

# BLS 640 FFP3 NR D



DISPOSABLE CUP SHAPED FILTERING FACEPIECES FOR MEDICAL/HEALTH ENVIRONMENT (PPE)



## EN 149:2001+A1:2009 TESTS

## FFP3 NR D REQUIREMENTS

Breathing resistance (mbar)	Inhalation 30 l/min	< 1,0
	Inhalation 95 l/min	< 3,0
	Exhalation 160 l/min	< 3,0
Filter material efficiency (%)	After 63 min (long exposure)	> 99

## DESCRIPTION

BLS 640 filtering facepiece is suitable for protection against non-volatile solid and/or liquid particles up to 50\* times the Threshold Limit Value (TLV-TWA).

- Cup shape
- Head harness made by two elastics
- Adjustable nose-clip between the layers of the filtering material and soft inner lining on nose, to ensure a good face seal over a range of face sizes
- NR marking to specify that the facepiece is a single use item and it is Not Reusable for more than one work shift
- D marking to specify that the facepiece meets the clogging resistance requirements and also offers a high level of filtering efficiency in very dusty environments.
- Tested and CE approved to EN 149:2001+A1:2009 standard

\* = NPf, Nominal Protection Factor (according to EN 529:2006)

## MATERIALS

The following materials are used in the production of BLS 640 FFP3 NR D filtering facepiece:

- Filtering material: layers of non irritating, polypropylene non-woven fabric
- Nose clip: reinforced plastic material
- Gasket: expanded foam
- Elastics: synthetic rubber, non irritating, latex free
- Elastics fixing: staples
- Weight: 11 g
- Latex free
- Phthalate free

## CERTIFICATION

BLS 640 FFP3 NR D filtering facepiece meets European Regulation 2016/425 (Personal Protective Equipments) requirements and is CE marked, as a III category PPE, according to EN 149:2001+A1:2009 standard. CE Certification and final product control (module D) have been issued by Italcert S.r.l. (Notified body n°0426). These filtering facepieces are just PPE and not MD. They do not have a CND code or identification number to the Italian National Inventory of Medical Devices. BLS certifies his own Quality management System according to standard ISO 9001.

## CERTIFICATION TESTS

### EFFICIENCY FILTERING MATERIAL

Penetration of filtering material has been tested with two test aerosols, sodium chloride (NaCl) and paraffin oil. The following results in terms of penetration are registered: 1) Initial penetration (3 minutes after test starting); 2) maximum penetration during the test until reaching the concentration of 120 mg of test aerosol (exposure test) 3) only for reusable device, initial penetration after exposure test and storage (24 h). Less is the quantity of aerosol inside the facepiece, better is the filtering efficiency of the filtering material.

### TOTAL FILTERING EFFICIENCY

The total inward leakage consists of two components: face seal leakage and filter penetration. Tests provide also that ten subjects carry out a sequence of exercises that simulates the practical working activity, wearing the filtering facepiece; less is the quantity of aerosol inside the product, better is the filtering efficiency of the facepiece.

### BREATHING RESISTANCE

The breathing resistance offered by the filter has been tested with 30 l/min and 95 l/min airflows for the inhalation and 160 l/min airflow for the exhalation.

### CLOGGING

Filtering facepiece is submitted to a clogging test with dolomite dust, clogging the filter with an air flow of 95 l/min until 883 mg\*h/m<sup>3</sup> have been reached of Dolomite have been deposited or until the is reached the value of breathing resistance for that class. After clogging, the filtering facepieces are submitted to a test of filtering efficiency again.

### FLAMMABILITY

The filtering facepieces subjected to the test are passed one by one through a flame with a temperature of 800°C +/- 50°C and at a speed of 6 cm/s. Filtering facepieces must not go on burning for more than 5 seconds after removal from the flame.



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## TRANSPORT

PRODUCT	CODE	WEIGHT (g)	Q.TY/BOX	Q.TY/CARTON	Q.TY/PALLET
BLS 640	8101010	11	10*	120 (12 boxes)	4.320

\*Single pack available

## APPLICATION

BLS 640 filtering facepieces are aimed at health workers who need higher protection compared to normal surgical masks in case of filtration of smaller micronsized particles. Filtering facepieces reduce the risk of potential exposure to non-volatile solid and liquid aerosols in the air, ensuring the individual protection of the upper respiratory tract from biological agents.

## WARNINGS

1. The operator must be trained to the proper use of the filtering facepiece, before using it.
2. This product does not protect the operator against gases and vapours. For gas and vapours protection are necessary gas respirators.
3. Not to be used in atmospheres containing less than 17% oxygen.
4. Do not use when the concentrations of the contaminants are immediately dangerous for life or health.
5. Do not use in explosive atmosphere and to escape.
6. Leave the workplace immediately:
  - if breathing becomes difficult;
  - if dizziness or other distress occur.
7. Do not alter or modify the product in any way.
8. Discard and replace the filtering facepiece if it becomes damaged, if breathing becomes difficult and in any case after 8 hours work if the facepieces is NR type (max 8 hours).
9. Operator must be clean shaven as facial hair will affect the efficiency of the product.
10. Store the filtering facepiece in a dry and clean room at a temperature within +5°C and +40°C and relative humidity < 60%. If stored correctly and in the original box the product has a shelf life of 10 years and 5 years for models with carbon layer.

## STORAGE AND TRANSPORTATION

BLS 640 FFP3 NR D filtering facepieces have a shelf life of 10 years. End of shelf life (expiry date) is marked on the product box. Product should be stored in clean, dry conditions within the temperature range: +5°C to +40°C with a maximum relative humidity of 60%. When storing or transporting this product, use original box provided.

## IMPORTANT

BLS declines any responsibility, direct or indirect, from any misuse of both devices and instructions. User is responsible for the determination of product compliance with the intended use.