

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 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)	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.