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DÉCLARATION DE CONFORMITÉ UE / EU KONFORMITÄTSEKLÄRUNG / EU CONFORMITEITSVERKLARING /**

(EN)

The manufacturer **BLS S.R.L.** (via dei Givi, 41 - 20032 - Cormano MI - Italy) declares that the Personal Protective Equipment (PPE) described hereafter, filtering facepiece against particles, model **Zer0 30C** /

- is in conformity with the provisions of the Regulation EU 2016/425 and the harmonized standard **EN 149:2001 + A1:2009 [UNI EN 149:2009]**
- is identical to the PPE that is subject of the EU type certificate n° **PPE011AT1955** issued by ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milan MI - Italy), notified body No. 0426
- is subject to the procedure set out in Annex VIII (module D) of the EU 2016/425 Regulation, under the control of ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milan MI - Italy) notified body No. 0426

(ES)

El fabricante **BLS S.R.L.** (via dei Givi, 41 - 20032 - Cormano MI - Italia) declara que el Equipo de Protección Individual (EPI) descrito a continuación, mascarilla desechable para partículas, modelo **Zer0 30C** /

- está en conformidad con las disposiciones del Reglamento UE 2016/425 y la norma armonizada **EN 149:2001 + A1:2009 [UNI EN 149:2009]**
- es idéntico al EPI que está sujeto al certificado de tipo UE n° **PPE011AT1955** emitido por ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milán MI - Italia), organismo notificado No. 0426
- está sujeto al procedimiento establecido en el Anexo VIII (módulo D) del Reglamento UE 2016/425, bajo el control de ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milán MI - Italia), organismo notificado No. 0426

(DE)

Der Hersteller **BLS S.R.L.** (via dei Givi, 41 - 20032 - Cormano MI - Italien) erklärt, dass die nachstehend beschriebene persönliche Schutzausrüstung (PSA), Staubmaske, Modell **Zer0 30C** /

- der Verordnung EU 2016/425 und dem harmonisierten **EN 149:2001 + A1:2009 [UNI EN 149:2009]** entspricht
- identisch zu der persönliche Schutzausrüstung (PSA) des von dem notifizierten Stelle N. 0426 (v.le Sarca, 336 - 20136 - Mailand MI - Italien) ITALCERT S.R.L., erlassenen EU-Zertifikates N. **PPE011AT1955** ist
- das vom notifizierten Stelle N. 0426 (v.le Sarca, 336 - 20136 - Mailand MI - Italien) ITALCERT S.R.L., kontrollierten Verfahren der Verordnung 2016/425 - Anlage N. VIII (Modul D) erfüllt

(IT)

Il fabbricante **BLS S.R.L.** (via dei Givi, 41 - 20032 - Cormano MI - Italia) dichiara che il Dispositivo di Protezione Individuale (DPI) di seguito descritto, facciale filtrante antipolvere, modello **Zer0 30C** /

- è conforme alle disposizioni del Regolamento EU 2016/425 e alla norma armonizzata **EN 149:2001 + A1:2009 [UNI EN 149:2009]**
- è identico al DPI oggetto del certificato UE di tipo n° **PPE011AT1955** rilasciato da ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milano MI - Italia) organismo notificato n° 0426
- è sottoposto alla procedura prevista all'Allegato VIII (modulo D) del regolamento EU 2016/425, sotto il controllo di ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milano MI - Italia) organismo notificato n°0426

(FR)

Le fabricant **BLS S.R.L.** (via dei Givi, 41 - 20032 - Cormano MI - Italie) déclare que l'Équipement de Protection Individuelle (EPI) décrit ci-dessous, pièce faciale filtrante, modèle **Zer0 30C** /

- est conforme aux dispositions du règlement UE 2016/425 et à la norme en vigueur **EN 149:2001 + A1:2009 [UNI EN 149:2009]**
- est identique à l'objet EPI du certificat de l'UE du type n° **PPE011AT1955** délivré par ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milan MI - Italie), organisme notifié n° 0426
- est soumis à la procédure décrite à l'annexe VIII (module D) du règlement UE 2016/425, sous le contrôle de ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milan MI - Italie), organisme notifié n° 0426

(NL)

De fabrikant **BLS S.R.L.** (via dei Givi, 41 - 20032 - Cormano MI - Italië) verklaart dat de persoonlijke beschermingsmiddelen (PBM) hieronder beschreven, stofmasker, model **Zer0 30C** /

