, operating priciples, raw materials, etc., as a medical device whose permission/certification/notification was revoked, and a year has elapsed from the date of revocation
2. When the same manufacturer (importer) applies for the permission/certification/notification of a product for which they previously withdrew the permission/certification/notification
3. When different importers import a product from the same origin of manufacture, and the specific importer name is recorded on the product

(3) A product item that falls under any of the classifications in the Regulation on Medical Device Product Items and Class by Product Item shall have its product item title in the subparagraphs of paragraph (1) and shall be recorded together with its product item classification number and class.
(4) For composite medical devices and medical devices packaged in a set, the information in paragraphs (1) through (3) shall be recorded for each device according to their primary intended use and higher classification.
(5) Notwithstanding the main text of paragraph (2), for product items whose intended use is similar to those of products already permittted, certified, or notified, their names may be recorded in the forms by adding or changing characters, words or numbers, etc., in the names of the products already permitted or certified (e.g., △△-ADS, etc., △△-2).

(6) When a separate name for export needs to be recorded, such shall be in parentheses, reading "Export name: ○○○○."

Article 9 (Shape and Structure) Shape and structure shall be recorded according to the following subparagraphs:

1. The shape, structure, weight, size, etc., including the mechanism of operation of the applied-for product shall be recorded.
2. Notwithstanding subparagraph 1, for medical devices with electrical/mechanical properties, the information that falls under the following Items shall be recorded:
   A. Shape/structure/weight/size and functions of each part
   B. Electrical rating
   C. Type and level of protection from electric shock
   D. Safety devices
   E. Block diagram (including communication configuration diagrams only for medical devices using wired/wireless communication) and principle of operation according to the block diagram
   F. Electric circuit diagram (including power unit, mounting unit, etc.) of the insulating component for verification of electrical/mechanical safety
   G. Structure and main functions of embedded software (including mobile medical apps that function as embedded software)
3. Notwithstanding subparagraph 1, for stand-alone software (including mobile medical apps that function as stand-alone software), information that falls under the following items shall be recorded.
   A. Shape/structure and functions of each part
   B. Structure of medical device software (including communication configuration diagrams only for medical devices using wired/wireless communication) and main functions
4. For medical devices packaged in a set, a list of each medical device shall be prepared, and information shall be documented as per subparagraph 1, 2, or 3.

Article 10 (Raw Materials) Raw materials shall be recorded according to the following subparagraphs:

1. For instruments/machines not using electricity, medical supplies, and dental materials, the information shall be documented according to the following Items:
   A. Raw materials shall be documented as per the following table:

Serial number	Component names	Raw material or ingredient names	Specifications	Amount	Remarks (Whether there is contact with the human body, location of such contact, and the purpose of the addition)

   B. The column for component names shall contain the name of each component of the relevant medical device.
   C. The column for raw material or ingredient names shall specify the common name or chemical name of each raw material of the components of the relevant medical device.
   D. The column for specifications shall indicate the name of the standard for raw materials, if any, such as KS, ASTM, ISO, etc. In the absence of such standard, the applicant's own standard shall be documented.
   E. The column for quantity shall indicate the quantities (including units of measurement) of raw materials/additives or coloring agents, etc., and mixture ratios used for finished products, components or materials, etc.
   F. The column for remarks shall contain information on any contact made with the human body and the location of such contact, and if it is deemed necessary to state the purpose of adding raw materials in direct or indirect contact with the human body, the purpose of addition (e.g., crosslinking agent, plasticizer, initiator, preservative, dispersant, stabilizer, emulsifier, lubricant, UV blockers, coloring agents, flavoring agents, catalysts, antioxidants, etc.) shall be recorded.
   G. In the case that any drug is added, the name, purpose of addition, ingredients, specifications, and dosage of the drug shall be recorded as per Item B or E, and the intended use of the drug shall be documented in the Remarks column.
2. For electronic instruments/machines, the following information shall be documented:
   A. Raw materials shall be documented as per the following table:

Serial number	Component Names	Component control numbers	Specification or characteristics	Quantity	Remarks

   B. The column for component names shall indicate the common name of the relevant component.
   C. The column for the component control numbers shall specify the model names or manufacturer's control numbers of the relevant components.
   D. The column for specifications or characteristics shall indicate the name of standard for the relevant component, if any, such as KS, ASTM, ISO, etc. In the absence of such standard, technical specifications of the relevant component shall be documented.

E. The column for quantity shall indicate the number of each component.
F. Information shall be documented as per subparagraph 1 for the following: medical devices in contact with or inserted into the human body, medical devices in contact with blood, body fluids or drugs that are injected into the human body, or medical devices that add drugs.
G. When embedded software (including mobile medical apps that function as embedded software) is used, the name and version of the software shall be stated in the specification or characteristics column as per Item A.

3. When stand-alone software (including mobile medical apps that function as stand-alone software) is used, the corresponding columns shall each be recorded as per the following table:

Serial number	Software name	Version and operating environment	Remarks

4. For medical devices packaged in a set, the information in subparagraphs 1 through 2 shall be documented for each medical device.

Article 11 (Method of Manufacture) (1) The statement “The method of manufacture shall be provided by the origin of manufacture” shall be recorded: Provided, That any of the following subparagraphs shall require additional information as specified:
1. The manufacturing method of sterile medical devices shall be documented as equivalent to or more stringent than the method specified in Attached Table No. 2.
2. For medical devices containing animal-derived substances in the finished product or using animal-derived substances during the manufacturing process, the relevant standards (KS, ASTM, ISO, etc.) shall be documented to verify the conformity of the animal’s name, country of origin, age, parts used, handling process, name of ingredients and results of handling process concerned.

(2) Notwithstanding p (1), medical devices of Class 4 shall be documented as follows:
1. A flow chart of the entire manufacturing process shall record descriptions of each process, including subcontracted processes, inspections, and sterilizations, from the purchase of raw materials to the release of final products.
2. For products whose design and manufacturing processes are performed outside of the origin of manufacture, the name of manufacture country, manufacturer name, and address of each factory shall be documented on the manufacturing flow chart.
3. The manufacturing method of sterile medical devices shall include the sterilization method and conditions as equivalent to or more stringent than those specified in Attached Table No. 2.

Article 12 (Intended Use) (1) The intended use shall be documented according to the following subparagraphs:
1. The intended use shall include indication(s), efficacy/effects, or the purpose as presented by supporting documents.
2. Notwithstanding subparagraph 1, for medical devices subject to notification following Article 4 of the Enforcement Rule, the intended use shall be documented as guided by the Regulation on Medical Device Product Items and Class by Product Item (Public Notification of the Ministry of Food and Drug Safety).
3. <Deleted.>

(2) For composite medical devices and medical devices packaged in a set, the intended use shall be documented as per paragraph (1), for the composite device and for each device in the set, respectively.
(3) Expressions without clear evidence or ambiguous and broad-meaning expressions shall not be used. Redundant expressions or overly exaggerated expressions, expressions with potential for misunderstanding or misused/abused shall not be used.

Article 12-2 (Performance) (1) Performance shall be documented, including the physical/chemical/electrical/mechanical properties of the product and features of the medical device software as claimed by the applicant shall be stated. If the performance of a class 1 medical device cannot be expressed due to product characteristics, it may be excluded.
(2) For composite medical devices, and medical devices packaged in a set, the performance shall be documented as per paragraph (1) for the composite device and for each device in the set, respectively.

Article 13 (Method of Use) The method of use shall be documented according to the following subparagraphs:
1. The method of use shall include detailed information on pre-use preparations, operation methods, and post-use storage and management. For medical devices used directly by general consumers who are not professionals, easy-to-understand terminology shall be used to prevent inconveniences for the user group (disabled persons, pregnant women, pediatric populations, etc.): Provided, That in the case of stand-alone software (including mobile medical apps with that function as stand-alone software), the pre-use preparation and description of post-use storage and management methodmay be omitted.
2. For medical devices requiring sterilization prior to use, the sterilization method as recognized by the Minister of Food and Drug Safety shall be accurately documented as per Attached Table No. 2.

3. For medical device software, accurate documentation shall be provided through screenshots (only if there is a screen printing function) that show the functions of the programs and methods of using such functions.
4. A “Do not reuse” warning shall be clearly indicated on single-use medical devices.

Article 14 (Precautions) Precautions shall be documented according to the following subparagraphs:
1. Precautions shall include all of the latest safety information to ensure the safe and rational use of the relevant medical device. The precautions shall reference medical dictionaries, etc. for easier understanding of the users
2. Information shall be documented according to the sequence and method provided by the following Items:
   A. Warning: Record any fatal or extremely serious and irreversible device-related adverse reaction, or a case where particular caution is needed because of the possible occurrence of an extremely serious incident accordingly.
   B. Cautions considering the characteristics of the medical device, the age, gender, health status, etc., of the subject of use shall be noted.
   C. Precautions for adverse reactions to medical devices that may occur as a result of the use and fatal side effects and accidents caused by carelessness in use shall be noted.
   D. General caution=: To prevent serious accidents caused by medical devices, precautions during use shall be listed, and, if necessary, countermeasures in case of an accident shall also be detailed.
   E. Interaction: If a medical device, when used in combination with another medical devices, enhances or attenuates the action of the combined medical device, causes a new adverse reaction to the medical device, or worsens the original disease, these matters of clinical significance shall be described: Provided, That the foregoing may be omitted in the case of stand-alone software (including mobile medical apps that function as stand-alone software).
   F. Use by pregnant women, lactating women, fertile women, newborns, infants, children, and the elderly: Matters that require particular caution compared to use by other patients, considering the functional characteristics and usage methods of the medical device, shall be described.
   G. Caution in application: The necessary precautions according to the method of use, etc., shall be described.
   H. If there are any matters necessary to prevent accidents, the related precautions shall be listed.

