



PROTECTING PEOPLE

Medical Masks

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Surgical Masks

Irema has been manufacturing face masks under the Facemate brand in Ireland for over 35 years.

All Facemate and partner branded surgical masks are compliant with European Medical Device Regulations (MDR) and tested by internationally accredited independent laboratories. They are manufactured using Irema's proprietary melt-blown filtration material.

Features

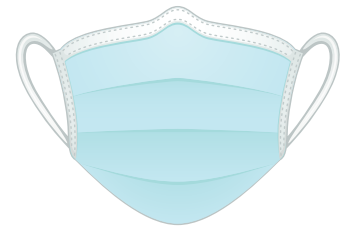
- Latex and glass fibre free
- Lightweight
- 100% synthetic
- 3-ply and 4-ply
- Hypoallergenic materials do not cause skin irritation
- Lowest possible breathing resistance

Specification

- EU Medical Device Regulation: 2017/745
- Test Standard: CE EN 14683
- Manufactured under ISO9001:2000 quality system and GMP CE marking approval
- Bacterial Filtration Efficiency BFE > 98%
- Breathing resistance (mbar) 8.0 L/min: <40.0 Pa/cm²

Facemate surgical masks are packaged either 40 or 50 masks per box with 6 boxes per case unless otherwise stated.

Earloop Surgical Masks



Facemate Classic

The Facemate Classic is a synthetic earloop or tie-on surgical mask providing continuous comfort.

- Also available in tie-on
- Type II and Type IIR earloop
- Blue (green and white available on request)



Facemate Anti-splash Type IIR

Facemate Anti-splash Type IIR mask is a 3 ply mask with elasticated earloops containing a splash resistant layer to protect the wearer against fluid splashes.

- Protects against liquid droplets
- Type IIR
- Blue and green



Facemate XtraComfort

Facemate XtraComfort surgical mask has a special inner layer of non-woven material that feels extra smooth and perfect for sensitive skin. It keeps the face cool during extended periods of use.

- Also available in tie-on
- Type II and IIR earloop
- Blue, green, or white



Tie on Surgical Masks



Facemate Anti-splash

Facemate Anti-splash Type IIR mask contains an additional splash resistant layer to protect the wearer against fluid splashes.

- 4-ply, Type IIR
- 40 per box
- Blue (green and white available on request)



Facemate Anti-fog

The Facemate Anti-fog is ideal for people who wear glasses or use optical equipment. It has a highly absorbent top binding layer that prevents glasses or surgical optics from fogging.

- Type II
- Highly absorbent top layer
- Blue (available in green and white on request)



Facemate Extra-large

Facemate Extra-large is a larger fitting mask with a wider open area to provide increased facial coverage. The mask has a foam top binding to provide a comfortable seal.

- Type II
- Suited for people with beards
- Blue (available in green and white on request)



Outsource your surgical face mask needs by partnering with Irema. All surgical and respirator masks are available in your branding.

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Respirator Masks



Facemate flat fold respirator masks protect people working in environments where harmful particles, pathogens and aerosols present a danger to their respiratory system and long-term health. They are horizontally flat folded for greater protection and comfort and without a valve, as per WHO Covid-19 guidelines.



N95, FFP2 and FFP3

Irema's Facemate respirator masks are compliant with European regulations NIOSH (N95) and CE EN 149:2001+A1:2009 (FFP2, FFP3). They are tested by internationally accredited independent laboratories.

Facemate respirator masks are manufactured using Irema's proprietary melt-blown filtration material.

Features

- Lightweight
- 100% synthetic
- Glass fibre and latex free
- Tested for differing face profiles and head sizes
- Hypoallergenic materials provide extra comfort when worn for extended periods
- Lowest possible breathing resistance
- Individually wrapped
- Adjustable nose piece with elastic straps for optimal fit and seal



Respirator masks are individually wrapped and packaged with 25 masks per box and 4 boxes per case.

Specification

- Classification in accordance with EN 149:2001 +A1:2009
- FFP2 and FFP3 CE Number 636991 NL
- N95 Approval number: TC-84A-8129, 42 CFR Part 84
- FFP2 Bacterial Filtration Efficiency (BFE): $\geq 94\%$ of all particles measuring up to $0.3\mu\text{m}$
- FFP3 Bacterial Filtration Efficiency (BFE): $\geq 99\%$ of all particles measuring up to $0.3\mu\text{m}$
- N95 Bacterial Filtration Efficiency (BFE): ≥ 95 of all particles measuring up to $0.6\mu\text{m}$

Item No:	Filter efficiency	Breathing Resistance (mbar) 30L/min	Defined Protection Level	Nominal Protection Factor
FFP2 NR	$\geq 94\%$	>0.7	10 OEL	12 OEL
FFP3 NR	$\geq 99\%$	>1.0	20 OEL	50 OEL

Item No:	Filter efficiency	Breathing Resistance (mmH2O) 85L/min
N95	95% min	≤ 35

MDR

All masks sold in the EU must be compliant with the MDR (Medical Devices Regulation (2017/745/EU) since May 2021.

The MDR governs the production and distribution of medical devices in Europe.

The regulation creates a robust, transparent and sustainable regulatory framework across the EU which improves clinical safety. Compliance with the regulation is mandatory for companies wishing to sell medical devices including face masks in Europe.

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EN 14683:2019

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 standardising 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/cm²

TYPE IR & IIR
(splash resistant) = < 49.0 Pa/cm²

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 ²)	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

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