


## SAFE+MASK SOFSKIN 2050-BFF-30 MEDICAL MASK TYPE IIR WITH TIES AND ANTI-FOG STRIP Medical Device, Class I

### FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer while providing protection from splashes of biological fluids.
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE)
- For maximum comfort, the inner layer is designed with a material that limits irritation to the face.
- Hypoallergenic.
- The anti-fog strip prevents the glasses from fogging up.

### TECHNICAL DESCRIPTION

Product Name	<b>MEDICOM - Safe+Mask SofSkin - Mask - Type IIR</b>
Product Type:	Single-use, non-sterile
Fasteners :	Ties
Option:	Anti-fog
Dimensions	95 mm (± 5 mm) X 175 mm (± 7 mm)
Unit Weight	4,8 g (± 10%)
Packaging Conditions	Dispenser box of 50 masks
Country of Origin	France

Article	Color
2050-BFF-30	Blue 

### PRODUCT PERFORMANCES EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2019	≥ 98%	Centexbel	21.06133.02 25/10/2021	99,8 %
DELTA P	EN 14683:2019	< 60 Pa/cm <sup>2</sup>	Centexbel	22.00530.08 22/02/2022	25,9 Pa/cm <sup>2</sup>
SPLASH RESISTANCE (kPa)	EN 14683:2019	≥ 16	Centexbel	22.00530.09 22/02/2022	Compliant
Particles Filtration Efficiency 0,1µm : PFE	/	Not required	Nelson	1362445-S01 03/12/2020	99,5 %
Viral Filtration Efficiency: VFE	/	Not required	Nelson	1362444-S01 22/12/2020	99,4 %

### Microbiological Information (by ICARE)

Assessment of initial microbial contamination according to standards EN 14683: 2019+AC:2019 & ISO 11737: 2018  
Additional microbiological controls : ASR, E.coli, Staphylococci, available upon request

## SAFE+MASK SOFSKIN

# 2050-BFF-30 MEDICAL MASK TYPE IIR WITH TIES AND ANTI-FOG STRIP

Medical Device, Class I

## PRECAUTIONS

The mask must be used on intact skin only.

The reuse or extended use may lead to infection or cross-contamination.

Please refer to your national legislation on the subject of disposal of this product once it has been used.

## CERTIFICATIONS & STANDARDS

Meets the requirements of Regulation (EU) 2017/745 on medical devices.

Complies with applicable standards EN 14683: 2019 + AC:2019.

Manufacturing site: ISO 9001 and ISO 13485 certified.

## STORAGE CONDITIONS

Normal conditions of conservation & storage : not to be exposed to moisture and sunlight, must be stored in a cool environment or at room temperature.

Shelf life of the product: 5 years.

## LOGISTICS



### Outer case Specifications

Article	Size (mm)	Unit weight (kg)	QTY/pallet
2050-BFF-30	400 x 335 x 180	2,0	78 cases

### Dispenser Box specifications

Size (mm)	QTY
210 x 104 x 140	6 Dispenser boxes of 50 pieces

### EAN Codes

Article	Carton	Dispenser Box
2050-BFF-30	3 662 036 014 030	3 662 036 014 023