

Annex II: The inspection methods and examination methodologies, items and scope to be checked of imported medical devices

Item: Condom

CCC Code	Codes of classification	Item	1. Inspection methods and frequency : Condoms with the same obligatory inspection applicant, same items, brand, country of origin, type, thickness and specification are subjected to batch-by-batch examination. For first inspection submission, randomly-selected batch inspection shall apply for those require compliance for three consecutive batches. For one out of three batches will be randomly selected. Randomly selected, batch shall be conducted examination, while those not randomly-selected are subjected to on-site inspection. If non-conformities are found during the randomly-selected batch inspection process, the originally announced procedure of three consecutive batch examination shall be applied before permitted for randomly-selected inspecting require.												
4014,10.00.10 ; 4014,10.00.90	L5300 ; L5310	Condom; Condom with spermicidal lubricant	2. On-site inspection: Items to be inspected: packaging, appearance and labels of products including: name of the product, name and address of the manufacturer, date of manufacture or batch number, or expiry date. 3. Examination items: Randomly selected 315 samples per batch of 500,000 or below, and 500 samples per batch of 500,001 or above. The ratio of Acceptable Quality Level (AQL) in accordance to ISO 2859-1, and the following test items are as follows according to Chinese National Standards (CNS) 6629 T2008 Standard of latex condom. <table><tr><td>Items</td><td>Testing Levels</td><td>Acceptable Quality Level(AQL)</td></tr><tr><td>Appearance</td><td>Normal test I(at least for the sample code M)</td><td>0.4</td></tr><tr><td>Pin-hole test</td><td>Normal test I(at least for the sample code M)</td><td>0.25</td></tr><tr><td>Labeling</td><td>Must fully comply with all requiring</td><td></td></tr></table>	Items	Testing Levels	Acceptable Quality Level(AQL)	Appearance	Normal test I(at least for the sample code M)	0.4	Pin-hole test	Normal test I(at least for the sample code M)	0.25	Labeling	Must fully comply with all requiring	
Items	Testing Levels	Acceptable Quality Level(AQL)													
Appearance	Normal test I(at least for the sample code M)	0.4													
Pin-hole test	Normal test I(at least for the sample code M)	0.25													
Labeling	Must fully comply with all requiring														
			Note: Minimum package shall label in Chinese for the following items: name of the product, date of												

			<p>manufacture or batch number, expiry date, and name and address of the manufacturer(import manufacturer may label in foreign languages), Medical device permit number and the importer. Single unit shall at least label date of manufacture or batch number ,name of the manufacture or brand(imported excluded) ,expiry date, and period of validity or shelf-life(limited in product with manufacturing date)in Chinese .For expiry date of the same series of mixed packaging, shall be based on the contents of a single package on the earliest date .</p> <p>4. If re-examination is required, resampling shall be proceeded according to the abovementioned requirements.</p>
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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 mask; surgical face mask; surgical D2 dust mask	1. Sampling inspection method and sampling rate: For medical masks of the same obligor, item, brand, and country of 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 randomly 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.								
			2. On-site inspection: Items to compare: manufacturer name and address.								
			3. Inspection items: A random sample of 100 PCE 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: General medical mask								
			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
			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						
			Surgical mask								
			Project	Inspection level	Acceptable quality level	Particle 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						
Particle 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									
Surgical D2 dust mask											
Project	Inspection level	Acceptable quality level	Particle 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			
Project	Inspection level	Acceptable quality level									
Particle 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									