Article 15 (Packaging Unit) The packaging unit of a medical device shall be stated as the minimum unit determined by the manufacturer or origin of manufacture, but may be described as the “company’s packaging unit” for manufactured medical devices, and the “ packaging unit of the origin of manufacture” for imported medical devices.

Article 16 (Storage Method and Usage Period) (1) The storage method shall be documented, in parallel, with detailed storage conditions (temperature, etc.) and precautions, etc., to ensure stability considering the characteristics of the medical device: Provided, That the foregoing may be omitted for stand-alone software (including mobile medical apps that function as stand-alone software).
(2) For medical devices that fall under any of the following subparagraphs, the storage method and use or validity period shall be established and documented as per the Standards for the Stability Testing of Medical Devices (Public Notification of the Ministry of Food and Drug Safety) publicly notified by the Minister of Food and Drug Safety.
1. Sterile medical devices
2. Medical devices whose safety or performance is anticipated to change with the passage of time in terms of the physical/chemical properties of raw materials, etc.

Article 17 (Test Specifications) (1) Test specifications shall specify the tests needed for the verification of safety and performance of the relevant medical device according to the following subparagraphs:
1. For safety, the following shall be documented: applicable specifications from the Common Standard Specifications Related to the Electrical/Mechanical Safety of Medical Devices announced by the Minister of Food and Drug Safety according to the characteristics of products, Common Standard Specifications Related to the Electromagnetic Safety of Medical Devices, Common Standard Specifications Related to the Biological Safety of Medical Devices and Standard Specifications of Medical Devices, relevant standards publicly notified by the Minister of Food and Drug Safety, or equivalent international standards (IEC, ISO, etc.): Provided, That if there is no standard publicly announced or notified by the Minister of Food and Drug Safety, the international standards of the medical device (IEC, ISO, etc.) shall be specified.
2. Regarding performance, the test parameters, standards, and methods based on the rationale established by the applicant or equivalent international specifications (IEC, ISO, etc.) shall be specified according to the following Items:
   A. For test standards, an allowable range of threshold values for determining the acceptability of the test result shall be clearly recorded. When the test result is affected by environmental conditions such as temperature, humidity, etc., such conditions shall be specified.
   B. Test methods shall be documented in bullet point format, describing the detailed sequence to ensure

accurate derivation of the result.

C. The standards announced by the Minister of Food and Drug Safety or relevant standard (IEC, ISO, KS, EN, ASTM, etc.) shall be documented for physicochemical tests on medical devices in contact with or inserted into the human body, medical devices in contact with blood and body fluids, or drugs that are injected into the human body: Provided, That in the case of the absence of a standard announced by the Minister of Food and Drug Safety or relevant standard, the test parameters, standards, and methods shall be documented based on the rationales established by the applicant and as per Items A and B.

(2) For composite medical devices, test specifications shall be defined separately for parameters to be evaluated as a single device and for parameters to be evaluated for individual devices in the combination, while for medical devices packaged in a set, test specifications shall be set separately for parameters to be evaluated for individual devices.

Article 18 (Origin of Manufacture) The origin of manufacture shall be recorded according to the following subparagraphs:

1. For imported medical devices, the country of manufacture and the manufacturer's name and address in relation to the origin of manfucature shall be documented.
2. In the case that an entire manufacturing process is contracted, the names and addresses of both the legal manufacturer and the contracted manufacturer shall be recorded: Provided, That if the manufacturer is a foreign entity, the country of manufacture shall be additionally recorded.

Article 19 (Changes in the Permission/Certification/Notification of Medical Devices) (1) In the case of changes in the permitted, certified or notified —items of a medical device already permitted, certified or notified for manufacture (import), the permission/certification or notification shall be amended. Changes that fall under any of the following subparagraphs shall require a new permission/certification or notification:

1. Change of application for permitted, certifiedor notified matters due to changes in the mechanism of action
2. Changes in the raw materials used for the first time in the domestic market for that product item (limited to medical supplies)

(2) For any changes that impact safety or efficacy as per Attached Table No. 4, documents in each of the following subparagraphs in Article 26 paragraph (3) of the Enforcement Rule shall be submitted: Provided, That in the case of any of the following subparagraphs, the documents in Article 26 (3) 2 of the Enforcement Rule need not be submitted.

1. When the Minister of Food and Drug Safety directs such change in relation to the amendment of the standard specification, etc., following Article 19 of the Act.
2. When a change corresponding to “the unnecessary review of technical documents” following Attached Table 4 occurs
3. Change in the notified product

(3) <Deleted.>

(4) Minor changes following Article 26 (5) of the Enforcement Rule shall be as in the following subparagraphs:

1. Changes in medical devices for export only (excluding changes in the intended use, changes in or addtition of location of the factory, and changes in the transfer or acquisition)
2. Minor changes as defined in Attached Table No. 3
3. <Deleted.>
4. <Deleted.>

(5) For minor changes of paragraph (4), a manufacturer/importer shall submit the report in accordance with Attached Form No. 1 (including electronic documents) to the Minister of Food and Drug Safety or Director of the National Institute of Medical Device Safety Information within 30 days from the date of each minor change or by the end of the month in which the date of permission/certification or notification of all the minor changes that occurred during the year dating back from the last day of the month preceding the date of report.

(6) Notwithstanding paragraph (5), changes that fall under any of the following subparagraphs shall require submission of the report as per Attached Form No. 1 (including electronic documents) to the Minister of Food and Drug Safety or Director of the National Institute of Medical Device Safety Information within 30 days after the change:

1. Deletion of some model names following the discontinuation of production and import
2. Change in or addition of a model name following a minor change
3. Change in the name of origin of manufacture and product name following a change of company name
4. Change in the address of the consigning manufacturer of the exporting country (a consignor) of an imported medical device
5. <Deleted.>

(7) For medical devices subject to certification/notification by product category, changes shall be managed autonomously within the scope of the same product item, but a list of changed model names shall be submitted if any model name is added. In such case, paragraph (5) shall apply *mutatis mutandis* to the document submission method.

(8) For minor changes under paragraph (4), a manufacturer/importer shall document the date and details of such changes on the back of the manufacturing (importing) permission/certificate, sectioned Changes and Dispositions, Etc., at the time of each change.
(9) A medical device produced using an already-permittedd 3D printer, or a medical device in the "orthopedic supply" or "human tissue or function replacement " intermediate categories whose shape, and structure are changed for manufacture or import by the manufacturer/importer upon the request of a physician in charge and fulfills all the requirements in the following subparagraphs (hereinafter a "patient-customized medical device") may be exempted from amended permission/certification or notification . In such case, such exemption shall be limited to up to 5 times a year per permitted, certified or notified product.
1. Medical devices manufactured/imported/designed according to the physiological and pathological characteristics of a patient
2. Medical devices manufactured/imported upon the request in writing for materials as per the following Items from the doctor:
   A. A doctor's request letter and doctor's opinion on the feasibility of applying the patient-customized medical device
   B. Written consent from the patient for the use of the patient-customized medical device
3. Medical devices that cannot be replaced by medical devices in circulation or medical devices used in patients who do not have means of treatment
4. Medical devices manufactured/imported and used under the joint responsibility of the manufacturer/importer and the doctor (requesting person) in charge
5. Medical devices manufactured/imported according to procedures such as the recording/management of documents concerning the warehousing and delivery of raw materials/finished products, manufacturing processes, and quality control and inspection, etc., following Articles 27 and 33 of the Enforcement Rule

(10) A manufacturer/importer who has obtained permission/certification for or notified the shape and structure pursuant to paragraph (9) shall, within 15 days from the date the relevant medical device is used, attach the following documents to the patient-customized medical device usage report in Attached Form No.1–2 and report it to the Minister of Food and Drug Safety.
1. Documents in the Items of paragraph (9) 2.
2. Data confirming the joint responsibility of the manufacturer (importer) and the doctor in charge according to Paragraph (9) 4 (e.g., Proof of clinical experiences such as the doctor's qualifications, and patient protection/compensation measures, etc., in the case of manufacturing technology and side effects, etc., through consultation with the manufacturer (importer))

(11) <Deleted.>

Article 19-2 (Handling of Changes in Medical Device Software permission/Certification/notification) (1) Notwithstanding Article 19, the documents in subparagraphs of Article 26 (3) of the Enforcement Rule shall be submitted for a medical software to obtain permission/certification or to notify the change in the submitted information on manufacturing (importing) permission/certification obtained or notification filed, if the medical software falls under any of the following subparagraphs: Provided, That for changes in the products notified as product items and changes under subparagraphs 2 and 3, the submission of documents in Article 26 (3) 2 and 3 of the Enforcement Rule may not be submitted:
1. A change that amounts to a software upgrades
2. Change in or addition to the location of the factory of a product for which related medical device software-related manufacture (import) permission/certification was accepted or notification was made
3. Change due to the transfer/acquisition of a product for which medical device software-related manufacture (import) permission/certification was accepted or notification was made

(2) Notwithstanding paragraph (1), in the case of embedded software (including medical mobile apps that function as embedded software), paragraph (1) shall apply only to changes in the software that do not accompany changes in hardware, such as in electrical/mechanical devices, and do not affect performance and safety.
(3) A manufacturer/importer to which paragraph (1) applies shall submit a report of minor changes for changes other than those in the subparagraphs of paragraph (1), applying Article 19 (5) through (8) *mutatis mutandis*, and describe the revision date, and revision details on the back of the relevant manufacturing (importing) permission/certification under the Changes and Dispositions, Etc. section whenever any change occurs.

