

Amendment of Attachment 3 of Article 17 of Regulations Governing Border Inspection and Examination of Imported Medical Devices

Attachment 3

Item	Fees (in NTD)	
1. Review fees;	<p>The review fees use duty-paying value (DPV) and are charged according to the following rates:</p> <p>Review fees of imported medical devices is 0.25%. When the review fees are less than 500 NTD, 500 NTD will be charged. When the review fees are over 100,000 NTD, the exceeding amount will be halved.</p>	
2. On-site inspection fees;	<p>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.</p> <p>Additional fees will be charged according to the following rates if inspections are to be performed outside aforementioned time.</p> <ol style="list-style-type: none"> 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. <p>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.</p>	
3. Notification fees;	<p>The fees for re-issuance, replacement, additional copy, or correction of the notification of import permit of imported medical device and notification of nonconformity.</p>	
4. Fees for updating information from on-line application.	<p>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.</p>	
4. Examination fees;	<p>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.</p>	
Item	Description	Fee-charging items and amount

Appearance of condom	Visible defects (severe and not severe)	Fees are charged in accordance with “A001: General test” of “Fee-Charging Standards for Lot Release, 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”.
General medical mask bacterial filtration efficiency	In accordance with CNS14774	Fees are charged in accordance with “B022: General medical face mask bacterial filtration efficiency” of “Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics”.
General medical mask differential pressure test	In accordance with CNS 14774	Fees are charged in accordance with “B023: General medical face 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 mask sub-micron particulate filtration efficiency test” of “Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics”.
Inhalation and exhalation resistance test	In accordance with CNS 14755	Fees are charged in accordance with “B021: Inhalation and exhalation resistance test” of “Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics”.
Analytical reactivity test of diagnostic reagent	Suitable virus strains will be tested to confirm if the positive and negative result of	Fees are charged in accordance with “B024: In Vitro Diagnostic Device (IVD)” of “Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods,

	the product is correct	Drugs and Cosmetics”.
Detection limit of the diagnostic reagent	Three test strips in the positive sample test group show lines in their test regions (T-line) with minimum viral concentration	Fees are charged in accordance with “B024: In Vitro Diagnostic Device (IVD)” of “Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics”.
Infectious biological materials test	If methods of testing listed in Attachment 2 requires a BSL-2 or above biosafety laboratory, this fees will be charged.	Fees are charged in accordance with “C013: Infectious biological materials 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.		