**Medical Device Act Enforcement Regulation**
**(Prime Minister Decree No. 1354, January 4, 2017**

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| **Article 29 (Application for Import Business License, etc.).** (1) Pursuant to Article 15 Paragraph (1) of the Act, a party seeking a license to import medical devices for business shall submit to the head of the concerned regional branch of the Ministry of Food and Drug Safety an application as per Attached Form No.1 (including an electronic application form), together with the documents specified in each Subparagraph of Article 3 Paragraph (1). |
| (2) The head of the regional branch of the Ministry of Food and Drug Safety, upon receiving the application under Paragraph (1), shall verify the certification of incorporation (applicable only to corporate applicants) through joint access to administrative information, pursuant to the Electronic Government Act Article 36 Paragraph (1). |
| **Article 30 (Application for Import Approval, etc.).** (1) Pursuant to Article 15 Paragraph (2) of the Act, a party seeking a license to import medical devices shall submit to the Minister of Food and Drug Safety Attached Form No.3 (including an electronic application form), together with the documents provided in the following Subparagraphs. |
| 1. Documents specified in Article 5 Paragraph (1) Item 2. Such documents may be exempt in the presence of an evidence, as specified by the Minister of Food and Drug Safety, that the medical device to be imported is identical to an approved medical device with the same origin of manufacture (the same country, the same manufacturer, and the same manufacturing site) |
| 2. Documents proving that the manufacturer of that imported medical device observes the good manufacturing practice system as per Article 15 Paragraph (4). |
| (2) Pursuant to Article 15 Paragraph (2) of the Act, a party seeking a certification to import medical devices shall submit to the Director of the Medical Device Information and Technology Assistance Center Attached Form No.5 (including an electronic application form), together with each document specified in the Subparagraphs of Paragraph (1) (including electronic documents). In such case, "approved" in the provision in Paragraph (1) Subparagraph 1 shall be deemed as "certified". |
| (3) Pursuant to Article 15 Paragraph (2) of the Act, a party seeking to report importation of medical devices shall submit to the Director of the Medical Device Information and Technology Assistance Center Attached Form No.7 (including an electronic application form). [Enforcement Date: January 29, 2016] Matters related to good manufacturing practice standard in Article 30 |

**Medical Device Act Enforcement Regulation**
**(Prime Minister Decree No. 1354, January 4, 2017**

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| **Article 31 (Standards for Quality Inspection of Facilities and Good Manufacturing Practices).** (1) The standard for quality inspection of facilities and good manufacturing practices to be established by a party seeking an import for business license, an import product approval, certification, or report pursuant to the main text of Article 15 Paragraph (4) of the Act shall be as described in Attached Table No.4. |
| (2) Cases provided by the Decree of the Prime Minister, such as subcontracting the testing for quality management in the proviso of Article 15 Paragraph (4) of the Act shall mean a party who seeks an import business license or an import product license, certification, or report and subcontracts the testing for quality management to any of the entities provided in the Subparagraphs below. In such case, the applicant who seeks an import business license or an import product approval, certification, or report may not be required to have a laboratory or a testing facility specified in Attached Table No.4 Subparagraph 1 Item C. |
| 1. Medical device testing or inspection institution |
| 2. Manufacturer recognized as acceptable under Attached Table No.2 Subparagraph 2 Item F.<br><br>[Enforcement Date: January 29, 2016] Matters related to good manufacturing practice standards in Article 31 |
| **Article 32 (Exemption of Medical Device Import Business License, etc.).** (1) Pursuant to Article 6 Paragraph (8) of the Act, medical devices provided in any of the Subparagraphs below may be imported without an import business license, an import product approval, certification, or report, mutatis mutandis pursuant to Article 15 Paragraph (6) of the Act: <Amended on June 15, 2016> |
| 1. Medical devices, for which a clinical trial plan is approved pursuant to the main text of Article 10 Paragraph (1) of the Act |

