Draft Regulations Governing Border Inspection and Examination of Imported Medical Devices

Articles	Description
Chapter I General Provisions	Name of chapter
Article 1 The present regulations are stipulated in accordance with Paragraph 2, Article 52 of the Medical Devices Act (hereinafter referred to as "the Act").	Article 52 of the Act stipulates that "(Paragraph 1) medical device items designated by the central competent authority may only be imported after passing required random tests or inspections at the time of import" and "(Paragraph 2) regulations governing the items, manners, methods, scope, and fees of the random tests and inspections of the imported medical device set forth in the preceding paragraph, and other matters to be complied with shall be established by the central competent authority." These two paragraphs are the legal basis for the stipulation of the present regulations.
Article 2 Terms used in the present 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 organization(s) appointed or commissioned by the central competent authority. 5. Obligatory inspection applicants: This refers to importers of medical devices.	Definitions of key terms used in the present regulations.
Chapter II Application for Inspection of Imported Medical Device	Name of chapter

Article 3 Provisions governing medical device items requiring border inspection by the central competent authority are listed in Annex I.	In accordance with the provisions of Paragraph 2 of Article 52 of the Regulations, medical device items requiring border inspection by the central competent authority are shown in the Annex of the present regulations.
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 copy of medical devices permit license. 2. A copy of application for import declaration. 3. Other documents, information or packaging and label designated by the central competent authority. 4. 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 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, 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.	Stipulates that the obligatory inspection applicant shall file the completed application form and submit the following documents and information to the inspection authority 15 days prior to the date of inspection and may require the application to be submitted electronically.
Article 5 Imported medical devices conform to one of the following situations can be exempted from inspection referred to the preceding Article: 1. Imported medical devices are for	Stipulates the situations when imported medical device does not require inspection. For example, in accordance with the provisions of Paragraph 4 of Article 35 of the Act, imported medical devices for

exclusive use as samples or for personal use only in accordance with the provisions of Paragraph 4 of Article 35 of the Act. 2. Imported medical devices are originally manufactured domestically for export and 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.	exclusive use as samples or for personal use only, or in accordance with the provisions of Article 25 of the Act, exported product originally manufactured domestically to be shipped back to Taiwan with the approval of the Administration.
Chapter III Inspection Procedures	Name of chapter
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. Inspection items, test items and testing methods of imported medical devices as prescribed in Annex II.	Stipulates the methods to inspect imported medical devices; and stipulates that inspection methods, test items and methods are listed in the Annex of the present regulations.
Article 8 Imported medical device applied for inspection that belong to one of the following situations shall be inspected on a batch-by-batch basis:	Stipulates the conditions for batch-by-batch inspection of medical devices.

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 for the preceding batch, the batches re-applied for inspection to such batch 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 regulations. 2. The inspection authority determines that it is necessary to carry out reinforced batch-by-batch inspection.	Stipulates the conditions for reinforced randomly-selected batch inspection of medical devices.
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 the provisions of Subparagraph 1, Paragraph 1 of Article 7 is conformity with the regulations. 2. The inspection results of the previous	Stipulates the conditions for regular randomly-selected batch of medical devices.

five batches in a row in accordance with the provisions of Subparagraph 2, Paragraph 1 of Article 7 or preceding Article are conformity 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 what is required for examination. After collecting the samples, the inspection authority shall issue a receipt for sampling to the obligatory inspection applicant.	Stipulates that the inspection authority may take samples required for inspection free of charge and the number of sampling.
Article 11 Sampling of inspection shall conduct in the place where the products were stored. 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.	Stipulates the sampling method and location for imported medical device.
Article 12 Examination 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.	Stipulates the timing of examination of imported medical device.
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 with an	Stipulates that imported medical device may be granted notice of prior for import with an Affidavit and the consequences when the content of the Affidavit is not followed.

