Article Content

Title： Regulations Governing Border Inspection and Examination of Imported Medical Devices CH

Amended Date： 2022-07-08

Category： Ministry of Health and Welfare（衛生福利部）

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Chapter I General Provisions

Article 1 The Regulations are stipulated in accordance with Paragraph 2, Article 52 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2 Terms used in the Regulations shall have the following meanings:
1. Inspection: This refers to batch-by-batch verification or examination or random-selected batch verification or examination of imported medical device before permitting the importation.
2. Verification: This refers to examination or verification of items, packaging, appearance, labels or other items of products carried out by inspectors in accordance with the law.
3. Examination: This refers to conducting sensory, chemical, biological, or physical examination or tests in a laboratory.
4. Inspection authorities: This refers to the central competent authority in charge of inspection of imported medical device or refers to the organization(s) appointed or commissioned by the central competent authority.
5. Obligatory inspection applicants: This refers to importers of medical devices.

Chapter II Application for Inspection of Imported Medical Device

Article 3 Provisions governing medical device items requiring border inspection by the central competent authority are listed in Attachment 1.
Attachment 1.pdf

Article 4 In accordance with the provisions of Paragraph 1 of Article 52 of the Act, obligatory inspection applicants who apply to import medical devices referred in the preceding article shall file the completed application form for inspection and submit the following documents and information to the inspection authority at the port where the medical devices are to be imported, 15 days prior to the date of inspection:
1. A photocopy of the medical device license or listing, or approval document to import the medical devices as a special case.
2. A photocopy of application for import declaration.
3. Other documents and information designated by the central competent authority.
If the application is to be filed by a representative, an identification document for the representative and a letter of power of attorney shall be provided unless the obligatory inspection applicant can provide a copy of the long-term entrustment agreement and has notified the inspection authority of the entrustment.
The central competent authority may require the obligatory inspection applicant to submit the application of the preceding paragraph electronically.
In the event that the inspection authority discovers that the application documents and information are not complete but corrections can be made, the inspection authority shall notify the obligatory inspection applicant who shall make corrections within 20 days. In the event that the applicant fails to make corrections before the designated deadline, the application shall be rejected.

Article 5 Imported medical devices conforming to one of the following situations can be exempted from inspection referred to the preceding article:

1. Imported medical devices are for exclusive use as samples or for personal use only in accordance with the provisions of Subparagraph 4, Paragraph 1 of Article 35 of the Act.
2. Imported medical devices are originally manufactured domestically and exported ,and they are shipped back to Taiwan with the approval of the central competent authority.
3. Imported medical devices are issued with a certificate of examination by the government of the country of origin who has signed an examination waiver reciprocity agreement with the government of the Republic of China.
4. The import has been approved by the central competent authority for national emergency situation or to improve the public welfare.

Chapter III Inspection Procedures

Article 6 The inspection authority may proceed inspection with one or more of the following measures:
1. Batch-by-batch inspection: Inspect each submitted batch of imported medical devices.
2. Randomly selected batch examination: Randomly select each submitted batch of imported medical devices by following inspection rate, and inspect the chosen medical devices:
(1) Regular randomly-selected batch inspection: The inspection is performed based on a 2-10% inspection rate.
(2) Reinforced randomly-selected batch inspection: The inspection is performed based on a 20-50% inspection rate.
3. On-site inspection: Verify the products at the storage site of medical devices.
Inspection items, test items and testing methods of imported medical devices as prescribed in Attachment 2.
Attachment 2：Verification items, test items and testing methods of imported medical devices.pdf

Article 7 Imported medical device applied for inspection that belong to one of the following situations shall be inspected on a batch-by-batch basis:
1. The first three batches of imported medical devices with the same item name, same trademark

(brand name) and same origin imported by the obligatory inspection applicant.
2. Reinforced random-selected batch was performed on the previous batch of imported medical devices of the same item name, same trademark (brand name) and same origin imported by the obligatory inspection applicant and the inspection result does not conform to regulations.
3. The inspection authority determines that it is necessary to carry out the inspection on a batch-by-batch basis.
Prior to the completion of the batch-by-batch inspection, the same obligatory inspection applicant applied for inspection of products shall be subject to inspection on a batch-by-batch basis.

