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.