

Comparison Table for the Draft Amendment to Article 24 of Regulations for the Inspection and Examination of Imported Medicaments

New Text	Current Text
<p data-bbox="236 495 820 577">Article 24 These regulations shall be implemented on the date of promulgation.</p> <p data-bbox="268 589 820 723">The amendment to Annex II of Article 22 promulgated on July 3rd, 2015 shall be implemented from July 1st, 2015.</p> <p data-bbox="268 734 820 913">The amendment to Annex II of Article 11 and Annex III of Article 22 promulgated on July O, 2020 shall be implemented from July O, 2020.</p>	<p data-bbox="842 495 1426 577">Article 24 These regulations shall be implemented on the date of promulgation.</p> <p data-bbox="874 589 1426 723">The amendment to Annex II of Article 22 promulgated on July 3rd, 2015 shall be implemented from July 1st, 2015.</p>

Item: Medical Mask

Classification No.	Classification Code	Product Name																												
(The Bureau of Foreign Trade shall assist in the classification of medical masks)	I.4040	General medical face (mouth) mask; surgical face (mouth) mask; surgical D2 dust mask	<p>1. Sampling inspection method and sampling rate: For medical masks of the same obligor, item, brand, and origin, the inspection shall start with three consecutive batches, and sampling inspection can be conducted if the first three batches are successful. The qualified vendor shall be subject to batch inspection by sampling one batch from 10 batches in future deliveries. If there is any failure found in the batch inspection, the batch inspection no longer be valid and shall not be resumed until another three-consecutive-batch successes have been achieved. All the required inspections have to be performed on site.</p> <p>2. On-site inspection: Items to compare: manufacturer name and address.</p> <p>3. Inspection items: A random sample of 100 pcs per batch. The acceptable quality level (AQL) ratio is based on the standard of CNS 2779, and different items are tested according to the national standards of CNS 14774 medical face (mouth) mask and CNS 14755 disposable dust mask:</p> <p>General medical face (mouth) mask</p> <table border="1" data-bbox="882 692 2024 863"> <thead> <tr> <th>Item</th> <th>Inspection level</th> <th>Acceptable quality level</th> </tr> </thead> <tbody> <tr> <td>Bacterial filtration efficiency</td> <td>Special inspection S-2 (but the sample pronoun shall be at least E)</td> <td>4</td> </tr> <tr> <td>Differential pressure</td> <td>Special inspection S-2 (but the sample pronoun shall be at least E)</td> <td>4</td> </tr> </tbody> </table> <p>Surgical face (mouth) mask</p> <table border="1" data-bbox="882 940 2024 1110"> <thead> <tr> <th>Project</th> <th>Inspection level</th> <th>Acceptable quality level</th> </tr> </thead> <tbody> <tr> <td>Submicron filtration efficiency</td> <td>Special inspection S-2 (but the sample pronoun shall be at least E)</td> <td>4</td> </tr> <tr> <td>Differential pressure</td> <td>Special inspection S-2 (but the sample pronoun shall be at least E)</td> <td>4</td> </tr> </tbody> </table> <p>Surgical D2 dust mask</p> <table border="1" data-bbox="882 1219 2024 1390"> <thead> <tr> <th>Project</th> <th>Inspection level</th> <th>Acceptable quality level</th> </tr> </thead> <tbody> <tr> <td>Submicron filtration efficiency</td> <td>Special inspection S-2 (but the sample pronoun shall be at least E)</td> <td>4</td> </tr> <tr> <td>Breathing air resistance</td> <td>Special inspection S-2 (but the sample pronoun shall be at least E)</td> <td>4</td> </tr> </tbody> </table>	Item	Inspection level	Acceptable quality level	Bacterial filtration efficiency	Special inspection S-2 (but the sample pronoun shall be at least E)	4	Differential pressure	Special inspection S-2 (but the sample pronoun shall be at least E)	4	Project	Inspection level	Acceptable quality level	Submicron filtration efficiency	Special inspection S-2 (but the sample pronoun shall be at least E)	4	Differential pressure	Special inspection S-2 (but the sample pronoun shall be at least E)	4	Project	Inspection level	Acceptable quality level	Submicron filtration efficiency	Special inspection S-2 (but the sample pronoun shall be at least E)	4	Breathing air resistance	Special inspection S-2 (but the sample pronoun shall be at least E)	4
Item	Inspection level	Acceptable quality level																												
Bacterial filtration efficiency	Special inspection S-2 (but the sample pronoun shall be at least E)	4																												
Differential pressure	Special inspection S-2 (but the sample pronoun shall be at least E)	4																												
Project	Inspection level	Acceptable quality level																												
Submicron filtration efficiency	Special inspection S-2 (but the sample pronoun shall be at least E)	4																												
Differential pressure	Special inspection S-2 (but the sample pronoun shall be at least E)	4																												
Project	Inspection level	Acceptable quality level																												
Submicron filtration efficiency	Special inspection S-2 (but the sample pronoun shall be at least E)	4																												
Breathing air resistance	Special inspection S-2 (but the sample pronoun shall be at least E)	4																												