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| 2. Separate medical devices necessary to conduct a clinical trial that is not subject to approval of a clinical trial plan under the provisions in Article 10 Paragraph 1 of the Act |
| 3. Separate medical devices necessary to conduct a clinical trial of a drug, etc. that are subject to approval of a clinical trial plan under the provisions in Pharmaceutical Affairs Act Article 34 |
| 4. Medical devices that are imported for the purpose of obtaining an import product approval or certification, or filing a report for import of a medical device |
| 5. Medical devices that are used for the purpose of research, such as, product development, etc.; |
| 6. Medical device that are specified and publicly announced by the Minister of Food and Drug Safety, such as, medical devices for self-use, relief purpose, etc. |
| 7. Medical devices, whose urgent use are deemed necessary by the Minister of Food and Drug Safety, to prevent an outbreak and pandemic of an infectious disease pursuant to the Infectious Disease Control and Prevention Act, Article 2 Subparagraph 1, as requested by the Minister of Health and Welfare or the Director of the Centers for Disease Control and Prevention. |
| (2) Pursuant to Article 1, the Minister of Food and Drug Safety shall define and publicly announce the procedure, subject of imported medical devices that are exempted from an import business license or an import product approval, certification, or report and the issuance of a certificate of confirmation. |
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| None |
| **Article 33 (Obligations of Importers, etc.).** (1) Pursuant to Article 13 Paragraph (1) of the Act, an importer of a medical device shall comply with the requirements provided in the following Subparagraphs, mutatis mutandis pursuant to Article 15 Paragraph (6) of the Act. |
| 1. Hygienic management of imported facilities to prevent harm to public health; practice sanitation |

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| and prevent cross contamination or contamination from external sources |
| 2. Prepare or keep in file documents related to receipt, release, and quality management of medical devices (including testing standards, methods, labeling, packaging, etc.) and records of storage and release of accessories, and strictly observe performance of import and quality inspections, accordingly. |
| 3. Prepare and keep records relating to importation, quality testing per import unit as per Subparagraph 2 and records of customer complaints; preserve such records for five years from the date of import (or equivalent to product lifespan for those whose lifespan exceed five years). |
| 4. Verify the status of sterilization before final release of sterile products. |
| 5. Ensure electrical, mechanical, or electro-magnetic safety before final release of electrical or mechanical products. |
| 6. Ensure biological safety before final release of products that come into direct or indirect contact with human body. |
| 7. Prepare and keep product master files to include the following information. |
| A. Name of medical device (product name, product group title and model name) |
| B. Name and country of manufacturer of the imported medical device |
| C. Shape, structure, and specifications for self-testing of the finished product |
| D. Information to be included in the labeling of the container of a medical device, etc. pursuant to Articles 20 through 23 of the Act. |
| E. Methods for and sequence of installation (applicable only to medical devices requiring installation and maintenance) |
| F. Methods and standards for sterilization and determination of sterility (applicable to sterile devices only). |
| G. Author and adoption date of the product master file (including author, revision date and reason for revision, if revised) |
| 8. Prepare or keep in file import management standards that includes the information provided in the following Items. |

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| A. Product management and testing and inspection |
| B. Interpretation of test or inspection results and disposition of the rejected devices |
| C. Management of test or inspection facility |
| D. Method of communication with the manufacturers of imported medical devices |
| E. Status of the manufacturing and quality management of the manufacturers of imported medical devices |
| F. Author and adoption date of the import management standard (including author, revision date and reason for revision, if revised). |
| 9. Verify the status of compliance to the requirements for labeling, packaging, and documentation of such records |
| 10. Inspect product storage facility and document such records |
| 11. Ensure that the quality management representative implements the requirements provided in the following Items. |
| A. Establish and implement the procedures to identify the cause of a complaint related to a medical device, if it occurs, and to take corrective actions, to document, and to retain such records. |
| B. Observe placement and utilization of a product master file and an import management standard to ensure adequate quality management of imported medical devices |
| C. Prepare work instructions based on the documents under Item B; inspect and verify as reflected in the operation. |
| 12. Take corrective actions, such as, immediate recall, etc. of any medical devices released, which are harmful, not safe, ineffective, or have poor quality |
| 13. Establish and regularly execute an education or training plan for employees to ensure high quality of the imported medical devices, document, and store such records |
| 14. When any new data or information (including side effects related to use of the medical device) related to safety and efficacy of the approved, certified, or reported medical device is obtained, report it as specified by the Minister of Food and Drug Safety, and develop safety measures as needed |

