# FFP2 Atemschutzmaske ohne Ausatemventil

CE 2163

## Modell JU FM0201-966

Voll zertifizierte Atemschutzmaske FFP2 nach **EN149:2001+A1:2009** Konformitätskennzeichen entsprechend der PSA-VO (EU) 2016/425. Trotz PSA Richtlinie ist die Verwendung einer FFP2 Maske im medizinischen Bereich nicht nur erlaubt, sondern wird die Verwendung auf Grund Ihrer filtrierenden Wirkung unter anderem von der BfArM, dem RKI und der IHK im medizinischen Bereich empfohlen.

## Produktinformationen

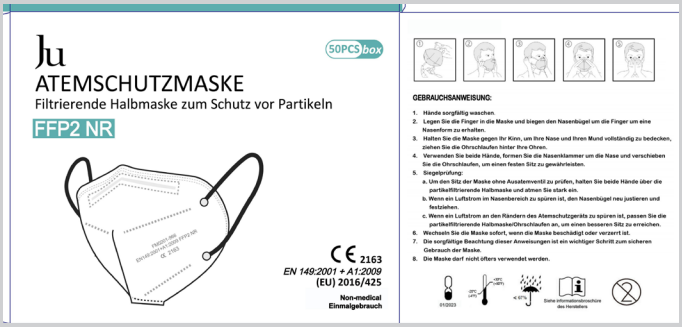
- 5-lagig
- Elastische Ohrschlaufen
- Material: 43% Vlies, 30% Meltblown Vlies, 27% Heißluft-Baumwolle
- Farbe: weiß
- Einmalgebrauch
- Latex-frei
- 2 Jahre Haltbarkeit unter Einhaltung der Lagervorgaben
- Abmessung: 20,8*18,5cm

## Verpackung durchgängig in deutscher Sprache

- Einzeln verpackte Maske im Polybag mit allen notwendigen Informationen
- Polybag inkl. Stanzung zum Aufhängen an Warenträgern (Polybag: 13*16cm)
- 50 Polybags in einer Box (Box: 20*14,5*16cm)
- 20 Boxen im Karton (1.000 Masken / Karton)
- Karton: 75*41,5*34 / 11,2 Kg
- Individueller Barcode je Verpackungseinheit

**Verpackung Polybag // Vorder- und Rückseite**

**Verpackung Box Vorderseite + Seitenansicht 1**




**Verpackung Box Rückseite + Seitenansicht 2**


# Informationen zum Hersteller // Qualitätssicherung

Da die Qualität bei jeglicher Schutzausrüstung höchstes Gut ist, verfügt der Hersteller über 70 Mitarbeiter in der Qualitätsprüfung. Diese stellen Schichtübergreifend bei jeder Charge die Qualität der Masken sicher. Hierbei werden zuerst optische und haptische Merkmale nach einer hinreichenden Checkliste überprüft (Passform, Überprüfung von Filtervliesen, Prüfung der Stabilität von Nasenklammern und Bändern). Anschließend erfolgen Funktionstests zur Überprüfung der Filterleistung sowie des Atemwiderstands.

Der Hersteller der Maske „Zhejiang Lily Underwear Co. Ltd." wurde im Jahr 1994 gegründet und zählt mit seinen über 2.000 Mitarbeitern zu den vier größten Textilherstellern Chinas. Bereits im Jahr 2002 führte der Hersteller ein international anerkanntes Qualitätsmanagementsystem (ISO 9001), ein Umweltmanagementsystem (ISO 14001:2004) sowie ein Managementsystem für Sicherheit und Gesundheit am Arbeitsplatz (OHSAS 18001:1999) ein. Ferner wurde der besondere Qualitätsanspruch durch die Zertifizierung einer von der europäischen Union zugelassenen benannten Stelle, unterstrichen. Dieses bescheinigte neben dem Modul B (Baumusterprüfung) das Modul C2, welches die Überwachung der Konformität mit der Bauart der Maske „JU FM0201-966" auf der Grundlage einer internen Fertigungskontrolle mit überwachten Produktprüfungen gemäß dem Standard EN 149:2001+A1:2009 in unregelmäßigen Abständen sicherstellt.

Die Produktionskapazität der FFP2-Maske „JU FM0201-966" liegt bei 2,5 Millionen Stück pro Tag. Ferner wird diese FFP2-Maske auch unter der Eigenmarke „Lux Tools" in einigen Filialen von dem Baumarktriesen Obi vertrieben. Weiter ist der Hersteller auf der sogenannten „White List" als Produzent für FFP2 Atemschutzmasken gelistet (Position 29 – Stand Dezember 2020)

# Informationen zur Umverpackung

CE 2163

**FFP2 Filtrierende Halbmaske**

JU - FM0201-966



## Polybag

Einzeln verpackt im Polybag.
(deutsche Verpackung)

