

Identifying Medical and Non-Medical Masks for China Export

Disclaimer: This document is an unofficial English translation and summary of the Chinese language advisory titled "How To Distinguish Between Medical and Non-Medical Mask" published by the General Administration of the Customs of China on 11 April 2020 at https://mp.weixin.qq.com/s/Xx_4xgG3mhjnR0ZU7pvixg. It is prepared by UPS for UPS customers only. It does not constitute legal advice nor interpretation of the advisory or the law. UPS makes no representations or warranties as to the accuracy, completeness, reliability or otherwise with respect to the information in this document. Questions relating to the advisory should be directed to the General Administration of the Customs of China.

Basic Classification of Masks

Medical masks are mainly used for medical protection and can be divided into three types:

- Medical protection mask
- Medical surgical mask
- Disposable medical mask

Non-medical masks are usually referred to as personal protective masks and can be divided into two types:

- Anti-particle mask
- Daily protective mask

Mask Categories in China

Below is usage information on the 5 classifications of medical and non-medical masks:

Categories	Classification	Usage
Medical Masks	Medical Protection Mask	Suitable for use by medical staff in high-risk medical environments, such as outpatient clinics, isolation wards, and intubation areas.
	Medical Surgical Mask	Suitable for use by medical staff when performing low-risk operations, as well as in environments such as medical institutions and crowded public places.
	Disposable Medical Mask	Suitable for use by any person for medical purposes in an indoor work environment, during normal outdoor activities or in crowded public places.
Non-Medical Masks	Anti-Particle Mask	Suitable for use by any person to filter out air particles in an industrial work environment.
	Daily Protective Mask	Suitable for use by any person to filter out air particles in any polluted environment.

Guidance on How to Identify Medical / Non-Medical Masks based on Product Design and Package Information

Product Design

- Medical masks generally do not have an exhalation valve so as to prevent droplets and microorganisms from passing through and coming into human contact.
- Non-medical masks, on the other hand, are allowed to have an exhalation valve.



Package Information

- Package information for masks typically includes a product description, production standards and a protection level, e.g. "for medical use". Check for terms including "医用" in Chinese or "Surgical" and "Medical" in English. This information can be used to determine how to classify the masks.



Guidance on How to Identify Medical / Non-Medical Masks based on Product Standards

- Classification of masks differs across countries. Shippers should check for relevant Chinese or destination product standards to assist with determining how to classify the masks for export from China.
- Chinese or destination product standards are typically available on the product packaging.
- If necessary, obtain a product test report or certification from the product manufacturer.

Summary of Product Standards for Medical Masks in China, the United States (US) and Europe (EU)

	China			US	EU
Standard Number	GB 19083	YY 0469	YY/T 0969	ASTM F2100	EN 14683
Standard Description	Standard for Medical Protection Mask	Standard for Medical Surgical Mask	Standard for Disposable Medical Mask	Standard Specification for Performance of Materials Used in Medical Face Masks	Medical Face Masks. Requirements and Test Methods

China Product Standards

- Masks that fall into the following three Chinese standards are categorized as medical masks: GB 19083, YY 0469, and YY / T 0969.
- In China, medical masks are regulated by the National Medical Products Administration. Product registration information is available at: <http://www.nmpa.gov.cn/WS04/CL2590/>


US Product Standards

- Medical masks are classified as medical devices and are subject to the "Standard Specification for Performance of Materials Used in Medical Face Masks" (ASTM F2100).
- Medical masks can be sold only if they are registered under FDA Section 501K.
- Product registration information is available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
- The FDA also publishes a list of Chinese manufacturers and corresponding respirator and mask models that it authorizes for import into the United States: <https://www.fda.gov/media/136663/download>
- Non-medical masks must be registered with the National Institute for Occupational Safety and Health (NIOSH) before marketing in the US can occur.
- If the above information is provided on the product packaging, the product can be considered a medical or non-medical mask.

Technical Standards

ASTM F2100 Test Standard	Level 1	LEVEL 2	Level 3
Particle Filtration Efficiency (PFE) Efficacité de filtration des particules (EFP) Eficiencia de filtración de partículas	≥ 95%	≥ 98%	≥ 98%
Bacterial Filtration Efficiency (BFE) Efficacité de filtration des bactéries (EFB) Eficiencia de filtración de bacterias	≥ 95%	≥ 98%	≥ 98%
ΔP (mmH ₂ O/cm ²)	<4.0	<5.0	<5.0
Flame Spread Classement d'inflammabilité Clasificación de inflamabilidad	Class 1	Class 1	Class 1
Resistance to penetration by synthetic blood Résistance à la pénétration du sang synthétique Resistencia a la penetración de sangre sintética	80 mmHg	120 mmHg	160 mmHg

Level of Protection



EU Product Standards and Certification

- The Conformité Européenne (CE) mark is required for both medical and non-medical masks, but with different standards.
 - Medical masks are classified as medical devices and must have a CE label affixed in accordance with EU Medical Device Directive (MDD) 93/42/EEC or Medical Devices (MDD) and Regulation (MDR) EU/2017/745 ((EN14683).
 - Non-medical masks are not classified as medical devices but must meet the requirements of the EU Personal Protective Equipment Certification EU2016 / 425 (EN149).
- Product registration information is available at: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13 and https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
- If the above information is provided on the product packaging, the product can be considered a medical or non-medical mask.



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