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| 15. With regard to manufacturers of imported medical devices, import and sell medical devices that have been manufactured in compliance with Attached Table No.4 Subparagraph 3. In case where a medical device is imported for the purpose of obtaining the recognition of compliance with Attached table No. 4 Subparagraph3, the medical device shall be deemed to have been imported after having obtained certification of compliance under the same Subparagraph when the device has been recognized to be compliant with the same Subparagraph. |
| 16. Comply with the instructions in importing or exporting regulations for medical devices as publicly announced by the Minister of Trade, Industry, and Energy pursuant to the Foreign Trade Act Article 12 and with the regulations on the management of imported medical devices as specified by the Minister of Food and Drug Safety |
| 17. Pursuant to Article 19 of the Act, maintain the execution of Good Manufacturing Practices to the latest standards and specifications as set forth by the Minister of Food and Drug Safety and execute import and quality administration and import administration. |
| 18. Observe strict post-market safety management, such as, re-examination, re-evaluation, management of medical devices subject to tracking, management of safety information (including management of side effect reports), etc. |
| 19. Accomplish the requirements provided in the following Items when importing used medical devices or purchasing back from a medical institution a medical device imported by itself. |
| A. Inspect medical devices against the test specifications as per Subparagraph 7 Item C, attach a label of test certificate to the product only when they are acceptable to the test specifications and release products |
| B. Prepare and keep records on the content or result of the inspection under Item A and the date of inspection certificate, etc. and store them for two years from the date of release. |
| 20. Pursuant to Article39 Subparagraph 1 Item A, accomplish the requirements provided in the following Items, if requested by a seller or lessor of a medical device to conduct testing. |
| A. Inspect medical devices and release them with inspection certificate labels attached to the products, only when they are acceptable from the standard in Attached Table No.2 Subparagraph 2 |
| B. Comply with the matters specified and publicly announced by the Minister of Food and Drug Safety in relation to procedures or methods of issuing inspection certificates, response period, instructions for sale or lease, etc. |
| (2) Pursuant to Article 13 Paragraph (2) of the Act, an importer shall report to the Minister of |

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| Health and Welfare and the Minister of Food and Drug Safety, mutatis mutandis, pursuant to Article 15 Paragraph (6), the import volume of that year, as specified and publicly announced by the Minister of Food and Drug Safety. Such report may be exempt if an importer has filed an Advance Notice of Standard Customs Clearance of Imported Products using an electronic trade document pursuant to the Electronic Trade Facilitation Act.<br><br>[Enforcement Date: January 29, 2016] Matters related to good manufacturing practice standard in Article 33 |
| **Article 34 (Application of Mutatis Mutandis)**. To importers and imported devices, Article 3 Paragraph (3), Article 4, Article 5 Paragraphs (2) through (7), Article 6 Paragraphs (2) and (3), Article 7 Paragraphs (2) and (3), Article 9, Articles 11 through 13, Articles 16 through 19, Article 26 (excluding Article 26 Paragraph (1) Subparagraph 1), Article 28 and Article 64 shall apply, mutatis mutandis. In such cases, the term "manufacturing site" shall be deemed as "import business establishment," "manufacture" as "import," and "Paragraph (1)" in Article 5 Paragraphs (4) as "Article 30 Paragraph (1)." "Article 27 Paragraph (1)" in Article 12 Paragraph (1) Subparagraph 9 shall be construed as "Article 33 Paragraph (1)", "import" in Article 12 Paragraph (3) Subparagraph 2 as "manufacture", Article 5 Paragraph (1) Subparagraph 2 in Article 16 Paragraph (2) as "Article 30 Paragraph (1) Subparagraph 1" and Article 5 Paragraph (1) Subparagraph 2 in Article 16 Paragraph (3) as "Article 30 Paragraph (1) Subparagraph 1".<br><br><Amended on July 29, 2016><br>[Enforcement Date: July 29, 2016] |