Article 20 <Deleted.>

Article 20-2 <Deleted.>

Article 21 (Application for Testing and Inspection) (1) A person seeking to apply for the testing and inspection of a medical device at a testing and inspection agency designated by the Minister of Food and Drug Safety shall submit to the agency an application as per Attached Form No. 4 and the materials provided for in the following subparagraphs together with the medical device for testing:
1. Data related to the technical documents, etc., of the applied-for device following Article 5 (1) 2 of the

Enforcement Rule
2. For imported medical devices, recommendation confirming exemption from medical device requirements in accordance with Regulation on the Exemption from Medical Device Import Requirement ~~Exemption~~, Etc. (Ministry of Food and Drug Safety Public Notice) and a copy of the certificate of import notification following the "Public Notification on Import Clearance Administrations~~, Etc.~~" (Korea Customs Service Notification) as data providing evidence for the medical device for testing

(2) Medical devices that shall be subject to a total inspection following Article 33 of the Act and shall be as per the following subparagraphs:
1. Medical devices deemed by the Minister of Food and Drug Safety to require special management for public health, safety, and efficacy

Article 22 (Issuance of Certificates of Inspection for Used Medical Devices) (1) When a manufacturer or importer purchases from a medical institution a medical device they manufactured or imported, such device shall be inspected as per Article 27 (1) 15 or Article 33 (1) 19 of the Enforcement Rule and shall be released with a labeling of the certificate of inspection as per Attached Form No. 10 on its outer package, if appropriate.

(2) When a distributor or a lessor purchases a medical device from a medical institution, they shall submit a request for inspection to its manufacturer, importer, or a testing and inspection agency with an application as per Attached Form No. 11 following subparagraph 1 of Article 39 of the Enforcement Rule and shall sell or lease only those devices labeled with certificates of inspection.

(3) When a manufacturer or importer receives a request for inspection by a distributor or a lessor under paragraph (2), they shall perform an inspection following Article 27 (1) 16 or Article 33 (1) 20 of the Enforcement Rule within 30 days from the date of the request, notify the client of the result as per Attached Form No. 12, issue a certificate of inspection, if appropriate, as per Attached Form No. 10, and attach the certificate to the outer package of the device.

(4) Notwithstanding paragraph (3), in the case that a manufacturer or an importer cannot issue a certificate of inspection within 30 days, a reason for the delay and the expected timeline shall be provided in a written response to the distributor or lessor.

(5) Notwithstanding paragraphs (1) and (2), medical devices that fall under any of the following subparagraphs may be exempted, at release, sale/lease from the labeling of the certificate of inspection for medical devices following Article 41 of the Enforcement Rule.
1. Diagnostic medical devices emitting radiation under Article 37 of the Medical Service Act
2. Class 1 medical devices, excluding those falling under the following Items:
   A. Medical devices that use electricity
   B. Instruments that protect from radiation, lasers, etc.
   C. <Deleted.>
   D. Devices that deliver energy to the human body

(6) When an importer imports a used medical device that has been permitted, certified or notified, paragraph (1) shall apply *mutatis mutandis*.

Chapter 4. Review of Technical Documents, Etc.

Article 23 (Subjects of Review, Etc.) (1) A review of technical documents, etc., shall be conducted on medical devices seeking manufacturing/importing permission/certification (including amendment permission/certification).

(2) For class 2 medical devices, a comparison table of essential equivalence as per Attached Form No. 3 and equivalent product criteria as per Attached Table No. 5 shall be used to classify and review medical devices as novel products, enhanced products, or equivalent products.

(3) Notwithstanding paragraph (1), medical devices that fall under the following subparagraphs shall be exempt from the review of technical documents, etc.:
1. Medical devices for export
2. Products publicly notified as equivalent
3. Medical devices verified as the same products following Article 3 (11)
4. Medical devices subject to minor changes

Article 24 (Expeditious Review, etc.) The Minister of Food and Drug Safety may allow the medical devices that fall under the following subparagraphs to receive an expeditious review for permission as priorities:
1. Medical devices designated by the Minister of Food and Drug Safety as necessary for industrial development or treatment of patients, such as high-tech medical devices or orphan medical devices, etc.
2. <Deleted.>
3. Medical devices subject to permission / new medical technology evaluation integrated operation under the Regulation on Integrated Operation for Medical Devices permission / New Medical Technology Assessment, etc.
4. Medical devices otherwise deemed by the Minister of Food and Drug Safety as requiring expeditious review

Article 25 (Criteria for Review, Etc.) (1) The Minister of Food and Drug Safety or the head of an institution reviewing technical documents, upon receipt of a written request for review of technical documents, etc., of medical devices following Article 9 (2) of the Enforcement Rule (hereinafter "written request for review"), shall review the device, on principle, by manufacturer (importer), product category, or product item (model name). Products added after the submission of the written request for review shall be excluded from the review: Provided, That the same product item may be reviewed through a single technical document.

(2) Terminologies, and symbols, etc., used in the written request for review shall be as per the Korean Standard (KS), international standards (IEC, ISO, etc.), Korean Pharmacopoeia (KP), and official compendia recognized by the Minister of Food and Drug Safety (USP, JP, etc.).

Article 26 (Types and Scope, Etc., of Data to be Reviewed) (1) The types of data that must be submitted for the review of technical documents, etc., shall be as in the following subparagraphs:

1. Comparison with previously permitted products
2. Data on intended use
3. Information on the mechanism of action
4. Information provided in the following items related to test specifications, their rationale, and actual measurement data for the verification of performance and safety: Provided, That in the absence of test specifications inside or outside of Korea, test specifications, rationales, and actual measurement data set by the person applying for a review of technical documents, etc., for the purpose of verifying performance and safety of the product:
   A. Information on electrical/mechanical safety (limited to the device/machine/equipment using electrical/electronic circuits)
   B. Information on biological safety (limited to medical devices requiring the confirmation of biological safety when coming in contact with the human body directly/indirectly)

1) Data on toxicity testing
   a) Data on cytotoxicity testing
   b) Data on systemic toxicity (acute) testing
   c) Data on subchronic (subacute) toxicity testing
   d) Data on chronic toxicity testing
   e) Data on genotoxicity testing
   f) Data on reproductive toxicity testing
   g) Data on toxicokinetic testing
   h) Data on immunotoxicity testing
2) Data on stimulation and sensitization testing
3) Data on transplant testing
4) Data on blood compatibility testing
5) Data on carcinogenicity testing
6) Data on biodegradability testing
7) Data on ethylene oxide residual quantity testing
8) Data on sterility testing
   c) Data on radiation safety (limited to medical devices that use or are exposed to radiation)
   d) Information on electromagnetic safety (limited to medical devices using electrical/electronic circuits)
   e) Data on performance
   f) Data on physical and chemical properties
   g) Data on stability

5. Data on the origin or discovery, and history of development
6. Data on clinical trials
7. Data on the current status of use in foreign countries, etc.

(2) The scope of data on biological safety under paragraph (1) 4 (B) to be submitted for review of technical documents, etc., shall be as per Attached Table No.12.

Article 27 (Preparation of Internationally Standardized Technical Documents) (1) Notwithstanding Article 26, an internationally standardized technical document shall be prepared for medical devices of Class 4. <Proviso deleted>

(2) For product items other than medical devices of Class 4, an internationally standardized technical document may be used if desired by the applicant.

(3) Instructions for preparing an internationally standardized technical document shall be as per Attached Table No. 10.

(4) The types of internationally standardized technical documents to be submitted shall be as the types of review data specified in Article 26 according to the comparison in Attached Table No. 11 and be subject to Article 28 (Exemption of Review Data), Article 29 (Requirements for Attached Data), Article 30 (Preparation of Data, Etc.), and Article 31 (Change of Technical Document Review Report).

Article 28 (Exemption of Review Data) (1) For class 2 medical devices classified as novel products, enhanced products, or equivalent products under Article 23 (2), the documents provided by the following

subparagraphs may be exempted as per Attached Table No. 7:
1. Data designated by subparagraphs 2, 3, and 5 through 7 of Article 26 (1)
2. For data designated by the provisions of the Items under Article 26 (1) 4, the rationale for setting test specifications and actual test data, excluding the test report

(2) For class 3 and 4 medical devices, data specified in subparagraphs 5 through 7 of Article 26 (1) may be excluded as per Attached Table No. 7.

(3) In the case the biological safety of raw materials or finished products is recognized and confirmed under any of the following subparagraphs, the submission of the data specified in subparagraph 4 (B) of Article 26 (1) may be excluded:.
1. Specifications publicly notified or announced by the Minister of Food and Drug Safety
2. Specifications for raw materials or finished products corresponding to KS, ISO, and ASTM

(4) Notwithstanding Article 26, in the ecase that a test is theoretically/technically impossible to implement or is deemed insignificant though possible to implement, the submission of the relevant data may be omitted (e.g., for a wound dressing containing silver sulfadiazine cream, the safety of each raw material may have been achieved, but the cytotoxicity test result will inevitably be unacceptable because of the antibacterial function of the cream, and, thus, such test will be insignificant).

Article 29 (Requirements for Attached Data) (1) Requirements for data attached for the review of technical documents, etc., shall be as in the following subparagraphs: Provided, That if the test data specified in Article 26 (1) 4 are 3 years or older as of the date of submission, documents evidencing that no modification has been made to the product since the inspections shall be additionally submitted.

