Medicom

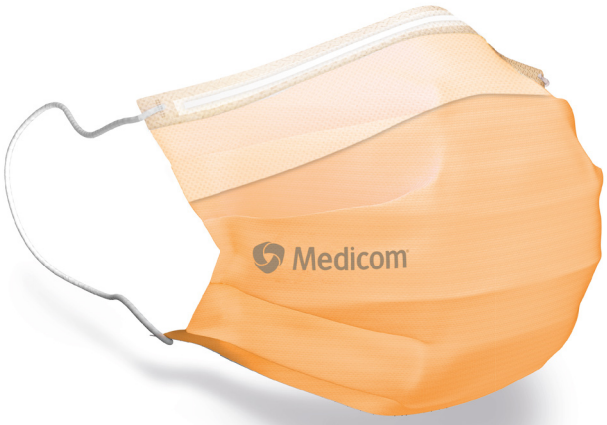
Product information

2155-FF-30 to 2162-FF-30

MEDICOM® SAFEMASK® SOFSKIN® FOG-FREE
MEDICAL MASK TYPE IIR WITH EARLOOPS
Medical Device, Class I

FEATURES & BENEFITS

- High filtration media (polypropylene)
- Integrated nose piece
- An anti-fog strip acts as a vapor barrier to minimize fogging on users' glasses
- 2 wide earloops for maximum comfort
- Anatomical folding limiting leakage to the face
- Fiber glass free filter



PRODUCT DESCRIPTION

Product name:	Medicom® SafeMask® SofSkin® fog-free - Mask - Type IIR
Product type:	Single use, non sterile
Material:	Interior layer: Wet laid cellulose
	Filter: PP Complex (Meltblown + Spunbond)
	Exterior layer: Spunbonded polypropylene
Link:	Elastic earloops
Option:	Fog-free
Dimensions:	90 mm (± 5 mm) x 175 mm (± 7 mm)
Unit weight:	4,8 g (± 10 %)
Packaging conditions:	Box of 50 units
Available colours:	White 2159-FF-30; Blue 2155-FF-30; Green 2158-FF-30; Pink 2156-FF-30; Lavender 2153-FF-30; Orange 2162-FF-30
Origin:	EU

Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 60
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Product is in compliance to Standard EN 14683: 2019.

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PRECAUTIONS
Should be used on clean, healthy skin only.
Their re-use or prolonged use can lead to infection and/or cross contamination.
After use, comply with the national regulations set in place for the disposal of the device.

CERTIFICATION & STANDARDS
Complies with the requirements of European Regulation 2017 745 relating to Medical Devices.
Manufactured under an ISO 9001 and ISO 13485 certified system.
Complies with applicable harmonized standards EN 14683.

STORAGE CONDITIONS
Normal conditions of conservation & storage: not to be exposed to moisture and sun, must be stored at a temperature between 5°C and 40°C.

LOGISTICAL INFORMATION

Outer case specifications

REF	Size mm	Unit weight kg	QTY/ pallet	EAN Code
2153-FF-30	492 x 207 x 215	2,6	73 cases	8720249903574
2155-FF-30	492 x 207 x 215	2,6	73 cases	8720249903581
2156-FF-30	492 x 207 x 215	2,6	73 cases	8720249903598
2158-FF-30	492 x 207 x 215	2,6	73 cases	8720249903604
2159-FF-30	492 x 207 x 215	2,6	73 cases	8720249903611
2162-FF-30	492 x 207 x 215	2,6	73 cases	8720249903628

Distributor Box specifications

Size mm	QTY/ Outer case	EAN Code
211 x 97 x 97	10 boxes of 50 units	8720249903383
211 x 97 x 97	10 boxes of 50 units	8720249903390
211 x 97 x 97	10 boxes of 50 units	8720249903406
211 x 97 x 97	10 boxes of 50 units	8720249903413
211 x 97 x 97	10 boxes of 50 units	8720249903420
211 x 97 x 97	10 boxes of 50 units	8720249903437

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