Affidavit of Imported Medical Device. 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 regulations, a notification of import permit will be issued to the obligatory inspection applicant; 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.	Stipulates the follow-up procedures after imported medical device are found to conform with regulations after inspection, including issuance of written permit and disposal of remaining samples.
Article 15 In the event that imported medical device fail to conform to regulations, 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 done according to Article 11. For medical devices that do not conform to regulations upon inspection, as referred to in Paragraph 1, the	Stipulates the follow-up procedures when imported medical device fail to conform with regulations after inspection, including issuance of a notification of noncompliance, application for re-examination and disposal of remaining samples.

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 regulations upon 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 regulations, the inspection authority 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.	Stipulates the disposal of the shipment of nonconforming imported medical device.
Chapter VI Statutory Fees	Name of chapter
Article 17 The obligatory inspection applicant shall pay all or part of 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 Annex 3.	Stipulates the charges for inspection of imported medical device.
Chapter V Supplementary provisions	Name of chapter
Article 18 Inspectors shall carry and present their identification papers when conducting field inspections under the present regulations.	Stipulates that inspectors shall carry their identification documents with them when performing inspection.
Article 19 These regulations shall be implemented on the date of promulgation of "the Act".	According to Article 85 of the Act, the date for enforcing the Act shall be determined by the Executive Yuan and the present regulations will follow the date of promulgation of the Act.

Annex 1

Item No.	Item Name	Classification Code	Chinese Name	English Name
1	4014.10.00.10	L.5300	Condom	Condom
2	4014.10.00.90	L.5310	Condom with spermicidal lubricant	Condom with spermicidal lubricant
3	6307.90.50.31-A	I.4040	General medical mask	General medical mask
4	6307.90.50.31-B	I.4040	Surgical mask	Surgical mask
5	6307.90.50.31-C	I.4040	N95 medical mask	N95 medical mask

Annex II: Verification items, test items and testing methods of imported medical devices.

Annex I: Item No. 1, 2: condom

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 500,001 (or more) and perform the following examination:

Test item	Testing methods
Appearance	In accordance with CNS 6629 T2008
Pin-hole test	In accordance with CNS 6629 T2008

Annex I: Item No. 3, 4: General 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:

General medical mask

Test item	Testing methods
Bacterial filtration efficiency (BFE)	In accordance with CNS 14774
Pressure difference	In accordance with CNS 14774

Surgical mask

Test item	Testing methods
Sub-micron Particulate Filtration Efficiency	In accordance with CNS 14774
Pressure difference	In accordance with CNS 14774

N95 mask

Test item	Testing methods
Sub-micron Particulate Filtration Efficiency	In accordance with CNS 14755
Respiratory impedance	In accordance with CNS 14755

Annex 3

<table>
<tr><td>Item</td><td colspan="2">Fees (in NTD)</td></tr>
<tr><td>1. Review fees;</td><td colspan="2">The review fees use duty-paying value (DPV) and are charged according to the following rates:
Review fees of imported medical devices is 0.2% 5. When the review fees is less than 500 NTD, 500 NTD will be charged. When the review fees is over 100,000 NTD, the exceeding amount will be halved.</td></tr>
<tr><td>2. On-site inspection fees;</td><td colspan="2">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.</td></tr>
<tr><td>3. Notification fees;</td><td colspan="2">The fees for re-issuance, replacement, additional copy, or correction of the notification of import permit of import.ed medical device and notification of nonconformity.</td></tr>
<tr><td>4. Fees for updating information from on-line application.</td><td colspan="2">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.</td></tr>
<tr><td>5. Examination fees;</td><td colspan="2">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.</td></tr>
<tr><td>Item</td><td>Description</td><td>Fee-charging items and amount</td></tr>
<tr><td>Appearance of condom</td><td>Visible defects (severe and not</td><td>Fees are charged in accordance with "A001: General test" of " Fee-Charging Standards for Lot Release,</td></tr>
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	severe)	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".
Surgical mask bacterial filtration efficiency	In accordance with CNS14774	Fees are charged in accordance with "B011: Surgical mask bacterial filtration efficiency" 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".
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 masks sub-micron particulate filtration efficiency test" of " Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics".
Respiratory impedance	In accordance with CNS 14755	Fees are charged in accordance with "B015: Surgical masks sub-micron particulate filtration efficiency 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.		