Amendments to Articles 4 and 19 of the Regulations Governing Border Inspection and Examination of Imported Medical Devices

Article 4 In accordance with the provisions of Paragraph 1 of Article 52 of this 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 designation 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 19 These Regulations shall be implemented on May 1st, 2021.

The amendments to the Regulations shall take effect on the date of promulgation.

Attachment 1 of Article 3 of the Regulations Governing Border Inspection and Examination of Imported Medical Devices--List of amendments

Attachment 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
6	3002.15.00.10	B.4020	COVID-19 Antigen Home/Self Test	COVID-19 Antigen Home/Self Test

Attachment 2 of Article 6 of the Regulations Governing Border Inspection and Examination of Imported Medical Devices--List of Amendments

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 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

Attachment 1: Item No. 3: General medical masks, 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:

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 test	In accordance with CNS 14774
Pressure difference	In accordance with CNS 14774

N95 medical mask

Test item	Testing methods
Sub-micron particulate filtration efficiency test	In accordance with CNS 14755
Respiratory impedance	In accordance with CNS 14755

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	Appropriate virus strains are used to confirm if the positive and negative result of the product is correct
Detection limit of the diagnostic reagent	The claimed detection limit for positivity will be tested with appropriate viral concentration.