Annexed table 3

1. Examination fee	<p>The examination fee shall be calculated and collected at the following rates based on the duty-paid price:</p> <ol style="list-style-type: none"> The examination rate for imported traditional Chinese medicinal materials is 1.5 ‰. If the examination fee is less than TWD200, it will be charged at TWD200 per case. If the amount exceeds TWD100,000, the exceeding amount will be charged by half. The examination rate for imported drugs is 2.5 ‰. If the examination fee is less than TWD500, it will be charged at TWD500 per case. If the amount exceeds TWD100,000, the exceeding amount will be charged by half. Active pharmaceutical ingredients are exempted from examination fee charges. The examination rate for imported medical equipment is 2.5 ‰. If the examination fee is less than TWD500, it will be charged at TWD500 per case. If the amount exceeds TWD100,000, the exceeding amount will be charged by half. 		
2. On-site examination fee	<p>According to the "Office Calendar of Government Administrative Offices" the service hours are from 8:30 am to 5:30pm during the work days of the week, and the charge will be TWD500 per site visit for each person. In case the services are required beyond the above-mentioned time period, additional fees shall be charged in accordance with the following provisions:</p> <ol style="list-style-type: none"> TWD400 per person each time on work days from 6:00 am to 8:30 am or 5:30 pm to 10:00 pm. TWD1,000 per person each time on off days from 6:00 a.m. to 10:00 p.m. TWD2,000 per person each time for services required beyond the time specified in the first two provisions. <p>In case an accommodation arrangement is required due to the actual status that the personnel who provide such services are unable to return on the same day, an extra fee shall be charged according to the Directions of the Domestic Travel Allowance Disbursement of the Executive Yuan.</p> <p>Active pharmaceutical ingredients are exempted from on-site inspection fee.</p>		
3. Notification Fee	A fee of TWD100 per copy for the re-issuance, renewal, additional copy of the drug import permit notification or registration content alteration.		
4. Inspection fee	The inspection fees shall be charged for the re-inspections of imported drugs, or the consequent inspections due to failure of sampling inspections.		
No.	Test items	Description	Charge amount
Traditional Chinese medicinal materials			Fees shall be charged based on the "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs, and Cosmetics".
A005	Heavy metals	Counted by each item and tested by colorimetry	
E011	HG		

E012	Arsenic	
E013	Lead	
E014	Copper	
E015	Cadmium	
E016	Organochlorine	
E017	Aflatoxin B1, B2, G1, G2	
Medical equipment		
A001	Ordinary inspection (Appearance of condom)	Visual defects (serious and non-serious)
B006	Pinhole test of condom	According to CNS6629
B011	Bacterial filtration efficiency of surgical masks	According to CNS14774
B012	Differential pressure test of surgical mask	According to CNS14774
B015	Submicron filtration efficiency	According to CNS14774

Being prepared by the research and inspection team	Breathing air resistance	According to CNS14755
API		
A002	Identification	Measured by one component or one method

Note: All charges shall be in TWD, and foreign currencies shall be converted into TWD according to the ten-day exchange rate table applicable to customs issued by the Customs Administration, Ministry of Finance.