1. Data comparing with the previously permitted, certified product

Comparison table as per Attached Form No. 3 that compares the names (product name, product item title, and model name), manufacturer (importer) name, origin of manufacture and address of manufacture, permission (certification) number, intended use, mechanism of action, raw materials, performance, test specifications, methods of use, etc. of the product with the previously permitted, certified product

2. Data on the intended use

Information on the indication and intended use(efficacy/effectiveness) of the product

3. Information on the mechanism of action

Information on the physical/chemical/electrical/mechanical mechanism of action that influences the achievement of the applied-for product's intended use

4. Information on electrical/mechanical safety

A. General Information

General information is required for medical devices using electricity, and any of the following data for products with the same model name as the product shall be submitted: Provided, That Wwhen there is a discrepancy in the model names because of the use of a prototype name, etc., evidence of their being the same model shall be submitted:

1) A test report issued by a testing and inspection agency designated by the Minister of Food and Drug Safety
2) A test report issued by the National Certification Body (NCB) according to the IEC System for Conformity Assessment Schemes for Electrotechnical Equipment and Components Certification Body Scheme (IECEE CB-Scheme) operated by the International Electrotechnical Commission (IEC)
3) A test report issued in compliance with the specification code confirmed by a medical devices testing and inspection agency accredited under the Korea Laboratory Accreditation Scheme (hereinafter "KOLAS")
4) A test report on the applicant product which was, at the time of permission, submitted to and evaluated by an Organization for Economic Cooperation and Development (OECD) member country, verifies or notarizes such submission to and permission by said country's government or a registered agency delegated with permission operations by said government
5) A test report that is accredited by ISO/IEC17025 per the Mutual Recognition Agreement (MRA) of the International Testing Laboratory Accreditation Cooperation (ILAC) and properly issued by an international testing/inspection agency that can test for all items of the international standard for the medical device

B. Criteria and Test Methods

The "Common Standard Specifications Related to the Electrical/Mechanical Safety of Medical Devices" (Public Notification of the Ministry of Food and Drug Safety) and "Standard Specifications for Medical Devices" (Public Notification of the Ministry of Food and Drug Safety), a specification publicly notified by the Minister of Food and Drug Safety, or an equivalent or higher international standard (IEC, ISO, etc.) shall be complied with; or when there is no specification notified or announced by the Minister of Food and Drug Safety, the international standards for the medical device, while also complying with standards such as Korean standard voltage, standard frequency, standard power plug under the Korean Standard (KS), etc., as set forth in the Electric Utility Act.

5. Data on biological safety

A. General Information

This information is required for medical devices or components that come in contact with or are inserted into the human body or come in contact with blood/body fluids or drugs injected into the human body, and shall be one of the following documents with the same model name as the

applicant product. If there is a discrepancy in the model names because of the use of a prototype name, etc., evidence of their being the same model shall be submitted. For the sterility and ethylene oxide (EO) residual quantity tests, a test report or data proving suitability under the "Medical Device Manufacturing and Quality Control Standards" (Public Notification of the Ministry of Food and Drug Safety) or the manufacturer's quality management system as per an equivalent or higher standard, or a test result appropriately issued by a testing and inspection agency in the medical devices field recognized through KOLAS with a recognized specification code may be submitted.

1) A test report (final report) under Article 24-2 of the Enforcement Rule tested in accordance with the "Nonclinical Trial Practice Standards" (Public Notification of the Ministry of Food and Drug Safety) at a medical device nonclinical trial center designated by the Minister of Food and Drug Safety (limited to the test items in Attached Table No. 2 of the "Nonclinical Test Management Standards" (Public Notification of the Ministry of Food and Drug Safety))
2) Test data issued by a nonclinical trial center in a member or a nonmember country of the Organization for Economic Cooperation and Development (OECD), recognized by the OECD as compliant with Good Laboratory Practices (GLP)
3) Data falling under 1) or 2) on the biological safety of a product that has the same raw materials as the applicant product and has at least the same time/area of contact with the human body

B. Criteria and Test Methods

The Common Standard Specifications Related to the Biological Safety of Medical Devices (Public Notification of the Ministry of Food and Drug Safety) and specifications notified by the Minister of Food and Drug Safety or an equivalent or higher International Standard (ISO, etc.) shall be complied with; or, if there is no standard publicly notified or announced by the Minister of Food and Drug Safety, the International Standards (ISO, etc.) of the relevant medical device shall be complied with.

6. Data on radiation safety

A. General Information

If a device requires a radiation safety test because it is a device that uses or is exposed to radiation, etc., this document shall be submitted in the form of one of the following and shall provide the information on the product with the same model name as the applicant product: Provided, That when there is a discrepancy in the model name mentioned in the documents and that of the actual product due to, e.g., the product having a different name during the development stage, evidence demonstrating such discrepancy shall be submitted.

1) A test report issued by a testing and inspection agency designated by the Minister of Food and Drug Safety
2) A test report issued by the National Certification Body (NCB), etc., according to the International Electrotechnical Commission (IEC) Electrotechnical Equipment and Components Certification Body Scheme (IECEE CB-Scheme) operated by the IEC
3) A test report issued in compliance with the specification code recognized by a medical device testing/inspection agency accredited under the KOLAS
4) A test report on the applicant product submitted to and evaluated by an Organization for Economic Cooperation and Development (OECD) member country at the time of permission, verifying or notarizing such submission to and permission by said country's government or a registered agency delegated with permission operations by said government
5) A test report that is ISO/IEC17025 accredited per the Mutual Recognition Agreement (MRA) of the International Testing Laboratory Accreditation Cooperation (ILAC) and properly issued by an international testing and inspection agency that can test for all items of the international standard for the medical device

B. Criteria and Test Methods

The Common Standard Specifications Related to the Biological Safety of Medical Devices (Public Notification of the Ministry of Food and Drug Safety) and specifications notified by the Minister of Food and Drug Safety or an equivalent or higher International Standard (ISO, etc.) shall be complied with; or, if there is no standard publicly notified or announced by the Minister of Food and Drug Safety, the International Standards (ISO, etc.) of the relevant medical device shall be complied with.

7. Data on electromagnetic wavessafety

A. General Information

This information is required for medical devices or components with electromagnetic safety requirements, and shall be one of the following documents with the same model name as the applicant product. If there is a discrepancy in the model names due to the use of a prototype name, etc., evidence of their being the same model shall be submitted.

1) A test report issued by a testing and inspection agency designated by the Minister of Food and Drug Safety
2) A test report issued by the National Certification Body (NCB), according to the International Electrotechnical Commission (IEC) Electrotechnical Equipment and Components Certification Body Scheme (IECEE CB-Scheme) operated by the IEC
3) A test report issued in compliance with the specification code recognized by a medical devices testing/inspection agency accredited under the KOLAS

4) A test report on the applicant product submitted to and evaluated by an Organization for Economic Cooperation and Development (OECD) member country at the time of permission, verifying or notarizing such submission to and permission by said country's government or a registered agency delegated with permission operations by said government
5) A test report that is ISO/IEC17025 accredited per the Mutual Recognition Agreement (MRA) of the International Testing Laboratory Accreditation Cooperation (ILAC) and properly issued by an international testing and inspection agency that can test for all items of the international standard for the medical device

B. Criteria and Test Methods

The "Common Standard Specifications Related to the Electromagnetic Safety of Medical Devices" (Public Notification of the Ministry of Food and Drug Safety), "Standard Specifications for Medical Devices" (Public Notification of Ministry of Food and Drug Safety), a standard announced by the Minister of Food and Drug Safety or an equivalent or higher international standard (IEC, etc.) shall be complied with; or, if there is no standard publicly notified or announced by the Minister of Food and Drug Safety, the international standards (IEC, etc.) of the relevant medical device shall be complied with along with standards such as standard voltage, standard frequency, standard power plug according to Korean Standard (KS), etc. as set forth in the Electric Utility Act.

8. Data on performance

A. General Information

Any of the following data for products with the same model name as the applicant product shall be submitted: Provided, That when there is a discrepancy in the model names because of the use of a prototype name, etc., evidence of their being the same model shall be submitted. The verification of software compatibility as per Attached Form No. 13 based on Attached Table No.13, software confirmation report, and efficacy validation report shall be submitted for medical device software. In the case that an animal performance test is needed, animal test data shall be submitted.

1) A test report issued by a testing and inspection agency designated by the Minister of Food and Drug Safety
2) A report of a test conducted by a domestic or foreign professional institution, such as a university or research institute. The report shall be issued by the head of the institution, and its substance (including an overview of test facilities, key facilities, research experience of the testing personnel, etc.) may be reviewed and recognized as reasonable
3) A test report proving suitability under the Medical Device Manufacturing and Quality Control Standards (Public Notification of the Ministry of Food and Drug Safety) or the manufacturer's quality management system as per an equivalent or higher standard

B. Criteria and Test Methods

The company's standard and test method shall be followed.

9. Data on physical and chemical properties;

A. General Information

For medical devices that come in contact with/are inserted into the human body or come in contact with blood/body fluids or drugs injected into the human body, the data on chemical structure, infrared absorption, ultraviolet absorption, atomic absorption, melting point, boiling point, durability, hardness, color tone, elution surface characteristics, the name of the animals according to the relevant standards (KS, ASTM, ISO, etc.) for medical devices using animal-derived substances, country of origin, age, parts used, treatment process, substance name, etc., shall be as in one of the following paragraphs, with the same model name of the applicant product: Provided, That when there is a discrepancy in the model name in the data and the model name of the applicant product due to the use of a prototype name during development, etc., evidence of their being the same shall be submitted.

