Medical Device Act Implementation Rules

[Enacted Jan. 17, 2025] [Prime Ministerial Decree No. 1936, Jan. 16, 2024, as amended].
Ministry of Food and Drug Safety (Medical Device Policy Division) 043-719-3778, 3783

Article 33 (Matters **to be observed by importers, etc.)** ① The matters to be observed by importers of medical devices pursuant to Article 13 (1) of the Act, which is applied pursuant to Article 15 (6) of the Act, are as follows. <Amended 2020. 12. 4., 2022. 1. 21.

1. hygienically manage the facilities of the importing business to prevent health and hygiene hazards, and prevent contamination from the outside
2. create and maintain documents on the import, export and quality control of medical devices (including test standards and methods, labeling and packaging, etc.) and management records on the storage and shipment of accessories, and thoroughly conduct import and quality inspection accordingly
3. create and maintain records for each importing unit regarding importation and quality inspection pursuant to paragraph 2 and records of customer complaints, and preserve them for five years from the date of importation (if the product life exceeds five years, the period corresponding to the product life)
4. if sterilized, verify that the product has been sterilized before shipping
5. for electrical and mechanical products, ensure electrical and mechanical safety and electromagnetic safety before shipping.
6. Ensure biosafety for products that come into direct or indirect contact with humans before shipping.
7. Prepare a product standard sheet for each item that includes each of the following items
   A. The name of the medical device (product name, item name, and model name)
   B. Name of manufacturer and country of manufacture of the imported medical device
   C. Self-quality control test standards for shape and structure and finished products
   D. Matters to be written on medical device containers, etc. in accordance with the provisions of Articles 20 through 23 of the Act
   E. Installation method and sequence (only for medical devices that require installation management)
   B. Sterilization methods, sterilization standards, and sterility determination (only for sterilized packaged products)
   c. The author and date of publication of the product standard (if revised, list the reviser, date of revision, and reason for revision)
8. complete and maintain an import control document that includes the following items
   A. Matters related to product management and testing
   B. Matters concerning the determination of test results and the handling of failed products

C. Management of testing facilities

L. How to contact imported medical device manufacturers

E. Checks on the manufacturing and quality control situation of imported medical device manufacturers

b. The author and date of issuance of the revenue recognition standard (if revised, list the reviser, date of revision, and reason for revision)

9. check the labeling and packaging of imported medical devices for conformity and make records of the same
10. inspect the product storage facility and document the inspection.
11. ensure that the Quality Lead fulfills each of the following

A. Establish and implement relevant procedures to investigate the cause and take corrective measures in the event of a complaint regarding the quality of the medical device shipped, and record and store the same

B. Provide and utilize product standards and import management guidelines to properly implement quality control of imported medical devices.

C. Create a work order based on the documents listed in the following table and check and verify that the operation is in compliance with the standards.

12. take corrective action, such as recalling the device without delay, if it compromises safety and effectiveness or is of poor quality.
13. establish an education plan for employees to ensure the quality of imported medical devices, and regularly conduct education and training in accordance with the plan, and create and maintain records thereof
14. report any new data or information related to the safety and effectiveness of a licensed, certified, or notified medical device, including the occurrence of adverse events related to the use of the medical device, and implement necessary safety measures as prescribed by the Commissioner of Food and Drug Safety
15. import and sell medical devices manufactured in conformity with the standards of subparagraph 3 of Annex 4 to an imported medical device manufacturing plant. In this case, a medical device that is imported for the purpose of being certified as conforming in accordance with subparagraph 3 of Annex 4 and is certified as conforming in accordance with the same subparagraph shall be deemed to have been imported after being certified as conforming in accordance with the same subparagraph.
16. comply with the import and export guidelines for medical devices notified by the Minister of Trade, Industry and Energy pursuant to Article 12 of the Foreign Trade Act and the regulations on the management of imported medical devices prescribed by the Minister of Food and Drug Safety
17. maintain facilities, manufacturing and quality control systems, and import and quality control or import management in accordance with the latest standards set by the Minister of Food and Drug Safety in accordance with Article 19 of the Act

18. thoroughly conduct post-market safety management, including post-market investigation, re-evaluation, management of medical devices under follow-up, and management of information on safety (including management of adverse event reports)
19. if you import a used medical device or purchase a medical device from a healthcare organization that your company has imported, follow these steps
    a. Inspect the product to ensure that it meets the test specifications under item 7, and only release it with an inspection certificate if it does.
    B. Create and maintain records of the contents and results of inspections under this item, the date of issuance of inspection certificates, etc. and preserve them for two years from the date of shipment.
20. if the inspection is requested by the seller or lessor of a medical device pursuant to Article 39 (1), the following items shall be observed
    a. inspect it for compliance with the criteria in paragraph 2 of Schedule 2 and issue an inspection stamp only if it is compliant
    B. Comply with the matters prescribed and notified by the Minister of Food and Drug Safety at regarding the procedure and method of issuing inspection stamps, response period, and instructions for sale or lease.

② Pursuant to Article 15 (6) of the Act, the importer shall report the following items to the Minister of Health and Welfare and the Minister of Food and Drug Safety as prescribed and notified by the Minister of Food and Drug Safety. However, if a standard customs clearance preliminary notification is made in an electronic trade document pursuant to the Act on Electronic Trade Facilitation, the importer may not report the items in paragraph 1.< Revised 2020. 4. 13.>

1. medical device imports for the year
2. the reason for suspending the import of medical devices, the amount of suspension, and the schedule for suspension (only in the case of suspending the import of medical devices that have a significant impact on public health and are notified by the Minister of Food and Drug Safety in consultation with the Minister of Health and Welfare)