

Comparison of Standards of Surgical Masks

Surgical masks are mainly used in the operating room or other similar medical environment. The focus is to prevent the possible spatter of blood, fluid through the mask to contaminate the wearer. The key core indicators are generally filtration efficiency, blood penetration, microorganisms, pressure difference, etc.

Surgical masks in China shall comply with YY0469 standard, and the surgical masks in EU shall comply with EN14683 standard:

- For **particle filtration efficiency**, YY 0469-2011 stipulates particle filtration rate (PFE) $\geq 30\%$, while EN14683-2019 has no requirement;
- For **bacterial filtration efficiency**, YY 0469-2011 stipulates that bacterial filtration efficiency (BFE) $\geq 95\%$, while in EN14683-2019 there're three classes: Type I: $\geq 95\%$, Type II and Type IIR: $\geq 98\%$;
- For **blood penetrability**, the requirement in YY 0469-2011 $\geq 16\text{kPa}$, while EN14683-2019 only requires Type IIR, with the index $\geq 16\text{kPa}$.

Comparison of key requirements between two standards is listed in

Table 1-1.

Table 1-1 Comparison of key requirements between two standards

Country	China	European Union
Product	surgical masks	surgical masks
Standard	YY0469-2011 Surgical Masks	EN 14683-2019 Surgical Masks-Requirements and Test Methods
Scope	Suitable for disposable masks worn by clinical medical personnel during invasive operation	Suitable for use in surgery or other similar medical environment to limit the spread of pollutants produced by other workers to patients, and to effectively block the discharge of pollutants from the mouth and nose of suspected carriers or patients with clinical symptoms.
Tightness	X	X
Particle Filtration Efficiency (PFE)	$\geq 30\%$	X
Bacterial Filtration Efficiency (BFE)	$\geq 95\%$	Type I: $\geq 95\%$ Type II、 Type IIR: $\geq 98\%$
Pressure Difference	$\sqrt{(\leq 49\text{Pa})}$	Type I and Type II: $\leq 40\text{Pa}$ Type IIR: $\leq 60\text{Pa}$ (kPa) $\sqrt{}$
Blood Penetration	$\sqrt{(\geq 16\text{kPa})}$	Type I and Type II: X Type IIR: ≥ 16 (kPa) $\sqrt{}$
Surface Moisture Resistance	X	X
Microbiological Index	$\sqrt{}$	$\sqrt{}$
Flammability	$\sqrt{}$ (The masks should burn no more than 5 S after leaving the flame)	X
Exhalation Value	X	X

Marking	Standard number, product name, production date and batch number, manufacturer's name and contact information, product registration certificate number, instructions for use, words and symbols of "disposable use". If the product is sterilized, the corresponding sterilization mark shall be provided, indicating the sterilization method and the sterilization period. Specification, size and tolerance. And product use.	Standard number and mask type (Type I, Type II or Type IIR)
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Note: The comparison provided is only technical information based on text comparison and cannot be used as a legal basis for the foreign party to choose Chinese products.