1) A test report issued by a testing and inspection agency designated by the Minister of Food and Drug Safety
2) A report or data of a test conducted by a domestic or foreign professional institution, such as a university or research institute. The report shall be issued by the head of the institution, and its substance (including an overview of test facilities, key facilities, research experience of the testing personnel, etc.) may be reviewed and recognized as reasonable
3) A test report or data on the physicochemical properties conducted under the manufacturer's quality management system according to the Medical Device Manufacturing and Quality Control Standards or equivalent or higher standards

B. Criteria and Test Methods

Standards and test methods suitable for the standards for raw materials and finished products recognized by the Minister of Food and Drug Safety shall be complied with: Provided, That if there is no specification recognized by the Minister of Food and Drug Safety, the company's standards and testing methods shall be followed.

10. Data on stability

A. General Information

Data falling under one of the following shall be submitted for products having the same as the name of the relevant product and model. If the model name of the product in the data and the model name of the applicant product are not the same due to the use of prototype names, etc. in

development, data proving the same shall be submitted.

1) A test report issued by a testing and inspection agency designated by the Minister of Food and Drug Safety
2) A test report conducted by a domestic or foreign professional institution, such as a university or research institute. The report shall be issued by the head of the institution, and its substance (including an overview of test facilities, key facilities, experience of researchers, etc.) may be reviewed and recognized as reasonable
3) A test report on stability, tested under the quality management system of the manufacturer in compliance with the Medical Device Good Manufacturing Practices or an equivalent or higher standard.

B. Criteria and Test Methods

They shall be according to the Standards for the Stability Testing of Medical Devices.

11. Data regarding the origin, discovery, and history of development

Data that clearly describe the 5Ws and 1H (e.g., when, where, who for the newly discovered mechanism of action and raw materials, and when and where for those used in basic experiments / clinical trials, etc.) to help review the applicant product

12. Data on clinical trials

A. General Information

General information shall be any of the following data on research conducted on humans for demonstrating the safety and efficacy of a medical device used in a clinical investigation for the permission of its application. In such cases, for medical devices in classes 1 and 2, data (including articles, literature, etc.) on the clinical investigation of a product equivalent to the applicant product may be submitted.

1) Data on a test conducted in a clinical trial center designated by the Minister of Food and Drug Safety
2) Foreign data on a test whose substance is reviewed, was conducted by a reliable institution, and is deemed to have been conducted in compliance with the Medical Device Clinical Trial Management Standards (Attached Table No. 3 of the Enforcement Rule)
3) A test report on the applicant product submitted to and evaluated by an Organization for Economic Cooperation and Development (OECD) member country at the time of permission, verifying or notarizing such submission to and permission by said country's government or a registered agency delegated with permission operations by said government

4) Information published in professional journals registered in the Science Citation Index or Science Citation Index Expanded

B. Information specified in Item A shall include the following information:

1) Clinical Trial Method

A clinical trial method shall include the following:

A) Inclusion criteria, exclusion criteria, and target number of subjects

Data proving statistical validity of the number of samples by comprehensive consideration of the characteristics of the applicant medical device and method of clinical trial method are required, on principle, for each indication: Provided, That for indications whose incidence is too low to secure clinical trial samples as a practical matter, data proving such fact shall be additionally submitted.

B) Method of operation or method of use and the rationale for the setting
C) When a comparator medical device is used, the rationale for such selection
D) Whether or not it is used in combination
E) Observation parameters, measurement parameters, clinical test parameters, measurement criteria, and test method
F) Criteria and method of efficacy evaluation, and method of interpretation
G) Criteria for safety evaluation, including side effects, and test method

2) Clinical Outcome

Clinical outcomes shall include the following information:

A) Clinical trial outcome (including the planned number of samples for the trial, actual number of subjects, number of subjects who completed the investigation, number of and reason for dropouts, in which case information on side effects experienced by each subject, etc., shall be included)
B) Summary of case reports
C) Other data needed to verify the clinical investigation outcome

3) Clinical Evaluation

Data demonstrating the clinical significance of the effective ratio of the applicant medical device for the proposed indication, based on the sciences of medicine and oriental medicine, may be recognized, if deemed reasonable.

C. Other Information

1) When the direct application of foreign clinical trial data is deemed infeasible because of difference in ethnic factors, the Minister of Food and Drug Safety may request the additional submission of data on clinical investigation conducted in Korea targeting the Korean population.
2) For orphan medical devices used for rare, life-threatening diseases, clinical investigation data recognized as reasonable by the Minister of Food and Drug Safety may suffice

13. Data on the current status of use in foreign countries, etc.

Data on the current status of use in foreign countries that may help review the efficacy of the applicant medical device, including data on sales or permission in overseas markets, side effects reported from use, status of manufacturing permission history, etc., reasons for non-use If it is not being used in its country of manufacture

(2) The attached data submitted as per paragraph (1) shall be submitted together with a summary table of attached data in Attached Table No. 16.

Article 30 (Preparation of Data, Etc.) (1) A person seeking to obtain a review of technical documents, etc., for a medical device shall prepare documents as per Attached Form No. 8 of the Enforcement Rule and shall submit the attached data (including electronic documents), etc. as per Article 29 to the Minister of Food and Drug Safety or the head of an institution reviewing technical documents.

(2) The submitted data shall be in compliance with the requirements of Article 29: Provided, That when some of the attached data is not needed, given the nature of the applicant product, the rationale shall be described in detail.

(3) Foreign data shall be submitted together with a summary of key points in Korean and the original text. A translation may be requested only if needed: Provided, That data in foreign languages other than English shall be submitted with a notarized translation of the entire text.

Article 31 (Change of Technical Document Review Report) (1) A person seeking to modify a technical document review report according to Article 9 (4) of the Enforcement Rule shall submit a request for review as per Attached Form No. 8 of the Enforcement Rule.

(2) The documents attached to the application for amended review under paragraph (1) shall be as in the following subparagraphs:

1. Comparative table of changes
2. Supporting data for changes in the data specified in Article 26 or Article 27

(3) The document under paragraph (2) 1 shall be prepared as below:

Serial number	Item	Before change	After change	Reason for change

Chapter 5 <Deleted.>

Article 32 <Deleted.>

Article 33 <Deleted.>

Article 34 <Deleted.>

Chapter 6. Designation of Orphan Medical Devices, Etc.

Article 35 (Application for the Designation of Orphan Medical Devices) (1) A person seeking to obtain designation as an orphan medical device shall submit to the Minister of Food and Drug Safety an application as per Attached Form No. 6 together with the documents provided by the following subparagraphs: Provided, That if there is evidence of designation as an orphan device in a foreign country, the submission of data under subparagraph 3 may be omitted.

1. Evidence of fulfillment of the criteria for designation as an orphan medical device as per Article 36. For devices specified in the latter part of Article 36 (1) 3, evidence of special benefit based on the intended use shall also be included.
2. Data on the intended use, shape and structure, raw materials, performance, method of use, mechanism of action, specifications, etc. as per Article 60 (1)
3. Recommendation for designation as an orphan medical device as per Attached Form No. 7 by the President of the Korean Medical Association, President of the Dental Association, President of the Association of Korean Medicine, President of the Korean Hospital Association, or head of professional societies on relevant diseases. Such recommendation shall include the following: background and reason for the recommendation, medical opinion on alternative treatment or alternative medical device, etc., and its rationale, statistics (incidence per population, etc.) on the subject diseases and its rationale, and other opinions for reference, etc.: Provided, That if such recommendation cannot be submitted, the submission may consist only of medical rationale for alternative treatment or alternative medical device, etc., and statistics (incidence per population, etc.) on the subject diseases.

(2) Notwithstanding paragraph (1), a person simultaneously seeking a manufacturing (importing) permission and orphan device designation shall indicate “Orphan medical device” in the Remarks section of the application form.

Article 36 (Criteria for the Designation of Orphan Medical Devices, Etc.) (1) The criteria for the designation of orphan devices shall be as in the following subparagraphs:

1. The applicant device is used for the treatment or diagnosis of rare diseases with not more than 20,000 patients in the domestic market (prevalence)

2. <Deleted.>
3. There is no appropriate method of treatment or diagnosis, such as alternative medication or medical devices available for that target disease in Korea, or the applicant device is recognized by the Minister of Food and Drug Safety as having special benefits for other purposes

(2) A medical device that is under development may be designated as an orphan device as per paragraph (1).

(3) Notwithstanding paragraphs (1) and (2), the applicant device may be designated as an orphan medical device if the Minister of the Ministry of Food and Drug Safety recognizes the need for the designation, such as a concern that suspended or limited supply in light of the current medical device supply system would significantly impede the patient's treatment and diagnosis, etc.

Article 37 (Obligations Following Designation as an Orphan Medical Device) A manufacturer or importer of a medical device designated as an orphan medical device shall comply with the requirements provided by the following subparagraphs:

1. Comply with the Regulation on Re-examination of Medical Devices (Public Notification of the Ministry of Food and Drug Safety), if ordered to receive re-examination according to Article 8 of the Act.
2. "The product is an orphan medical device, and its clinical effectiveness undergoing validation" shall be written in the medical device attachment document (excluding orphan medical devices whose safety and effectiveness were validated during the permission review): Provided, That if an orphan medical device to which a re-examination order was issued is deemed suitable as a result of re-examination, the notation shall be deleted.

Article 38 (Orphan Medical Device Designation and Notification of Result, Etc.) (1) When a medical device is reviewed according to Article 36 and found to meet the criteria for orphan medical device designation, Tthe Minister of Food and Drug Safety may, designate it as an orphan medical device together with the product's title of item and intended use including of the indicated patients, disease, and product characteristics, and make a public announcement of the same.

(2) The Minister of Food and Drug Safety shall notify the applicant of the result of designation as an orphan medical device according to paragraph (1).

(3) For the designation of orphan medical devices, the Minister of Food and Drug Safety may be advised by the Medical Devices Committee under Article 5 of the Act or opinions from relevant organizations such as academic societies.

Article 39 <Deleted.>

Chapter 7 <Deleted.>

Article 40 <Deleted.>

Article 41 <Deleted.>

Article 42 <Deleted.>

Article 43 <Deleted.>

Article 44 <Deleted.>

Article 45 <Deleted.>

Article 46 <Deleted.>

Article 47 <Deleted.>

Article 48 <Deleted.>

Chapter 8. Operation of By-Stage Review

Article 49 (Subject of Review) The Minister of Food and Drug Safety may review a medical device that falls under any of the following subparagraphs that is under development for manufacturing permission at each stage of product development:

1. High-tech medical devices
2. Newly developed medical devices
3. Other medical devices as deemed necessary by the Minister of Food and Drug Safety

Article 50 (Application for Review) A person who desires a by-stage review shall submit the Application for Medical Device Review provided in Attached Form No. 15 (Including an electronic document) and data described in Attached Table No. 15 (including electronic documents) to the Minister of Food and Drug

Safety.

Article 51 (Type of Review Data, Etc.) (1) The data to be submitted for by-stage review shall be as in the following subparagraphs:
1. Data on the product design and development review stage (applicable only at Stage 1)
2. Data on the safety and performance review stage (applicable only at Stage 2)
3. Data on the clinical trial protocols review stage (applicable only at Stage 3)
4. Data on technical documents and clinical data (applicable only at Stage 4)

(2) The scope of data submitted at each stage according to paragraph (1) shall be as per Attached Table No. 15.

(3) The applicant may submit more than one set of data at the point the data required for the relevant stage is prepared. In such cases, the Minister of Food and Drug Safety may request that the applicant supplement each piece of data submitted.

Article 52 (Review Procedure) (1) The submitted data shall be reviewed by stage, and the review will proceed to the next stage if deemed suitable; Upon completion of the review for Stage 4, the review procedure shall be completed.

(2) The Minister of Food and Drug Safety may, on reviewing the data submitted by stage, request a review meeting with the applicant on the summary of product details and data to be submitted by stage, if needed.

Article 53 (Notification of Review Result, Etc.) (1) The Minister of Food and Drug Safety shall review the data submitted by stage and inform the applicant of the review result within 30 days from the date of each submission: Provided, That the period of notice for the review result may be extended if needed due to advice from external experts, meeting, review of additionally submitted data, etc.

(2) Upon completion of the four-stage reviews by stage, the Minister of Food and Drug Safety shall notify the applicant of a notice of the results of reviewing technical documents, etc. on medical devices in Attached Form No. 9 of the Enforcement Rule.

Article 54 (Change of Review Result) (1) Notwithstanding Article 53, the Minister of Food and Drug Safety may change the already notified review result that falls under any of the following subparagraphs:
1. A change occurs during product development that affects the safety and efficacy
2. When requiring security on a product's safety and efficacy upon newly suggested information on safety
3. The necessity of a change is recognized upon the applicant's request

(2) When review data is changed in accordance with paragraph (1), the applicant shall re-submit amended data for the previous stage, and the Minister of Food and Drug Safety shall notify the review result.

Chapter 9. Designation of Medical Devices Exempted from Distribution Business Notification

Article 55 (Medical Devices Exempted from Distribution Business Notification) The medical devices that may be distributed without a distribution business notification under Article 38 (3) of the Enforcement Rule shall be as in the following subparagraphs:
1. Electronic thermometer
2. Infrared ear thermometer
3. Infrared skin thermometer
4. Automatic electronic sphygmomanometer
5. Self-diagnostic medical mobile applications (hereinafter "apps") and products with such apps installed (cellular phones, tablet PCs, etc.)
6. <Deleted.>
7. Colour display thermometer

Chapter 10. permission of Medical Devices for Exhibition Purposes

Article 56 (Application for permission) A person seeking to display a medical device for exhibition purposes following Article 46 of the Enforcement Rule (hereinafter "medical devices for exhibition") shall submit the documents provided by the following subparagraphs to the head of the regional office of the Ministry of Food and Drug Safety for permission: Provided, That the medical device-related institution etc. organizing or hosting such exhibition may make a collective application on behalf of participants based on identified demand.
1. Data on the exhibition plan, including the purpose, venue, and duration of the exhibition, etc.
2. Product description and promotional information that fall under the following items: Provided, That for devices permitted, certifiedor notified as medical devices for export purposes, the submission of the following information may be omitted:
   A. Information on the intended use
   B. Information on product shape and structure, performance, characteristics, mechanism of action, method of use

3. Information on methods for notation and labeling indicating that the device is a medical device for exhibition

Article 57 (Criteria for permission) The head of the regional office of the Ministry of Food and Drug Safety shall, upon receiving an application for the permission of a medical device for exhibition in accordance with Article 50, review suitability based on the criteria in the following subparagraphs:
1. The proposed fair, exposition, exhibition, or an equivalent display shall be organized or hosted by the central or local government or by an organization related to medical devices
2. Product descriptions and promotional information shall not include content prohibited under subparagraphs 1 and 3 of Article 24 (1) and subparagraphs 1 through 4 of paragraph (2) of the Act
3. A label indicating “medical device for exhibition” or “unor notified medical device” shall be placed in an easily visible or recognizable manner

Article 58 (Notification of permission) (1) The head of the regional hoffice of the Ministry of Food and Drug Safety shall notify the permission or non-permission in writing within 10 days of the date of the application and notify the permission information to the head of the regional office of the Ministry of Food and Drug Safety having jurisdiction over of the exhibition, etc.
(2) Notification of the permission shall include the information specified in the following subparagraphs:
1. Name and venue of the exhibition, etc.
2. The approved duration of the exhibition and the applicant product
3. Information on the scope of allowance as in the following Items for the approved medical device for exhibition:
   A. Simple operation for describing the method of use or intended use, etc.
   B. Posting and placement of product description/promotional information in the exhibition venue for the approved product

Article 58-2 (Change in the Use of the Medical Devices for Exhibition) (1) A person who wants to change the use of a medical device for exhibitions as per Article 46 (4) of the Enforcement Rule shall submit the application for the change of use of medical devices for exhibition in Attached Form No. 17 and to the head of a Regional Office of the Ministry of Food and Drug Safety along with a usage plan that includes details such as the period of use and methods of disposal after use, etc.
(2) The head the regional office of Food and Drug Safety shall issue the permission for changing the use of the medical device for exhibition of Attached Form No. 18 if the application under paragraph (1) is suitable.

Chapter 11. Allowed Scope of Performance Improvement of Medical Devices

Article 59 (Medical Devices Eligible for Performance Improvement) A medical device software or embedded software (including mobile medical apps with embedded software functions) for which improvement is sought may be improved according to the proviso of Article 26 (4) of the Act and Article 47 of the Enforcement Rule within the scope of amended permission/certification obtained by the manufacturer or importer or the amended notification of the manufacturer or importer.

Chapter 12. Review of Medical Device Regulation Applicability

Article 60 (Review of Medical Device Regulation Applicability, Etc.) (1) A person seeking to request a review of whether a product is defined as a medical device under Article 2 (1) of the Act for the purpose of permission/certification/notification/review, etc. shall prepare the data provided for in the following subparagraphs and submit it to the Minister of Food and Drug Safety:
1. Data on the intended use of the product
2. Data on the shape and structure, raw materials, performance, method of use, etc., of the product
3. Other data on mechanism of action and specifications, etc., related to the product
(2) The Minister of Food and Drug Safety shall, upon a request for review in accordance with paragraph (1), review whether the product falls under Article 2 (1) of the Act, whether the product is defined as an individual product item under the “Regulation on Medical Device Groups and Class by Group,” and whether it is possible to classify and designate the product, etc., and shall notify the applicant of the result within 10 days.

Chapter 13 Supplementary Provisions

Article 61 (Advice) When necessary for permission/certification/notification/review, the Minister of Food and Drug Safety may receive advice from the Medical Devices Committee and National Institute of Food and Drug Safety Evaluation (NIFDS).

Article 62 (Verification of the Reliability of Submitted Data) The Minister of Food and Drug Safety may conduct an on-site inspection, if necessary, to verify the reliability of the test reports or data submitted following Article 29 of the Act.

Article 62-2 (Request for and Supplementation of Data, Etc.) (1) The Minister of Food and Drug Safety may request the relevant information for preliminary review within 5 days from the date of application, if the attached data fails to meet the requirements for submitted data.
(2) The Minister of Food and Drug Safety or Director of the National Institute of Medical Device Safety Information shall request, specifying the necessary information, that the applicant supplement the application for medical device manufacture (import) permission/certification, medical device manufacture (import) notification, application for change of medical device permission/certification, or review of technical documents, etc. for a cause that falls under any of the following subparagraphs occurring during the review:
1. The type, scope, or requirements of the application or notification do not comply with the provisions of any Article
2. There is a concern during the review of the submitted materials that serious problems with safety and efficacy, etc. may arise, and additional materials are deemed particularly necessary to resolve such concerns
(3) The data supplementation period under paragraph (2) shall be sufficient for the applicant to prepare supplemental documents,taking a processing period of civil petition into account The time of data submission shall be regarded as the end of the supplementation request period, and the review shall start over. If some or all the data for which supplementation is requested is not submitted within this period, supplementation may be requested again with a period of 10 days: Provided, That if a petitioner who has received a request for supplementation requests an extension by specifying the period necessary for the supplementation because the supplementation request cannot be met within the given period, the supplementation period shall be determined in consideration thereof. In such case, the petitioner's request for an extension of the petition period shall be limited to 2 times.
(4) The Minister of Food and Drug Safety or Director of the National Institute of Medical Device Safety Information may return certain documents to the applicant during the review process, such as an application for medical device manufacture (import) permission/certification, medical device manufacture (import) notification, an application for change of medical device permission/certification, or technical document, etc., if it is determined during the review or as a result of the review that such document falls under any of the following subparagraphs:
1. Data is not submitted within the period granted for the repeated request for supplementation as per paragraph (2)
2. When the document does not meet the criteria for review under Articles 8 through 18, 26, and 29, or does not meet the requirements for attached data

Article 62-3 (Video Conferencing, Etc.) (1) The Minister of Food and Drug Safety shall hold a meeting to the extent it does not affect the processing period of a civil petition when a person who has applied for a newly developedmen/orphan medical device permission as per Article 6 or 15 of the Act requests a meeting in any of the following subparagraphs, and the result shall be notified to the applicant within 10 days of the meeting date:
1. Initiation meeting: when it is necessary to explain matters to be considered during permission/review, such as product development history, etc.
2. Supplementation meeting: when it is necessary to explain reasons for the type, scope, requirements, etc., of the data for which supplementation is requested,
3. Additional supplementation meeting: when further explanation is required for the submitted data for which supplementation is requested, or an explanation is required for the data for which repeat supplementation is requested.
(2) Meetings in accordance with paragraph (1) may be conducted by video or in person.

