

## EN 14683:2005

This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements. This European Standard is not applicable to masks intended exclusively for the personal protection of staff.

This standard is intended to help facilitate the choice of surgical face masks in the European Market by standardizing the information and performance data required for the masks.

There are three test methods used to classify surgical masks:

### 1. Bacterial Filtration Efficiency in vitro (BFE) (ASTM F2101-07)

This test is used to determine the amount of infective agent that is retained by the surgical facemask, which is directly related to the amount of bacteria released through the mask into the air of the surgical theatre.

Classification:

BFE => 95% TYPE I

BFE => 98% TYPE II

### 2. Breathing Resistance (Delta P)

This test is used to determine the resistance airflow of the facemask.

Classification:

TYPE I & II (non splash resistant) = < 29.4 Pa/cm<sup>2</sup>

TYPE IR & IIR (splash resistant) = < 49.0 Pa/cm<sup>2</sup>

### 3. Splash Resistance (ASTM F1862-07)

This test is used to determine the resistance penetration of potentially contaminated fluid splashes.

Classification:

TYPE I & TYPE II not applicable

TYPE IR & TYPE IIR >120 mmHg

120 mmHg is a minimum value. It corresponds to the average systolic arterial blood pressure, and intends to protect against ruptures in small arteries causing small sprays of blood. Some products offer protection even in excess of the 120 mmHg.

## Minimum Performance Requirements According to the New Facemask Standard

### EN14683

EU Standard Class	Bacterial Filtration Efficiency	Breathing Resistance (Pa/cm <sup>2</sup> )	Splash Resistance (mmHg)
Type I	95%	< 29.4	NA
Type IR	95%	< 49.0	> 120
Type II	98%	< 29.4	NA
Type IIR	98%	< 49.0	> 120