Article 8 Imported medical device applied for inspection that belong to one of the following situations shall be inspected on a reinforced random-selected batch basis:
1. Regular randomly-selected batch inspection is performed on the previous batch of imported medical devices of the same item name, same trademark (brand name) and same origin imported by the obligatory inspection applicant and the inspection result does not conform to the Regulations.
2. The inspection authority determines that it is necessary to carry out reinforced batch-by-batch inspection.

Article 9 Imported medical device applied for inspection that belong to one of the following situations shall be inspected on a regular random-selected batch basis:
1. The result of batch-by-batch inspection performed in accordance with Subparagraph 1, Paragraph 1 of Article 7 of the Regulations is in conformity with the provisions.
2. The inspection results of the previous five batches in a row in accordance with Subparagraph 2, Paragraph 1 of Article 7 or preceding Article of the Regulations are in conformity with the provisions and the quantity of the five

conforming batches are three times of the quantity of non-conforming products.

Article 10 The samples required for inspection by the inspection authority shall be taken free-of-charge. The number (amount) of sampling shall be limited to requirements for examination.
After collecting the samples, the inspection authority shall issue a receipt for sampling to the obligatory inspection applicant.

Article 11 Sampling for inspection shall be conducted at the storage site of medical devices.
If the products were shipped in full container load, sampling shall be conducted in the centralized inspection area of port designated by the customs or designated area recognized by the inspection authority; but if it takes too long for sampling or has other difficult situations, the inspection authority may ask to open container for warehouse delivery.
During the inspection in preceding paragraph, the obligatory inspection applicant shall cooperate accordingly and cannot appoint any specific sample.

Article 12 Examination of imported medical device shall be conducted in the order of sampling. However, the examination laboratory shall prioritize inspection on products applying for re-examination in accordance with Article 15 of the Regulations.

Article 13 For inspection of medical devices that are difficult to sample in a container yard, require five or more days for examination, perishable, or lack stability on safety efficacy, the inspection authority shall issue a Notice of Prior for Import for custom clearance after the obligatory inspection applicant declares to bear the responsibility for the safety and storage of products imported by signing an Affidavit.
In the event that the pledged storage location of medical devices released for customs clearance with a Notice of Prior Release for Import in accordance with the preceding Paragraph does not

conform to the actual storage location, or if the medical devices are put to use, are moved or sold before receiving the import permit, the inspection authority may temporarily suspend acceptance of an application for prior release of imports by the obligatory inspection applicant for a period of 1 year.

Article 14 In the event that imported medical device conforms to inspection, an import permit will be issued and the obligatory inspection applicant will be notified; the obligatory inspection applicant may apply for the inspection authority to issue a written import permit.
The obligatory inspection applicant can claim remaining samples by presenting the sampling receipt within 15 days after receipt of the notice of inspection results. However, if the sample is not collected within the time period or has short shelf life, the inspection authority may dispose of the samples directly.

Article 15 In the event that imported medical device fails to conform to inspection, the inspection authority shall issue a notification of noncompliance to the obligatory inspection applicant.
The obligatory inspection applicant can apply for re-examination to the original inspection authority within 15 days after receipt of the notification of results. However, applications for re-examination is limited to one time only.
The inspection authority can perform the re-examination using remaining samples; if the remaining samples are not adequate for re-examination, additional sampling may be required according to Article 11 of the Regulations.
For medical devices that do not conform to regulations upon inspection, as referred to in Paragraph 1, the remaining samples of products shall be destroyed after the end of the period of application for re-examination, unless otherwise stated by law.

Article 16 Imported medical devices that do not conform to provisions of inspection, unless otherwise stated

by law, shall be shipped back or destroyed by the obligatory inspection applicant.
If imported medical devices that have been released via a prior release notice do not conform to inspection , the inspection authority shall notify the obligatory inspection applicant to dispose the medical devices in accordance with the provisions of the preceding Paragraph and notify the municipality (county/city) competent authority.