Article 63 (Refund of Fees) (1) Fees shall not be returned after receipt of a civil petition whose application is filed as normal without problem: Provided, That fees shall be returned in part or in full if any of the following subparagraphs applies:
1. When the review of technical documents, etc., has already been completed or is unnecessary
2. When the fee has been mistakenly paid, other than the case of subparagraph 1
3. When an applicant who has been requested to submit data under Article 62-2 (1) voluntarily withdraws an application for permission under Article 5 (1) or Article 30 (1) of the Enforcement Rule within the period specified in Article 62-2 (1) (80% of the fees paid shall be refunded).
(2) When the fee is returned to the applicant as per the proviso of (1), the relevant department for permission/certification, etc., shall notify the payer about the return and request the revenue collection officer to return the fee.
(3) The revenue collection officer requested to return the fee following paragraph (2) shall return the fee to the payer by transfer to the payer's account in a financial institution.

Article 64 (Review examination of Regulations) Under Article 8 of the Framework Act on Administrative Regulations and Regulation on the Issuance and Management of Instructions and Established Rules, Etc. (Presidential Instruction No. 248), the reasonableness of the regulations shall be reviewed every 3 years (meaning by December 31 of every third year) starting from January 1, 2014, and actions such as

improvements, etc., shall be taken.

ADDENDA <Act No.2014-178, October 31, 2014>

Article 1 (Enforcement Date) (1) This Public Notification shall enter into force on the date of public notification.
(2) Notwithstanding paragraph (1), Article 6 (1) and (2) of the ADDENDA shall enter into force on November 10, 2014.

Article 2 (Transitional Measures) Notwithstanding the amendments, the application for the designation of an orphan medical device submitted as of the date of enforcement of this Public Notification shall follow the previous regulations.

Article 3 (Transitional Measures on permission of Changes, Etc.) If the test specifications (including test items) of a product item permitted under former provisions prior or subsequent to enforcement date of the Common Standard Specifications Related to the Electrical/Mechanical Safety of Medical Devices (Public Notification of the Ministry of Food and Drug Safety No. 2014-122, May 30, 2014; hereinafter “Common Standard Specifications”) differ from the Common Standard Specifications, such specifications shall be deemed to have been permitted for changes or to have had changes notified under the test specifications of the Common Standard Specifications without separate procedures for such changes.

Article 4 (Transitional Measures on Manufacturer Compliance, Etc.) A person who is deemed to have obtained permission for or notified a change under Article 4 of the ADDENDUM shall maintain the facility and quality control system, manufacture, import, quality control, or production control in compliance with the Common Standard Specifications, and only medical devices suitable to the Common Standard Specifications may be manufactured, imported, and sold.

Article 5 (Transitional Measures on Raw Materials with Safety/Efficacy Concerns, Etc.) Medical devices permitted or notified prior to the Enforcement Date of “The Regulations on the Permission, Notification, Review, Etc. of Medical Devices” (Public Notification of the Ministry of Food and Drug Safety No.2014-142, August 11, 2014) containing raw materials falling under Article 5 may not be manufactured, imported, sold, or used from January 1, 2015: Provided, That products under subparagraph 3 of Article 5 may not be used from July 1, 2015, while raw materials under subparagraph 1 of Article 5 may not be used from the date on which the Minamata Convention on Mercury takes effect in Korea.

Article 6 (Amendments of Other Public Notifications) (1) The Regulations on the Permission, Notificatin, Review, Etc. of Medical Devices shall be amended in part as follows:

Subparagraph 4 of Article 2 shall be deleted, and “drugs (including in vitro diagnostic radiopharmaceuticals)” in subparagraph 6 of the same Article shall be amended to “drugs.”
“Drugs (excluding in vitro diagnostic drugs)” in all parts other than the Items of Article 4 (4) 1 shall be amended to “drugs,” and subparagraph 2 of the same paragraph shall be deleted.
The proviso other than the subparagraphs of Article 5 (1) shall be deleted.
In the main text of Article 6 (1), “and other in vitro diagnostic drugs, etc.” shall become “and others.”
Articles 8 and 23 shall be deleted.
Article 25 (1) 3 and Article 25 (2) 11 shall be deleted.
“The scope and submitted data for in vitro diagnostic drugs of Attached Table No. 2” in Article 27 (1) shall become “scope,” and the proviso to paragraph (6) of the same Article shall be deleted.
Article 40 shall be deleted.
Attached Table 2-1 shall be deleted.
The column for in vitro diagnostic drugs in Attachment No. 1 shall be deleted.
(2) The Regulations on Imported Drugs, Etc., shall be amended in part as follows:
Article 5 Paragragh (2) Subparagaragh 2 shall be deleted.
(3) The Regulations on the permission of Clinical Trial Protocols for Medical Devices shall be amended in part as follows:
In Article 4 (1) 3, “Article 24” shall be “Article 26 or Article 33.”
(4) The Standards for the Stability Testing of Medical Devices shall be amended in part as follows:
“Articles 16 and 26” of the parts other than the subparagraphs of Article 4 (2) shall be amended to “Articles 17 and 29, or 33,” and “the reagents for in vitro diagnostic analyzers” in paragraph (4) 4 of the same Article shall be amended to “in vitro diagnostic medical devices.”
(5) The Regulation on Medical Device Product Items and Class by Product Item shall be amended in part as follows:
Article 4 shall be deleted.

ADDENDA <Act No. 2015-46, July 29, 2015>

Article 1 (Enforcement Date) This Public Notification shall enter into force on July 29, 2015.

Article 2 (Transitional Measures on the Application for permission, Etc.) Notwithstanding the amendments, previous provisions shall apply to the application for the permission of medical device manufacture (import), application for changed permission for medical device permission items, request for the review of medical device technical documents, etc. submitted under the previous provisions on the date of Enforcement Date this Public Notification.

ADDENDA <Act No. 2015-114, December 30. 2015>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Transitional Measures on Medical Devices Subject to Certification as Product Categories) A person who has obtained permission for the manufacture (import) of medical devices under previous provisions at the time Enforcement Datethis Public Notification enters into effect shall be deemed to have obtained certification as product categories under the amended regulations of Attached Table No.1.

ADDENDA <Act No. 2016-65, June 30, 2016>

Article 1 (Enforcement Date) (1) This Public Notification shall enter into force on the date of public notification.
(2) Notwithstanding paragraph (1), the amended Article 20-2 shall enter into force on August 1, 2016.

Article 2 (Transitional Measures on the Application for permission/Certification/Notification, Etc.) Notwithstanding the amendments, if an application for permission of medical device manufacture (import), application for changed permission for medical device permission items, application for medical device manufacture (import) certification, application for changed medical device manufacture (import) certification items, notification of medical device manufacture (import), request for review of medical device technical documents, etc., is submitted under the previous provisions on the date of Enforcement Date this Public Notification, the previous provisions shall apply.

ADDENDA <Act No.2016-96, August 31, 2016>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application to the Review of Technical Documents for In Vitro Diagnostic Medical Devices, Etc.) The amendment of item (B) of Article 33 (3) 2 shall be also apply to applications for permission of medical device manufacture (import), a request for review of medical device technical documents, etc., or applications for changed medical device permission items that were filed before the enforcement date of this Public Notification.

Article 3 (Transitional Measures on Minor Changes) Notwithstanding the amendments of Attached Table No. 3, an application for changed permission items for medical devices, and application for changed certification items for medical devices filed under the previous provisions as of the enforcement date of this Public Notification shall follow the previous provisions.

ADDENDA <Act No. 2016-105, September 30, 2016>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Transitional Measures on Application for permission/Certification/Notification, Etc.) Notwithstanding the amendments, an application for changed permission items or an application for changed certification items filed under the previous provisions as of the enforcement date of this Public Notification shall follow the previous provisions.

ADDENDA <Act No. 2016-132, Dec 7. 2016>
This Public Notification shall enter into force on the date of public notification.

ADDENDA <Act No. 2017-58, July 10, 2017>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Transitional Measures) Notwithstanding the amendments, if an application for permission of medical device manufacture (import), application for changed permission for medical device permission items, application for medical device manufacture (import) certification, application for changed medical device manufacture (import) certification items, notification of medical device manufacture (import), request for review of medical device technical documents, etc., is submitted under the previous provisions on the date of the enforcement of this Public Notification, the previous provisions shall apply.

ADDENDA <Act No. 2018-10, February 27, 2018>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification: Provided, That the amendments of Article 19 (3) shall take effect 3 months after the date of public notification.