- in overeenstemming is met de bepalingen van de EU-verordening 2016/425 en de geharmoniseerde norm **EN 149:2001 + A1:2009 [UNI EN 149:2009]**
- identiek is aan de PBM die is onderworpen aan het EU-typecertificaat nr. **PPE011AT1955** uitgegeven door ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milaan MI - Italië), aangemeld instantie nr. 0426
- zijn onderworpen aan de procedure die is vastgesteld in bijlage VIII (Module D) van de EU-verordening 2016/425, onder de controle van ITALCERT S.R.L. (v.le Sarca, 336 - 20136 - Milaan MI - Italië), aangemeld instantie nr. 0426

Cormano, 11/02/2021

Luciano Zani
Chairman / Presidente /
Presidente / Président /
Vorsitzende / Voorzitter /



BLS Zer0 30C FFP3 R D

DISPOSABLE CUP SHAPED FILTERING FACEPIECES WITH VALVE AND ACTIVATED CARBON FOR MEDICAL/HEALTH ENVIRONMENT (PPE)



EN 149:2001+A1:2009 TESTS

FFP3 R 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 Zer0 30C filtering facepiece is suitable for protection against non-volatile solid and/or liquid particles up to 50* times the Threshold Limit Value (TLV-TWA). Carbon layer allows to keep unpleasant smell of organic and inorganic gases and vapours present in low concentration. The cup shaped form, the elastic head harness attached to four points and the internal nose clip which can be modelled on the facepiece ensure the best fit for most facial types.

- Pre-shaped support, increases the strength of the face covering
- The exhalation valve reduces breathing resistance and the humidity inside the facepieces, making breathing more secure even in humid or very hot workplaces
- The soft inner lining on nose ensures the best fit for most facial types
- Adjustable nose-clip between the layers of the filtering material to sure a good face seal over a range of face sizes
- The external protective layer ensures the protection of the filtering material from dirt, dust and liquids extending and preserving filtering efficiency, thanks to a reduced mechanical stress, which could damage the material
- R marking to specify that the facepiece is 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 Zer0 30C FFP3 R D filtering facepiece:

- Filtering material: layers of non irritating, polypropylene non-woven fabric
- Nose clip: reinforced plastic material
- Face gasket: expanded polymers combined with polyester fabric.
- Elastics: thermoplastic elastomer
- Elastics fixing: welded
- External protective layer: polyethylene
- Valve: polypropylene
- Weight: (16 ± 1) g
- Latex free - Phthalate free
- Anti-odour filter: activated carbon

CERTIFICATION

BLS Zer0 30C FFP3 R 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/m³ 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.

BLS Zer0 30C FFP3 R D



DISPOSABLE CUP SHAPED FILTERING FACEPIECES WITH VALVE AND ACTIVATED CARBON FOR MEDICAL/HEALTH ENVIRONMENT (PPE)



01 HIGH EFFICIENCY VALVE

The exhalation valve reduces breathing resistance and reduces the humidity inside the facepieces, making breathing more secure even in humid or very hot workplaces.



03 EXTERNAL PROTECTIVE LAYER

Waterproof, ensures the protection of the filtering material from dirt, dust and liquids as well as the normal mechanical stress due to prolonged use thus extending and preserving filtering efficiency and making the device safer.



02 PRE-SHAPED SUPPORT

Increases the strength of the face covering while ensuring breathability.



04 ACTIVATED CARBON LAYER

Allows to keep unpleasant smell of organic and inorganic gases and vapours present in low concentration.

TRANSPORT

| PRODUCT | CODE | WEIGHT (g) | Q.TY/BOX | Q.TY/CARTON | Q.TY/PALLET |
|---------------|---------|------------|----------|----------------|-------------|
| BLS Zer0 30 C | 8006333 | 16 | 10* | 120 (12 boxes) | 3840 |

*Single packing available

APPLICATION

BLS Zer0 30C filtering facepieces are aimed at health workers who need higher protection compared to normal surgical masks in case of filtration of smaller micron-sized particles. The FFP3 class offers a minimum filtration efficiencies of 99%. The properties of these filtering facepieces remain unchanged in terms of filtration efficiency even after exposure after long times. Ideal for the manipulation and treatment of antineoplastic drugs.

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 Zer0 30C FFP3 R 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.