**CE 2163**



| Produktzertifikat Konformität PRODUCT CERTIFICATE OF CONFORMITY | |
|---|---|
| Marke | JU |
| Produkt | Filtrierende Atemschutzmaske FFP2 NR |
| Kategorie | Nicht medizinisch |
| Modell / Abmessung | FM0201-966 / 20.8cm * 18.5cm |
| Material | 43 % Vlies, 30% Meltblown Vlies, 27% Heißluft-Baumwolle |
| Menge | 1 Stück |
| Lot | OC21000057 |
| Produktionsdatum | 15/01/2021 |
| Haltbarkeitsdatum | 14/01/2023 |
| Prüfer | (05) |
| Zertifiziert nach Standard | EN149:2001+A1:2009 PSA Verordnung (EU) 2016/425 |
| Importeur | Agentur Pflichtfeld / 70191 Stuttgart |
| ZHEJIANG LILY UNDERWEAR CO., LTD. 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China. | |

## Box

50 Masken einzeln verpackt in Polybags in einer Box.
(deutsche Verpackung)




**Karton**

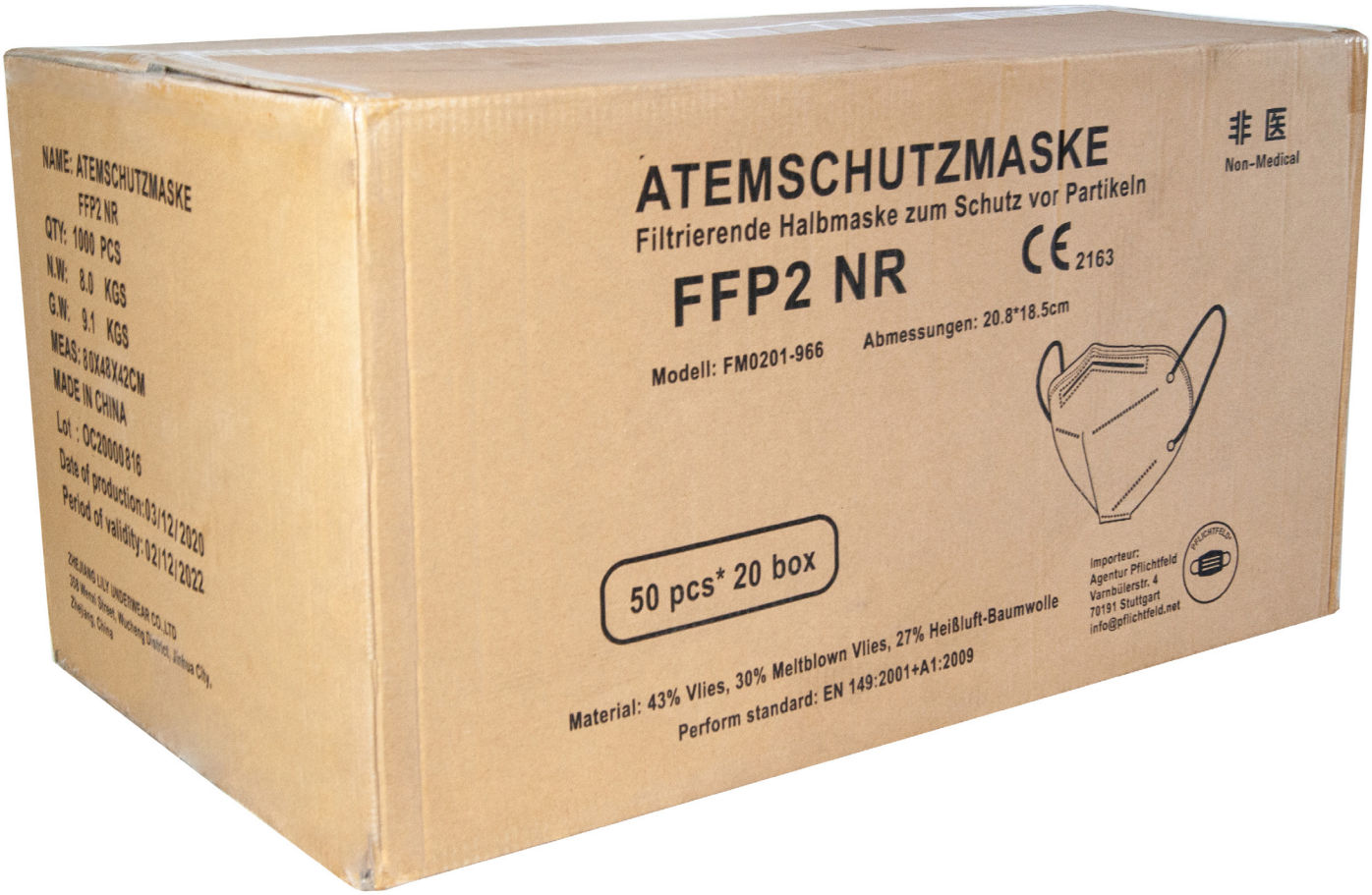
20 Boxen in einem Karton.