Article 2 (Examples of Application to Permission/Certification/Notification Application, Etc.) Notwithstanding the amendments, amended provisions shall also apply to an application for medical device manufacture (import) permission or changed permission, application for medical device manufacture (import) certification or modified certification, or request for review of technical documents for medical devices, etc. submitted prior to the enforcement of this Public Notification.

Article 3 (Transitional Measures) (1) Medical devices falling under subparagraph 4 of Article 5 which are permitted, certified or notified under the previous provisions before this Public Notification entered into effect shall not be manufactured, imported, or sold from January 1, 2019.
(2) Changes in a product notified under the previous regulations may be notified according to Article 19 (4) and (5) up to the enforcement date of the amendments under Article 19 (3).

ADDENDA <Act No. 2018-52, June 28, 2018>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application to Permission/Certification/Notification Application, Etc.) For applications for medical device manufacturing (importing) permission or changed permission, certification medical device manufacturing (importing) or changed certification, notification of manufacture (import), request for review of technical documents, etc., submitted before the enforcement of this Public Notification, the amended regulations may also apply.

ADDENDA <Act No. 2018-55, July 24, 2018>

Article 1 (Enforcement Date) This Public Notification shall enter into force on July 25, 2018.

Articles 2 and 3 are omitted.

Article 4 (Amendment of Other Public Notifications) The Regulation on the Permission, Notification, Review, Etc. of Medical Devices shall be amended in part as follows:

Article 20 and Attached Form No.2 shall be deleted.
In Article 21 (1) 2, “the Standard Customs Clearance Scheduled Report according to the ‘Integrated Public Announcement’ (Public Notification of the Ministry of Trade, Industry and Energy)” shall be amended to “a recommendation letter to confirm requirements for exemption from medical device requirements following the ‘Regulations on Exemption from Confirmation of Medical Device Import Requirements’ (Notice of Food and Drug Safety).”

ADDENDA <Act No. 2018-59, Aug 7, 2018>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application to Permission/Certification/Notification Application, Etc.) For applications for medical device manufacturing (import) permission or modified permission, applications for certification medical device manufacture (import) or modified certification, notification of manufacture (import), application for review of technical documents, etc., submitted before the enforcement of this Public Notification, the amendment regulations may also apply.Amended provisions may also apply to an application for medical device manufacture (import) permission or changed permission, application for

medical device manufacture (import) certification or modified certification, medical device manufacture (import) notification, or request for review of technical documents for medical devices, etc. submitted prior to the enforcement of this Public Notification

Article 3 (Transitional Measures on the Designation of Orphan Medical Devices) Notwithstanding the amended regulations, previous provisions shall apply to applications for the designation of orphan medical devices submitted under the previous provisions at the time of the enforcement of this Public Notification.

ADDENDA <Act No. 2018-92, Nov 19. 2018>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification: Provided, That the amendments of Article 29 (5) shall enter into force on May 1, 2019.

Article 2 (Examples of Application to Permission/Certification/Notification Application, Etc.) If an application for permission of medical device manufacture (import), application for changed permission for medical device permission items, application for medical device manufacture (import) certification, application for changed medical device manufacture (import) certification items, notification of medical device manufacture (import), request for review of medical device technical documents, etc., is submitted under the previous provisions on the date of the enforcement of this Public Notification, the amended provisions may apply.

Article 3 (Transitional Measures on Test Reports, Etc.) Test results issued by a nonclinical trial center under Article 3 of the ADDENDA of the Enforcement Rule of the Medical Devices Act the <Prime Minister's Decree No. 1389, May 1, 2017> before the enforcement date in subparagraph 5 of Article 29 shall be deemed to have been tested according to the amended provision of subparagraph 5 of Article 29.

ADDENDA <Act No. 2019-13, February 28, 2019>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application for Minor Changes) The amendments for minor changes shall apply first to medical devices with minor changes after the enforcement of this Public Notification.

ADDENDA <Act No. 2019-62, July 23, 2019>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application for Permission/Certification/Notification, Etc.) Item A-4, subparagraph 12 of Article 29 shall apply to the applications submitted for the first time after the enforcement of this Public Notification for medical device manufacture (import) permission, application for changed medical device manufacture (import) permission items, application for manufacture (import) certification, application for changed manufacture (import) certification items, notification of manufacture (import), request for review of medical devices technical documents, etc.

ADDENDA <Act No. 2019-103, November 12. 2019>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application to permission of Medical Devices for Exhibition Application) The amended regulations of Article 56 shall apply to the medical device for which the first application for permission since the enforcement of this Public Notification was made.

Article 3 (Examples of Application to Internationally Standardized Technical Document) The amendments of Attached Table No. 10 (related to Article 27 (3)) shall apply to the medical device first to apply for permission (including the changed permission) after the enforcement of this Public Notification.

Article 4 (Transitional Measures for Application for Permission/Certification/Notification, Etc.) Notwithstanding the amended provisions of Article 6, previous provisions shall apply to application for medical device manufacture (import) permission, application for changed medical device manufacture (import) permission items, application for medical device manufacture (import) certification, application for changed medical device manufacture (import) certification items, notification of manufacture (import), request for review of medical device technical documents, etc. filed under previous provisions as of the date of enforcement of this Public Notification.

ADDENDA <Act No. 2020-26, April 24, 2020>

Article 1 (Enforcement Date) This Public Notification shall enter into force on May 1.

ADDENDA <Act No. 2020-95, October 8. 2020>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification: Provided, That the amendments of Article 63 shall enter into force on October 14, 2020.

Article 2 (Examples of Application to Permission/Certification/Notification Application, Etc.) Previous provisions shall apply to Applications for medical device manufacture (import) permission or modified permission, medical device manufacture (import) certification or modified certification, medical device manufacture (import) notification, request for review of medical device technical document, etc., submitted before the enforcement of this Public Notification.

Article 3 (Transitional Measures on Minor Changes) Notwithstanding the amendments of Attached Table No. 3, an application for changed permission for medical devices and modified certification for medical devices submitted as of the enforcement date of this Public Notification under the previous provisions shall follow the previous provisions.

ADDENDA <Act No. 2021-10, February 22, 2021>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Articles 2 and 3 shall be deleted.

Article 4 (Other Amendments of Public Notifications)
1. The Regulation on the Permission, Notification, Review, Etc. of Medical Devices (Public Notification of the Ministry of Food and Drug Safety No. 2020-26, April 24, 2020) shall be amended in part as follows:

The provisions of Articles 40 through 48 shall be deleted.
2. The Regulation on the Permission, Notification, Review, Etc. of In Vitro Diagnostic(Ministry of Food and Drug Safety Public Notification No. 2020-29, May 1, 2020) shall be amended in part as follows:

The provisions of Articles 34 through 42 shall be deleted.

Article 5 shall be omitted.

ADDENDA <Act No. 2021-15, February 26, 2021>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application) The provisions of Article 6 shall also apply to medical devices applied for expeditious review before the enforcement of this Public Notification and undergoing review.

Article 3 (Amendment of Other Public Notifications) (1) The Regulation on the Permission, Notification, Review, Etc. of Medical Devices shall be amended in part as follows:

“Article 5 (6) of the Enforcement Rule and Article 24 (4) of the ‘Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices’” in Article 1 shall be amended to “Article 5 6) of the Enforcement Rule.”

Article 19-2 shall be deleted.

(2) The Regulation on the Permission, Notification, Review, Etc. of In Vitro Diagnostic Medical Devices shall be amended in part as follows:

“Article 5 (6) and Article 24 (4) of the Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices” in Article 1 shall be amended to “Article 5 (6).”

The “In vitro diagnostic equipment (innovative medical devices software)” section in Attached Table No. 4 shall be deleted.

ADDENDA <Act No. 2021-35, April 22, 2021>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application for Using Raw Materials with Safety/Efficacy Concerns, Etc.) The amended provision of Article 5 shall apply to medical devices applied for approval or certification for the first time since the enforcement of this Public Notification.

Article 3 (Transitional Measures on Using Raw Materials with Safety/Efficacy Concerns, Etc.) No medical device certified prior to the enforcement of this Public Notification containing raw materials that fall under the amended provision of Article 5 may not be manufactured, imported, or sold from January 1, 2022, and may not be used from July 1, 2022.

ADDENDA <Act No. 2021-107, Dec 21. 2021>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application for Permission/Certification/notification Application, Etc.) If an application for permission of medical device manufacture (import), application for changed permission for medical device permission items, application for medical device manufacture (import) certification, application for changed medical device manufacture (import) certification items, notification of medical device manufacture (import), request for review of medical device technical documents, etc., is filed under the previous provisions prior to the enforcement of this Public Notification, the amended provisions may also apply: Provided, That in case of Attached Table No. 16, the provisions shall apply first to applications for medical device manufacture (import) permission and applications for changed medical device manufacture (import) permission items.

Article 3 (Examples of Application to Minor Changes) The amendments for minor changes shall apply first to medical devices with minor changes after the enforcement of this Public Notification.

Article 4 (Transitional Measures on the Change in Use of Medical Devices for Exhibition) The amended provision of Article 58-2 may apply to medical devices approved for the purpose of exhibition before the date of enforcement of this Public Notification.

ADDENDA <Act No. 2022-52, July 29, 2022>

Article 1 (Enforcement Date) This Public Notification shall enter into force on the date of public notification.

Article 2 (Examples of Application to permission/Certification/notification Application, Etc.) The amended regulations may apply to applications for changed medical device permission items and applications for changed medical device certification items filed before the date of enforcement of this Public Notification.

Note: MFDS offers the English version as a service to an international audience. Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. The official version of this document is the Korean version.