

# CHOOSE THE RIGHT MASK

## THE RIGHT MASK IS AN ASTM-RATED MASK



## MEDICAL FACE MASK TESTS & REQUIREMENTS

U.S.A.: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS

EUROPE: EN 14683:2019 MEDICAL FACE MASKS –REQUIREMENTS AND TEST METHODS

|                  |                                      |                                               | ASTM F2100-19                                                                                                                         |                                         |                  | EN 14683:2019 BARRIER LEVELS                                                                                                                                |         |                                |
|------------------|--------------------------------------|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------------------------|
|                  |                                      |                                               | Level 1                                                                                                                               | Level 2                                 | Level 3          | Type I                                                                                                                                                      | Type II | Type IIR                       |
| BARRIER TESTING  | BFE %<br>ASTM F2101, EN 14683        | Bacterial Filtration Efficiency               | ≥95                                                                                                                                   | ≥98                                     |                  | ≥95                                                                                                                                                         | ≥98     |                                |
|                  | PFE %<br>ASTM F2299                  | Sub-Micron Particulates Filtration Efficiency | ≥95                                                                                                                                   | ≥98                                     |                  | Not required                                                                                                                                                |         |                                |
|                  | Synthetic Blood ASTM F1862, ISO22609 | Resistance to Penetration By Synthetic Blood  | Pass at 80 mmHg                                                                                                                       | Pass at 120 mmHg                        | Pass at 160 mmHg | Not required                                                                                                                                                |         | Pass at ≥ 16.0 kPa (>120 mmHg) |
| PHYSICAL TESTING | Differential Pressure EN 14683       | Differential Pressure (Breathability)         | <5.0 mmH <sub>2</sub> O/cm <sup>2</sup>                                                                                               | <6.0 mmH <sub>2</sub> O/cm <sup>2</sup> |                  | <40 Pa/cm <sup>2</sup>                                                                                                                                      |         | <60 Pa/cm <sup>2</sup>         |
| SAFETY TESTING   | Flammability 16 CFR Part 1610        | Fammability                                   | Class 1 (≥ 3.5 seconds)                                                                                                               |                                         |                  | See European Medical Directive (2007/47/EC, MDD 93/42/EEC)                                                                                                  |         |                                |
|                  | Microbial Cleanliness ISO 11737-1    |                                               | Not required                                                                                                                          |                                         |                  | ≤30 cfu/g                                                                                                                                                   |         |                                |
|                  | Biocompatibility ISO 10993           |                                               | 510 K Guidance recommends testing to ISO 10993                                                                                        |                                         |                  | Complete an evaluation according to ISO 10993                                                                                                               |         |                                |
|                  | Sampling ANSI/ASQC Z1.4 ISO 2859-1   |                                               | •AQL 4% for BFE, PFE, Delta P<br>•32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)<br>•14 masks for Flammability |                                         |                  | •Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness<br>•32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) |         |                                |

## THE “4 FS” OF SELECTING THE RIGHT MASK

\*Use ASTM standards to support choices around Filtrations and Fluid Resistance



### FILTER IT

When you're around smoke or maybe interacting with a infected patient, properly protect yourself with a **high filtration mask** (KN 95 FFP2 MEDICAL MASK or NIOSH N95).



### IN MATTERS OF SPLATTER

When at risk of encountering Blood and/or bodily fluid splatter, wear the recommended **ASTM Level 3 fluid-resistant** mask and get the best protection for the Operating Room.



### BELLS AND WHISTLES, TIES AND LOOPS

Mask with certified earloops not only makes the fitment of the masks better, it also increase comfort around the ears after long mask wearing sessions. Medical graded earloops are designed to be **soft** and **flat** in shape.



### THE FIT IS IT

Even the right mask not worn correctly could put you at risk. Nose and mouth must be covered completely. Create a seal around the face to prevent gaps that increase the risk of inhalation exposure. Good **quality nose clip** is also important.

## Feel: Bonus Comfort & Breathability

### THE DIFFERENCE IN PROTECTION BETWEEN A LEVEL 2 MASK AND A LEVEL 3 MASK IS MINIMAL.

When it is solely a matter of micromillimeters, level up your mask selection and get the best protection with an ASTM Level 2 or 3 mask.

The risk of exposure to blood and bodily fluid splatter in the OR is significant and the protection offered in an ASTM Level 1 mask is minimal.

When the risk is unknown or too great to ignore, level up your mask selection and get the best protection with ASTM **LEVEL 2** masks for better **Breathability** and **LEVEL 3** for better **Fluid Resistance**.



### PROCEDURE MASKS ASTM LEVEL 2

**Patient & Staff isolation:**  
Clean environments, sterile cores, processing departments, ER and ICU for bedside procedures



### SURGICAL MASKS ASTM LEVEL 3

OR Staff in sterile environments: closeness of fit protects against fluid transmission or -Intended for a high-risk of fluid exposure



### KN 95 FFP2 MEDICAL MASK OR NIOSH N95

Protection against residual surgical smoke or on patients with known or suspected aerosol transmittable diseases

- Tuberculosis
- Rubeola2
- Varicella
- Covid-19