



NATIONAL INSTITUTE OF RESEARCH -
DEVELOPMENT FOR OCCUPATIONAL SAFETY
"Alexandru Dărăbont" Bucharest
Certification Body
Ed. Ghencea no. 35 A, sector 6, București, România
tel.: 021.313.31.58/021.313.17.26; fax: 021.315.78.22
tel - Certification Body: 021.314.43.30
Notified Body: NB 2756



SR EN ISO 9001:2015
CERTIFICAT DE ACREDITARE
ON 092

LICENCE

1. **This licence is issued to the organisation:** Dongyang Fenglin Luyzhou Household Co.,Ltd., 1F Building, No.3, Minghai Street No. 1036, Linshi Street, Dongyang City, Jinhua, China/Zhejiang, Unique Registration Number: Unique Registration Number: 91330783MA2HTDFT28, acting as manufacturer of the type/model of category III PPE „Single shift use filtering half mask against particles, class FFP2 NR, Model FL-KN95”, for which the notified body from INCDPM (NB 2756) have issued the EU type examination certificate No. 3556/EIP/30.06.2020

2. **Following the application of the procedure „Conformity assessment of PPE applying the procedure “EU type-examination (Module B)” set out in Regulation (EU) 2016/425”, PG EIP R MODUL B, and following the manufacturer's option to be applied, within the next 12 months, by the notified certification body of INCDPM Bucharest (NB 2756), the procedure „Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)” set out in Annex VII to Regulation (EU) 2016/425**

through this document, the notified certification body shall authorize the manufacturer:

2.1 To affix the identification number of the notified body, „2756” to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of Regulation (EU) 2016/425

2.2 To refer to the name of the certification body, its identification number as a notified body and the procedure applied in the EU declaration of conformity, the instruction and information booklet accompanying the PPE, and other informative material relating to the PPE.

3. **Licensing conditions:** The licensee must comply with the conditions set out in the above legislation, the “Regulation on the use of the conformity mark (R - MC R 7 - 01 MARCA)” set out by the notified body and the additional conditions underlying the certifications granted.

4. **Date of issue:** 30.06.2020

5. **Date of expiry of the licence:** 30.06.2021

PRESIDENT
NOTIFIED BODY

dr. eng. Dorel Constantin DARABONT



HEAD OF PPE CERTIFICATION UNIT

dr. eng. Nicoleta CRĂCIUN



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EU TYPE – EXAMINATION CERTIFICATE

No. 3556/EIP/30.06.2020

1. This certificate is issued for:

- **Type (model) of PPE:** Single shift use filtering half mask against particles, class FFP2 NR, Model FL-KN95
- **Type designation:** « FL-KN95 »
- **PPE category:** category III PPE – Equipment providing respiratory system protection
- **Manufacturer:** Dongyang Fenglin Lvzhou Household Co., Ltd., 1F Building, No.3, Mingkai Street No. 1036, Linshi Street, Dongyang City, Jinhua, China/Zhejiang, Unique Registration Number: Unique Registration Number: 91330783MA2HTDFT28
- **Trade mark of manufacturer:** -

2. General references and applied procedure for conformity assessment/applied certification scheme: Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, annex V "EU type-examination (Module B)"

3. Conclusions of the conformity assessment: Following the carrying of the conformity assessment, the notified body attests that:

- the technical design of the PPE meets the requirements of the Regulation (EU) 2016/425 that apply to it, taking into account the intended use claimed by the manufacturer and specified in the annex of this certificate;
- The PPE type complies with the applicable essential health and safety requirements set out in Annex II of the Regulation (EU) 2016/425, which apply to it, taking into account the intended use claimed by the manufacturer and specified in the annex of this certificate;
- PPE conforms to the following harmonised standard: SR EN 149+A1:2010 (EN 149:2001+A1:2009) – class FFP2 NR.

4. Validity of the certification:

- Date of expiry of the certificate: 30.06.2025.
- This certificate is valid only with Annex, as an integrated part of the former.
- The object of this certification is classified as category III PPE and consequently this certificate is to be used only in conjunction with an in force document issued by a notified body containing a statement that the PPE is submitted to one of the conformity assessment procedures referred to in point (c) of Article 19 of the Regulation (EU) 2016/425.

PRESIDENT
NOTIFIED BODY

dr. eng. Doru Costin DARABONT



HEAD OF PPE CERTIFICATION UNIT

dr. eng. Nicoleta CRĂCIUN

ENCDPM
Notified body

ANNEX

1. Designation of the model

Single shift use filtering half mask against particles, class FFP2 NR, Model FL-KN85

2. Product description

Half-mask covering the nose, mouth and partially the chin, consisting of a semicircle folded and cut obliquely towards the center of the circle, after which these parts are welded so as to generate an anatomical shape during wearing. It is made of electrostatic multilayer filter, made of cotton fibers and synthetic fibers, with a metal adjustment flange on the nose inserted between the nonwoven layers and a head fastening system consisting of 2 straps made of elastic spandex material each fixed on one side of the spring circle that can be inserted into the slots of a plastic/double hook piece. It has a pattern obtained by hot pressing the materials, in the form of a network on the edges and in the form of broken lines on both sides and around the adjustment flange on the nose. Weight: about 10 g. Each half mask is packed in a sealed plastic bag.



- **Materials:** multilayer electrostatic filter made of cotton fibers and non-woven fabrics of synthetic fibers; aluminum nose strap; head fastening system made of spandex elastic material; clamp fixing elastic straps (double hook) made of plastic

- **Location for the manufacture of the PPE:** Dongyang Fenglin Luchou Household Co., Ltd., 1F Building, No.3, Mingkai Street No. 1036, Lishui Street, Dongyang City, Jinhua, China/Zhejiang. Unique Registration Number: Unique Registration Number: 91330783MA2HTDFT28

3. Intended use: respiratory protection against solid and liquid aerosols; it is used as a single-use half-mask (for only a shift), in environments with an atmosphere without oxygen deficiency; with pollutant concentrations up to 10 times maximum admissible concentration; not used for evacuation

4. References for the conformity assessment/certification:

4.1 Procedures of the notified body: general procedure: «PPE conformity assessment applying the procedure "EU type-examination (Module B)" referred to in Regulation (EU) 2016/425 », PG EIP R MODUL B and specific procedure for equipment providing respiratory system protection, PSC EIP R-04.

4.2 Health and safety requirements to be met by the model: set out in Annex II of the Regulation (EU) 2016/425, which apply to it, taking into account the intended use claimed by the manufacturer, respectively the requirements:

- **GENERAL REQUIREMENTS APPLICABLE TO ALL PPE:** 1.1. (Design principles); 1.1.1. (Ergonomics); 1.1.2. (Levels and classes of protection); 1.1.2.1. (Optimum level of protection); 1.1.2.2. (Classes of protection appropriate to different levels of risk); 1.2.1.1. Suitable constituent materials; 1.2.1.2. (Satisfactory surface condition of all PPE parts in contact with the user); 1.2.1.3. (Maximum permissible user impediment); 1.3. (Comfort and effectiveness); 1.3.1. (Adaptation of PPE to user morphology); 1.3.2. (Lightness and strength); 1.4. (Manufacturer's instructions and information);
- **ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE:** 2.1. (PPE incorporating adjustment systems); 2.3. (PPE for the face, eyes and respiratory systems); 2.4. (PPE subject to ageing); 2.6. (PPE for use in potentially explosive atmospheres); 2.8 (PPE for intervention in very dangerous situations); 2.9. (PPE incorporating components which can be adjusted or removed by the user); 2.12. (PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety);
- **ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS:** 3.10. (Protection against substances and mixtures which are hazardous to health and against harmful biological agents) 3.10.1 (Respiratory protection).

4.3 Standards and other specifications

- **Harmonised standards**

- SR EN 149+A1:2010 (EN 149:2001+A1:2009) «Respiratory protective devices-Filtering half masks to protect against particles- Requirements, testing, markings»

5. Information related to the carried out type testing and examination

- Code of technical file at the notified body: EIP 4/222
- Language of technical file submitted to examination: English.
- Reference model: -.
- Conformity assessment activities: The conformity assessment has been carried out
- Technical file submitted to examination: code 2020IU FL-KN95+ manufacturer information file code 2020IU FL-KN95.
- Test reports and certificate s used in evaluation of conformity:
 - Test report Nr. 5783/16.06.2020 issued by Laborator MIP din INCDPM
 - Test Report Nr. BT20050601626-1 of 27.05.2020, issued by BeFitLab Test Test Ltd, China

- Evaluation report: RE/EIP/2387/30.06.2020 (confidential)

6. Conclusion of the EU type examination

The technical design of the PPE model "Single shift use filtering half mask against particulate Model FL-KN95" meets the requirements of the Regulation (EU) 2016/425 and essential requirements corresponding to the intended use. The model submitted to the conformity assessment according to the technical file, meets the specifications included in the technical file and the

- SR EN 149 + A1: 2010 (EN 149: 2001 + A1: 2009) - all requirements for single-use particulate filter half mask, without exhalation valve, class FFP2 NR, having the following

- total inward leakage: $\leq 11\%$ for at least 46 out of 50 individual results and $\leq 8\%$ for 10 results per wearer;
- penetration of the test filter material with sodium chloride, 95 l / min: maximum 6%;
- penetration of the test filter material with paraffin oil, 95 l / min: maximum 6%;
- resistance to inhalation at an air flow of 30 l / min: maximum 0.7 mbar,
- resistance to inhalation at an air flow of 90 l / min: maximum 2.4 mbar;
- resistance to exhalation at an air flow of 160 l / min: maximum 3.0 mbar.
- carbon dioxide content of the inhaled air (dead space): $\leq 1.0\%$ (average value per volume).

According to the manufacturer's option, PPE production shall be submitted to the procedure based on internal production control plus supervised product checks at random intervals (Module "Annex VII" at the notified body of INCDPM Bucharest.

The permanent marking on each item shall be conform to the following model (mini

Marking symbols	Significance	PI
Fenglin	Identification of manufacturer	O
FL-KN95	Manufacturer's type/model designation	pr
EN 149:2001+A1:2009 FFP2 NR	European Standard to comply with + class of PPE according the standard + symbol for single shift use only	
CE 2756	CE marking including the identification number of notified body involved in the procedure set out in Annex VII.	

DECLARAȚIE DE CONFORMITATE UE
NR.....

The manufacturer: Dongyang Fenglin Lvzhou Household Co.,Ltd.

Established in:

1F Building

No.3, Mingkai Street No. 1036, Liushi Street, Dongyang City, Jinhua

Tel: +86 (0)15157006607, e-mail: ywag@163.com; Unique Regis

91330783MA2HTDFT28

We declare on our own sole responsibility that the new products provided by the

Single shift use filtering half mask against particles, class FFP2 NR, Mo
batch..... indicated on the collective batch /items accompanied by this declar

is in conformity with:

- **The provision of the Regulation (EU) 2016/425 corresponding to cat**
that are specified at letter (a) in Annex I (a) and to the scope of use
manufacturer's instruction and information sheet
- **The harmonised standards:**
 - **SR EN 149+A1:2010 (EN 149:2001+A1:2009) – class FFP2 NR**

The items put on the market are identical to the model being the obje
„EU type-examination (module B) set out in annex V of the Regulation (EU) 2016
„EU type-examination Certificate No. 3556/EIP/30.06.2020 has been issued by t

INCDPM București

B-dul Ghencea nr. 35 A

Sector 6, București

(notified body NB 2756)

Production of the PPE is submitted to the conformity assessment procedure «Conf
on internal production control plus supervised product checks at random intervals
out in Annex VII of the Regulation (EU) 2016/425 under surveillance of the notifi
Bucharest.

Signed for and on behalf of: ...

General manager,

Yiqing Zheng

Place of issue: official site of manufacturer

Date of issue: