

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 |