>> 1.000 Masken pro Karton

>> 74*41,5*34cm / 12 KG

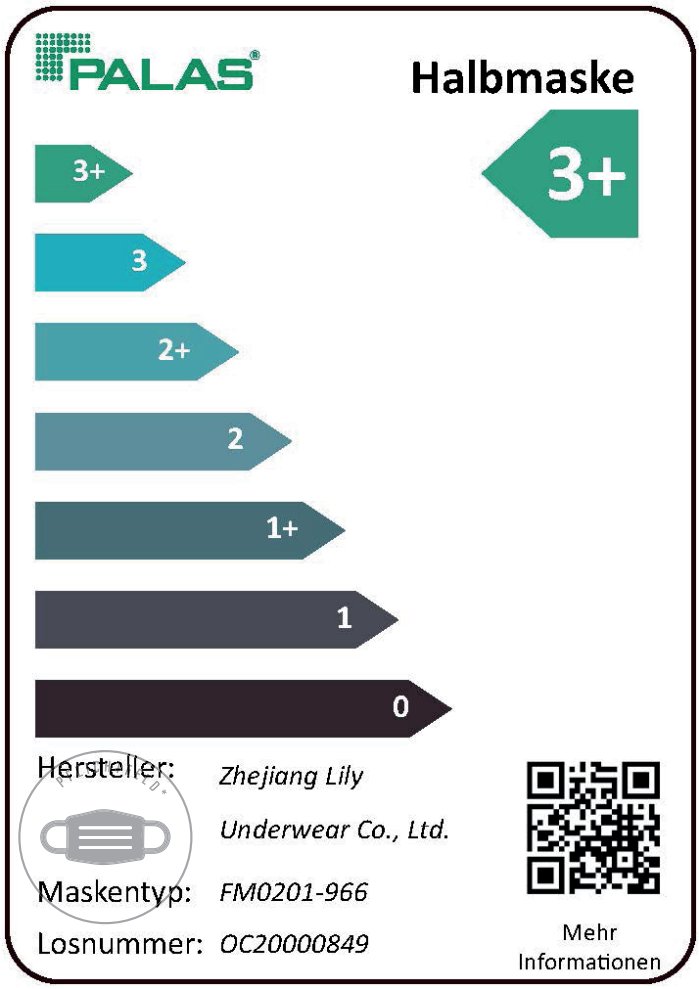
(deutsche Verpackung)

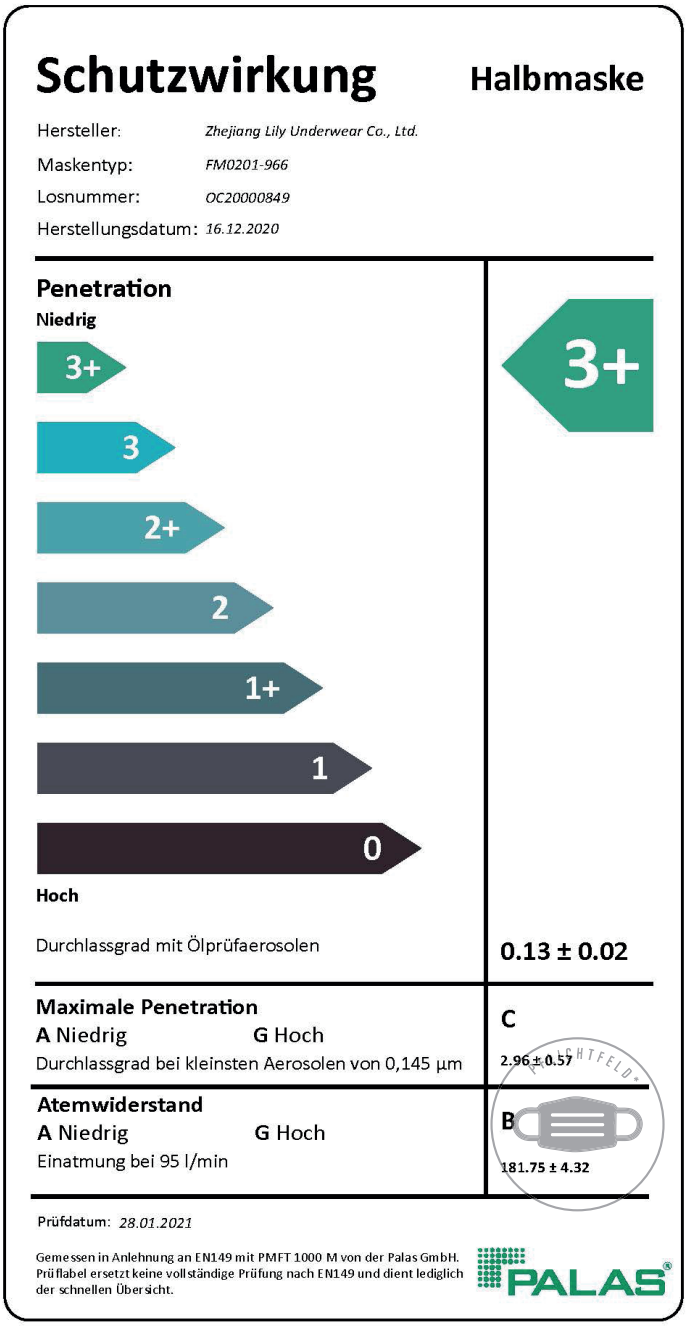
**CE 2163**



# Prüfergebnisse Palas

CE 2163




## Erklärung

Messungen werden an fabrikfrischen Mustern durchgeführt.

**Penetration*:**
Durchlassgrad der Maske; prozentualer Anteil der Partikel, die die Maske passieren und potentiell eingeatmet werden können. Je kleiner der Wert, desto sicherer die Maske, bei optimalem Tragen.

| | | |
|---|---|---|
| 3+: | < 0,5 % | (FFP1, FFP2, FFP3) |
| 3: | 0,5 – 1 % | (FFP1, FFP2, FFP3) |
| 2+: | 1 – 3,5 % | (FFP1, FFP2) |
| 2: | 3,5 – 6 % | (FFP1, FFP2) |
| 1+: | 6 – 13 % | (FFP1) |
| 1: | 13 – 20 % | (FFP1) |
| 0: | > 20 % | |

**Maximale Penetration*:**
Durchlassgrad bei 0,145 µm. Je kleiner der Wert, desto sicherer die Maske, bei optimalem Tragen.

| | |
|---|---|
| A: | < 0,5 % |
| B: | 0,5 – 1 % |
| C: | 1 – 3,5 % |
| D: | 3,5 – 6 % |
| E: | 6 – 13 % |
| F: | 13 – 20 % |
| G: | > 20 % |

*Basierend auf einer Partikelgrößenverteilung mit Median =0,29 µm und geom. Standardabweichung = 1,85
(Abweichende Ergebnisse nach EN149 möglich, da der Median zwischen 0,29 und 0,45 µm und die geometrische Standardabweichung zwischen 1,6 und 2,2 liegen darf.)

**Atemwiderstand:**
Widerstand, der beim Atmen überwunden werden muss. Je geringer, desto angenehmer.

| | | |
|---|---|---|
| A: | < 150 Pa | (FFP1, FFP2, FFP3) |
| B: | 150 - 210 Pa | (FFP1, FFP2, FFP3) |
| C: | 210 - 240 Pa | (FFP2, FFP3) |
| D: | 240 - 300 Pa | (FFP3) |
| E: | 300 - 350 Pa | |
| F: | 350 - 400 Pa | |
| G: | > 400 Pa | |

PALAS

## Palas Prüfung

Wir haben unsere FFP2 JU FM0201-966 bei der Palas GmbH den Mas-Q-Check durchlaufen lassen.

https://www.youtube.com/watch?v=xmiG-Rptnog&feature=emb_title

# EU-Konformitätserklärung

Diese Erklärung wird in die für das Bestimmungsland des Produkts geeignete Sprache übersetzt.

1. Persönliche Schutzausrüstung (Produkt, Typ): FFP2

Product Code: FM0201-966 Foto des Produkts:

Name: Ju

2. Name und Anschrift des Herstellers und seines Bevollmächtigten (falls zutreffend)

Hersteller

Firmenname: Zhejiang lily Underwear Co., Ltd.

Adresse: no.358 Wenxi street, Wucheng District, Jinhua City, Zhejiang Province, China

Zugelassener Vertreter der EU:

Name: medpath GmbH

Adresse: Mies van der Rohe Straße 880807, München, Deutschland

3.Diese Konformitätserklärung liegt in der alleinigen Verantwortung des Herstellers:

4. Gestellter Zweck (Identifizierung der PPE, Rückverfolgbarkeit möglich; falls erforderlich

Die Identifizierung der persönlichen Schutzausrüstung kann ein ausreichend klares Farbbild umfassen: eine Gesichtsmaske mit CE-Kennzeichnung (FFP2 NR: fm0201-966).

5. Der Zweck der Erklärung gemäß Buchstabe 4 ist mit den einschlägigen harmonisierten EU-Rechtsvorschriften vereinbar:

Verordnung der PPE (EU) 2016 /425.

6. Verweis auf die einschlägigen harmonisierten Normen, einschließlich des Datums der Norm, oder Verweis auf andere technische Spezifikationen, einschließlich des Datums der Spezifikation, in der die Einhaltung erklärt wird:

EN 149:2001+A1:2009

7.Unterrichtet die Agentur gegebenenfalls über die allgemeinen Zertifizierungs- und Aufsichtsdienste.NB 2163, necip FAZ Kombi353I bulvar Kombi353535; keyap sitesi E2 Blok Nr: 44 / 84 Yukar-353; duduilu, Omraniye, Istanbul, Türkei, EU-Baumusterinspektion (Modul B) wurde durchgeführt und das EU-Baumusterinspektionsbescheinigung 2163-ppe-634 wurde ausgestellt.

8. Soweit zutreffend, persönliche Schutzausrüstung wird gemäß dem Konformitätsbewertungsverfahren durchgeführt, das auf der Zufallskontrolle interner Fertigungskontroll- und Überwachungserzeugnisse (Modul C2) basiert, und das Modul C2-Zertifikat wird gemäß der überwachten Produktinspektion der benannten Stelle Universalzertifizierung und Aufsicht Service Trade Co., Ltd. ausgestellt.NB 2163 necip fezftl Bulvar /T keyap sites'e2 Lot Nr. 44 / 84 yukark dudududududullu, omraniye, Istanbul, T ürkei,

9 Zusatzinformationen: nicht zutreffend

Name und Position: Vorsitzender Huang Xuxiao

Ort und Datum der Ausstellung: 7.09. 2020

Unterschrift:

ASDET

# EU Declaration of Conformity

According to Regulation (EU) 2016/425

Manufacturer Name: Zhejiang Lily Underwear Co., Ltd
Address: No. 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China
Product name: Filtering Half Mask
Classification: FFP2 NR
Product Model No.: FM0201-966
Product Size: 20,8 cm x 18,5 cm
Color: White
Brand Name: JU

Conformity Assessment Procedure: Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notify Body NB 2163 Universal Certification and Surveillance Service Trade Ltd. Co., Necip Fazil Bulvari Keyap Sitesi E2 Blok No: 44/84 Yukari Dudullu Ümraniye-Istanbul, Turkey, (Certificate No. 2163-PPE-634/01)
Conformity Assessment Route: Annex VII
Applicable standard(s): EN 149:2001 + A1:2009 Official Journal L81/77 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking
LOT: OC20000268

The undersigned herewith declare that the stated Personal Protective Equipment meets the transposition into national law, the provisions of council regulation (EU) 2016/425 and with the essential health and safety requirements of Annex II. The Notify Body NB 2163 Universal Certification and Surveillance Service Trade Ltd. Co. has performed the EU Type-Examination (Module B and Module C2) according to Annex V and issued the EU Type-Examination Certificate No. 2163-PPE-634 and 2163-PPE_634/01. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DOC.

Signatures (on behalf of the manufacturer):

Name of authorized signatory: Huang Xu Xiao
Position held in the company: Chairman

Manufacturing date: 2020-05-06
Place: Jinhua, Zhejiang, China

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# EU TYPE EXAMINATION CERTIFICATE

## Certificate Nr: 2163 - PPE - 634

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**ZHEJIANG LILY UNDERWEAR CO. LTD.**

No 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, CHINA

are tested and evaluated according to

**EN 149:2001+A1:2009 Respiratory Protective Devices - Filtering Half Masks To Protect Against Particles - Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation. The details of essential requirement compliance is given in technical report numbered KKD-2163-635.

**Product Definition**

**Brand Name:** JU **Model :** FM0201-966

Filtering half mask

**Total Inwards Leakage:** Class – FFP2

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **27/04/2020** and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80

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# CERTIFICATE OF CONFORMANCE

## Certificate Nr: 2163 - PPE – 634/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**ZHEJIANG LILY UNDERWEAR CO. LTD.**

at the following manufacturing site

No 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, CHINA

Continues to fulfil the requirements of

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation. The details of compliance is given in technical report numbered PPE-2163-635/01

**Product Definition**

| Model | Class | EU Type Examination Certificate | | |
|---|---|---|---|---|
| | | Serial Nr. | Date | Issuing NB Nr. |
| FM0201-966 | FFP2 | 2163-PPE-634 | 27.04.2020 | 2163 |

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **27.04./2020** and will be valid for one year, until **26/04/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

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# EU TYPE EXAMINATION CERTIFICATE

## Certificate No: 2163-PPE-634

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**ZHEJIANG LILY UNDERWEAR CO. LTD.**

No 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, CHINA

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

### Product Definition

Single shift use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 5 layers polypropylene non-wowen fabrics, without valve, fitted with ear loops, internal nose clip.

**Brand Name:** JU **Model:** FM0201-966
Filtering half mask
**Classification:** FFP2 NR
For more details, refer technical evaluation report provided to the manufacturer, dated 04.01.2021 and number 2163-KKD-635-R1

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation.

This certificate is initially issued on **27/04/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

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Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

*This certificate is re-issued on 04.01.2021(Rev1) with include more information on the certified model.*

Verify the validity with the QR code

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**TECHNICAL ASSESSMENT REPORT**

**REPORT DATE / NO:** 04.01.2021 / 2163-KKD-635-R1
Initial report date and number: 27.04.2020 / 2163-KKD-635
This report is updated to include more information on the certified model.

**Manufacturer:** ZHEJIANG LILY UNDERWEAR CO. LTD.
**Address:** No 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, CHINA

This report is for the, given above, manufacturer prepared according to the test results obtained for the product dated 25.04.2020 with ID 04-2020-T-049 based on EN 149:2001 + A1:2009 standard, The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate No. 2163 - PPE - 634 issued to the manufacturer. The test results and issued certificate belongs only to the tested product. The technical report consists of a total of 6 pages.

**Product Description:** Single shift use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 5 layers polypropylene non-wowen fabrics, without valve, fitted with ear loops, internal nose clip.

**Component and Materials:**

| Component | Material | Grade / Size |
|---|---|---|
| 1st layer (Outer) | Non-woven fabric | 50 g/m2 (± 2.5 g/m2) |
| 2nd layer | Melt-blown - non-wowen fabric | 25 g/m2 (± 2.5 g/m2) |
| 3rd layer | Melt-blown - non-wowen fabric | 25 g/m2 (± 2.5 g/m2) |
| 4th layer | Hot Air Cotton | 50 g/m2 (± 2.5 g/m2) |
| 5th layer (Inner) | Non-woven fabric | 30 g/m2 (± 2.5 g/m2) |
| Nose Clip | PE coated Iron wire | 85 mm (± 5 mm) |
| Ear Loops | 70% polyamide 30% elastane | Length 18.0 cm (± 0.5 cm) |

**Classification:** FFP2 NR
**Brandname:** JU Model: FM0201-966




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## ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

**1.1. Design principles**

**1.1.1. Ergonomics**

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest prossible level.

**1.1.2. Levels and classes of protection**

**1.1.2.1. Highest level of protection possible**

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

**1.1.2.2. Classes of protection appropriate to different levels of risk**

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

**1.2. Innocuousness of PPE**

**1.2.1. Absence of risks and other inherent nuisance factors**

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

**1.2.1.1. Suitable constituent materials**

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

**1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

**1.2.1.3. Maximum permessible user impediment**

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

**1.3 Comfort and effectiveness**

**1.3.1. Adaptation of PPE to user morphology**

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

**1.3.2. Lightness and design strength**

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

**1.4. Information supplied by the manufacturer**

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

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## 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

### 2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

### 2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

### 2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

### 2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

### 2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

### 2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

### 2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

### 3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.
The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.
The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.




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Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

## Conforming to EN 149:2001 + A1:2009 Standard Requirements

*Article* 5

**Classification:** Particle Filtering Half Mask
The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as;
Filtering Efficiency and Maximum Total Inward Leakage: Classified as **FFP2**
Mask is classified for single shift use, **NR**

*Article* 7.4

**Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report. Details given in Annex 9.1 of Technical File

*Article* 7.5

**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users. Manufacturer declares that the material do not have any adverse effect for the wearers health in Section 7 of the Technical File.
Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.

*Article* 7.6

**Cleaning and Disinfection:** Particle filtering half mask is **not** designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.

*Article* 7.7

**Practical Performance :**
The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfactions reported during total inward tests about the comfort, field of vision and fastening issues.

| Assessed Elements | Positive | Negative | Requirements in accordance with EN 149:2001 + A1:2009 and Result |
|---|---|---|---|
| 1.The face piece fitting | 2 | 0 | Positive results should be obtained from the performance tests related to the implementation under real conditions.<br><br>**No imperfections** |
| 2.Head harness comfort | 2 | 0 | |
| 3.Security of fastenings | 2 | 0 | |
| 4.Speech clearness | 2 | 0 | |
| 5.Field of vision | 2 | 0 | |
| 6.Materials compatibility with skin | 2 | 0 | |

**Conditioning :** (A.R.) As Received, original

*Article* 7.8

**Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

*Article* 7.9.1

**Total Inward Leakage:**

The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report.

| Test Subject | No.of sample | Condition | 1.Walk | Head left /right | Head up /down | Speech | 2. Walk | Average |
|---|---|---|---|---|---|---|---|---|
| 1 | 32 | A.R | 4,99 | 5,21 | 4,79 | 5,12 | 4,72 | 4,97 |
| 2 | 33 | A.R | 4,96 | 5,39 | 4,88 | 5,49 | 4,78 | 5,10 |
| 3 | 34 | A.R | 4,91 | 5,62 | 4,96 | 5,74 | 4,91 | 5,23 |
| 4 | 35 | A.R | 4,78 | 5,56 | 4,61 | 5,43 | 4,67 | 5,01 |
| 5 | 36 | A.R | 4,83 | 5,61 | 4,66 | 5,63 | 4,78 | 5,10 |
| 6 | 16 | T.C. | 5,10 | 5,42 | 5,09 | 5,30 | 5,14 | 5,21 |
| 7 | 17 | T.C. | 5,24 | 4,79 | 5,21 | 5,41 | 5,13 | 5,16 |
| 8 | 18 | T.C. | 5,19 | 4,36 | 5,16 | 5,34 | 5,17 | 5,04 |
| 9 | 19 | T.C. | 5,23 | 5,56 | 5,28 | 5,52 | 5,23 | 5,36 |
| 10 | 20 | T.C. | 5,20 | 5,66 | 5,26 | 5,24 | 5,17 | 5,31 |
| | | | | | | | | |
| Average | | | 5,04 | 5,32 | 4,99 | 5,42 | 4,97 | 5,15 |
| Min | | | 4,78 | 4,36 | 4,61 | 5,12 | 4,67 | 4,97 |
| Max | | | 5,24 | 5,66 | 5,28 | 5,74 | 5,23 | 5,36 |

All 50 individual exercise results were not greater than 11 %.
At 10 individual wearer arithmetic means were not greater than 8 %.

**Conditioning :** (A.R.) As Received, original
(T.C.) Temperature conditioning

Results P (%) Leakage Value

**Results meet with FFP2 requirements**

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*Article* 7.9.2

**Penetration of filter material:** Sodium Chloride Testing

| Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 23 | 3,94 | FFP1 ≤ 20 %<br>FFP2 ≤ 6 %<br>FFP3 ≤ 1 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class **(FFP1, FFP2)** |
| (A.R.) | 24 | 3,88 | | |
| (A.R.) | 25 | 3,79 | | |
| (S.W.) | 1 | 4,16 | | |
| (S.W.) | 2 | 4,22 | | |
| (S.W.) | 3 | 3,95 | | |
| (M.S. T.C.) | 7 | 4,26 | | |
| (M.S. T.C.) | 8 | 4,35 | | |
| (M.S. T.C.) | 9 | 4,42 | | |

**Conditioning :** (M.S.) Mechanical Strength, (T.C.) Temperature Conditioning, (A.R.) As Received, original (S.W.) Simulated wearing treatment

*Article* 7.9.2

**Penetration of filter material: :** Paraffin Oil Testing

| Condition | No. of Sample | Paraffin Oil Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 26 | 4,20 | FFP1 ≤ 20 %<br>FFP2 ≤ 6 %<br>FFP3 ≤ 1 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class **(FFP1, FFP2)** |
| (A.R.) | 27 | 4,26 | | |
| (A.R.) | 28 | 4,13 | | |
| (S.W.) | 4 | 3,96 | | |
| (S.W.) | 5 | 3,94 | | |
| (S.W.) | 6 | 3,86 | | |
| (M.S. T.C.) | 10 | 4,15 | | |
| (M.S. T.C.) | 11 | 4,08 | | |
| (M.S. T.C.) | 12 | 4,17 | | |

**Conditioning:** (M.S.) Mechanical Strength, (T.C.) Temperature Conditioning, (A.R.) As Received, original (S.W.) Simulated wearing treatment

*Article* 7.10

**Compatibility with skin:** In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

*Article* 7.11

**Flammability :**

| Condition | No. of Sample | Visual inspection | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 37 | 1,4 | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | **Passed**<br>Filtering half masks fulfill requirements of the standard |
| (A.R.) | 38 | 1,3 | | |
| (T.C.) | 21 | 1,2 | | |
| (T.C.) | 22 | 1,2 | | |

**Conditioning :** (A.R.) As Received, original (T.C.) Temperature Conditioning

*Article* 7.12

**Carbon dioxide content of the inhalation air:**

| Condition | No. of Sample | $CO_2$ content of the inhalation air [%] by volume | An average $CO_2$ content of the inhalation air | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|---|
| (A.R.) | 41 | 0,86 | 0,87 | $CO_2$ content of the inhalation air shall not exceed an average of 1,0% by volume | **Passed**<br>Filtering half masks fulfill requirements of the standard |
| (A.R.) | 42 | 0,82 | | | |
| (A.R.) | 43 | 0,93 | | | |

**Conditioning :** (A.R.) As Received, original

*Article* 7.13

**Head harness:** In Practical Performance report, No adverse effects have been reported for holding the mask of the head harness firmly in position, for total inward leakage properties.

*Article* 7.14

**Field of vision :** In Practical Performance report, No adverse effects were reported for the field of vision features.

*Article* 7.16

**Breathing Resistance:** Inhalation

| Condition | Inhalation Resistance (mbar) | | | | | |
|---|---|---|---|---|---|---|
| | No. of Sample | Flow Rate 30 L/min | Requirements in accordance with EN 149:2001 + A1:2009 | Flow Rate 95 L/min | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
| (A.R.) | 29 | 0,5 | FFP1 ≤ 0,6<br>FFP2 ≤ 0,7<br>FFP3 ≤ 1,0 | 1,3 | FFP1 ≤ 2,1<br>FFP2 ≤ 2,4<br>FFP3 ≤ 3,0 | **Passed** |
| (A.R.) | 30 | 0,5 | | 1,1 | | |
| (A.R.) | 31 | 0,4 | | 1,3 | | |
| (S.W.) | 1 | 0,5 | | 1,4 | | |
| (S.W.) | 2 | 0,5 | | 1,3 | | |
| (S.W.) | 3 | 0,6 | | 1,5 | | |
| (T.C.) | 13 | 0,6 | | 1,6 | | |
| (T.C.) | 14 | 0,5 | | 1,3 | | |
| (T.C.) | 15 | 0,5 | | 1,3 | | |

**Conditioning :** (A.R.) As Received, original (S.W.) Simulated wearing treatment (T.C.) Temperature Conditioning

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*Article* 7.16

**Breathing Resistance** : Exhalation

| No. of Sample | Condition | Flow rate | Facing directly | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity /Nonconformity |
|---|---|---|---|---|---|---|---|---|---|
| 29 | As received | 160 l/min | 2,1 | 2,0 | 2,0 | 2,0 | 2,0 | FFP1 ≤ 3,0<br>FFP2 ≤ 3,0<br>FFP3 ≤ 3,0 | Passed |
| 30 | | | 2,0 | 2,1 | 2,1 | 2,0 | 1,9 | | Passed |
| 31 | | | 2,0 | 2,1 | 2,0 | 2,1 | 2,3 | | Passed |
| 1 | Simulated wearing treatment | | 2,2 | 2,2 | 2,0 | 2,0 | 2,0 | | Passed |
| 2 | | | 2,0 | 2,2 | 1,9 | 2,0 | 2,0 | | Passed |
| 3 | | | 2,0 | 2,3 | 2,0 | 2,2 | 2,1 | | Passed |
| 13 | Temperature conditioned | | 2,0 | 2,1 | 2,2 | 1,9 | 2,1 | | Passed |
| 14 | | | 2,1 | 2,2 | 2,1 | 2,2 | 2,2 | | Passed |
| 15 | | | 2,0 | 2,1 | 1,9 | 2,0 | 2,0 | | Passed |

| | |
|---|---|
| *Article* 7.17.2 | **Clogging :** This test is not applied to Particle Filtering Half Mask which is not reusable.<br>***(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*** |
| *Article* 7.17.3 | **Penetration of filter material:** This test is not applied to Particle Filtering Half Mask which is not reusable. |
| *Article* 7.18 | **Demountable Parts:** There are no demountable parts on the product. |
| *Article* 8 | **Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask. |
| *Article* 9 | **Marking – Packaging:** Necessary markings are available on the product package (box). The name and trademark of the manufacturer is stated to exist on the carton boxes. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the year of end of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file.<br><br>The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing Annex 6. The mask template (drawing) indicates that the mask will carry information about the brandname of the manufacturer, type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested samples by the laboratory do not carry necessary marking information, as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. FM0201-966 drawing, which exists in the technical file of the manufacturer, as Annex 6 of technical file. |
| *Article* 10 | **Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate, Annex 8. The manufacturer shall include this documented user information text in every smallest commertially available package. |

| PREPARED BY | APPROVED BY |
|---|---|
| **Murat AYDEMİR**<br>PPE Expert | **Suat KAÇMAZ**<br>General Manager |

UNIVERSAL CERTIFICATION CE 2163 Notified Body



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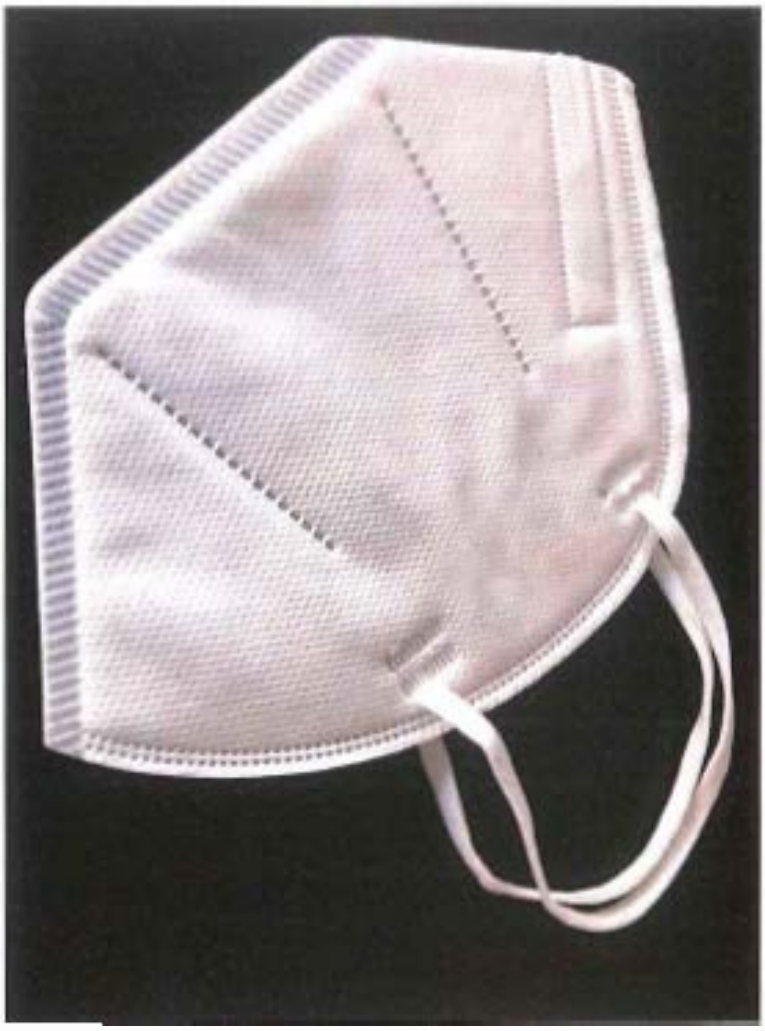
## TECHNICAL ASSESSMENT REPORT

**REPORT DATE / NO :** 27.04.2020 /PPE-2163-635

**Client:** ZHEJIANG LILY UNDERWEAR CO. LTD
Address: No 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, CHINA
This report is for the, given above, manufacturer prepared according to the test results obtained for the product dated 25.04.2020 with ID 04-2020-T-049 based on EN 149: 2001 + A1: 2009 standard. The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate No. 2163 - PPE - 634 issued to the manufacturer. The test results and issued certificate belong only to the tested product. The technical report consists of a total of 6 pages.
**Product Description :** Particle Filtering Half Mask
Total Inward Leakage: Classification – FFP2
**Trademark :** JU
**Model :** FM0201-966





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## THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE EU 2016/425 REQUIREMENTS

**1.1. Design principles**

**1.1.1. Ergonomics**

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest prossible level.

**1.1.2. Levels and classes of protection**

**1.1.2.1. