

# Guide to FACE MASK Tests & Requirements



**Choose the correct  
mask for the task!**

## Medical Face Mask - Standards/Directives/Legislative requirements

- All products must be **CE marked** which shows the product meets EU safety, health and environmental requirements
- Product and packaging must conform to **Medical Devices Regulation 2017/745**
- **EN 14683:2019** Requirement and test methods on medical face masks
- Product and packaging must be latex free where possible
- The government guidance for healthcare professionals is Type IIR face masks



|                                       | Low                     | Moderate                | High                    |
|---------------------------------------|-------------------------|-------------------------|-------------------------|
|                                       | Example of requirements |                         |                         |
| Fluid/Splash resistance               | 80 mmHg                 | < 120 mmHg              | ≥ 120 mmHg              |
| BFE % Bacterial Filtration Efficiency | ≥ 95%                   | ≥ 98%                   | ≥ 98%                   |
| Differential Pressure                 | < 40 Pa/cm <sup>2</sup> | < 40 Pa/cm <sup>2</sup> | < 60 Pa/cm <sup>2</sup> |
| Flammability                          | Class 1                 | Class 1                 | Class 1                 |
| EN 14686 Rating                       | Type I                  | Type II                 | Type IIR                |

Masks should be single use. Masks with ties or ear loops must not detach from the face mask when in use.

|                                       | Performance explanation  |
|---------------------------------------|--|
| Fluid/Splash resistance               | Mask resistance to penetration by synthetic blood under pressure (mmHg). Higher resistance – higher protection.                              |
| BFE % Bacterial Filtration Efficiency | Percentage of particles filtered out at a pore size of 1.0 – 5.0 microns (μ)   |
| Differential Pressure                 | Pressure drop across mask, or resistance to air flow in Pa/cm <sup>2</sup><br>Greater resistance = better protection but less breathability. |
| Flammability                          | Measures the flammability of the mask material.  |