Chapter IV Statutory Fees

Article 17 The obligatory inspection applicant shall pay the following administrative charge for inspection performed in accordance with the Regulations:
1. Review fees;
2. On-site inspection fees;
3. Notification fees;
4. Fees for updating information from on-line application;
5. Examination fees;
The inspection fees in the preceding Paragraph is described in Attachment 3.
Attachment 3.pdf

Chapter V Supplementary Provisions

Article 18 When conducting field inspections under the Regulations, inspectors shall carry and present certification documents related to the inspection operation or their credentials that show their identity.

Article 19 The Regulations shall be implemented on May 1st, 2021.
The amendments to the Regulations shall take effect on the date of promulgation.

Amendment of Attachment 1 of Article 3 of Regulations Governing Border Inspection and Examination of Imported Medical Devices

Attachment 1

Item No.	Item Name	Classification Code	Chinese Name	English Name
1	4014.10.00.10	L.5300	衛生套（保險套）	Condom
2	4014.10.00.90	L.5310	含殺精劑的衛生套	Condom with spermicidal lubricant
3	6307.90.50.31-A	I.4040	一般醫用口罩	General medical mask
4	6307.90.50.31-B	I.4040	外科手術口罩	Surgical mask
5	6307.90.50.31-C	I.4040	N95醫用口罩	N95 medical mask
6	3822.19.10.10	B.4020	COVID-19家用型抗原檢測試劑	COVID-19 Antigen Home/Self Test

Amendment of Attachment 2 of Article 6 of Regulations Governing Border Inspection and Examination of Imported Medical Devices

Attachment 2: Verification items, test items and testing methods of imported medical devices.

Attachment 1: Item No. 1: Condom; Item No. 2: Condom with spermicidal lubricant

1. Verification item: Name and address of the manufacturer (labeling shall be completed before importation; a letter from the original manufacturer shall be attached when the documents are not in English.)
2. Test items and testing methods: Randomly select 315 samples when the batch has 500,000 (or less) units and 500 samples when the batch has over 500,000 units and perform the following examination:

Test item	Testing methods
Appearance	The test is carried out in accordance with CNS 6629 T2008 and the same standard is used to determine conformity.
Pin-hole test	The test is carried out in accordance with CNS 6629 T2008 and the same standard is used to determine conformity.

Attachment 1: Item No. 3: General medical mask; Item No. 4: Surgical mask; Item No. 5: N95 medical mask

1. Verification item: Name and address of the manufacturer (labeling shall be completed before importation; a letter from the original manufacturer shall be attached when the documents are not in English.)
2. Test items and testing methods: Randomly select 100 samples from each batch and perform the following examination:
3.

General medical mask

Test item	Testing methods
Bacterial filtration efficiency (BFE)	The test is carried out in accordance with CNS 14774 and the same standard is used to determine conformity.
Differential pressure	The test is carried out in accordance with CNS 14774 and the same standard is used to determine conformity.

Surgical mask

Test item	Testing methods
Sub-micron particulate filtration efficiency test	The test is carried out in accordance with CNS 14774 and the same standard is used to determine conformity.
Differential pressure	The testing is carried out in accordance with CNS 14774 and the same standard is used to determine conformity.

N95 medical mask

Test item	Testing methods
Sub-micron particulate filtration efficiency test	The test is carried out in accordance with CNS 14755 and the same standard is used to determine conformity.
Inhalation and exhalation resistance test	The test is carried out in accordance with CNS 14755 and the same standard is used to determine conformity.

Attachment 1: Item No. 6: COVID-19 Antigen Home/Self Test

1. Verification item: Name and address of the manufacturer (labeling shall be completed before importation; a letter from the original manufacturer shall be attached when the documents are not in English.)
2. Test items and testing methods: Randomly select 100 samples from each batch and perform the following examination:

Test item	Testing methods
Analytical reactivity test of diagnostic reagent	According to "Method of Test for In Vitro Diagnostic Device for SARS-CoV-2 Antigens" announced by Taiwan Food and Drug Administration of the Ministry of Health and Welfare, virus strains of the product applying for registration and market approval or change of registration will be tested and "Quality Acceptance Criteria of Border Inspection and Examination of Imported COVID-19 Antigen Home/Self Test" stipulated by the Ministry of Health and Welfare will be used to determine conformity.
Detection limit of the diagnostic reagent	According to "Method of Test for In Vitro Diagnostic Device for SARS-CoV-2 Antigens" announced by Taiwan Food and Drug Administration of the Ministry of Health and Welfare, virus strains of the product applying for registration and market approval or change of registration will be tested and "Quality Acceptance Criteria of Border Inspection and Examination of Imported COVID-19 Antigen Home/Self Test" stipulated by the Ministry of Health and Welfare will be used to determine conformity.

Amendment of Attachment 3 of Article 17 of Regulations Governing Border Inspection and Examination of Imported Medical Devices

Attachment 3

Item	Fees (in NTD)
1. Review fees;	The review fees use duty-paying value (DPV) and are charged according to the following rates: Review fees of imported medical devices is 0.25%. When the review fees are less than 500 NTD, 500 NTD will be charged. When the review fees are over 100,000 NTD, the exceeding amount will be halved.
2. On-site inspection fees;	Inspectors work from 8:30 am to 5:30 pm on work days in accordance with the Official Work Calendar for Government Agencies. 500 NTD will be charged per location per inspector. Additional fees will be charged according to the following rates if inspections are to be performed outside aforementioned time. 1. 400 NTD per person-time for 6 am to 8:30 am or 5:30 pm to 10 pm on a work day. 2. 1000 NTD per person-time for 6 am to 10 pm on a holiday. 3. 2000 NTD will be charged per person-time for inspection outside the aforementioned time. If the inspector needs to stay overnight and requires accommodation, the fees for travel and accommodation will be charged in accordance with “The Standards for Reimbursement of Domestic Business Trip Expenses” stipulated by the Executive Yuan.
3. Notification fees;	The fees for re-issuance, replacement, additional copy, or correction of the notification of import permit of imported medical device and notification of nonconformity.
4. Fees for updating information from on-line application.	If the obligatory inspection applicant or the representative applies for updating information from on-line application for reasons that the obligatory inspection applicant or the representative is responsible for, 100 NTD will be charged for each application. The fees include a copy of re-issued permit with notification stating the correction.
4. Examination fees;	The fees required for re-inspection of imported medical device or the fees for batch-by-batch inspection when the product fails to conform with the regulation upon random-selected batch inspection.

Item	Description	Fee-charging items and amount

Appearance of condom	Visible defects (severe and not severe)	Fees are charged in accordance with "A001: General test" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Condom pin-hole test	In accordance with CNS 6629	Fees are charged in accordance with "B006: condom pinhole test" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
General medical mask bacterial filtration efficiency	In accordance with CNS14774	Fees are charged in accordance with "B022: General medical face mask bacterial filtration efficiency" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
General medical mask differential pressure test	In accordance with CNS 14774	Fees are charged in accordance with "B023: General medical face mask differential pressure test" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Surgical mask differential pressure test	In accordance with CNS 14774	Fees are charged in accordance with "B012: Surgical mask differential pressure test" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Sub-micron particulate filtration efficiency test	In accordance with CNS 14774 or CNS 14755	Fees are charged in accordance with "B015: Surgical mask sub-micron particulate filtration efficiency test" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Inhalation and exhalation resistance test	In accordance with CNS 14755	Fees are charged in accordance with "B021: Inhalation and exhalation resistance test" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Analytical reactivity test of diagnostic reagent	Suitable virus strains will be tested to confirm if the positive and	Fees are charged in accordance with "B024: In Vitro Diagnostic Device (IVD)" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".

	negative result of the product is correct	
Detection limit of the diagnostic reagent	Three test strips in the positive sample test group show lines in their test regions (T-line) with minimum viral concentration	Fees are charged in accordance with "B024: In Vitro Diagnostic Device (IVD)" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Infectious biological materials test	If methods of testing listed in Attachment 2 requires a BSL-2 or above biosafety laboratory, this fees will be charged.	Fees are charged in accordance with "C013: Infectious biological materials test" of "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Note: When the inspection fees are calculated in foreign currency, Currency Exchange Rate Inquiry System provided by the Customs Administration, Ministry of Finance will be used to calculate the amount in New Taiwan Dollar.		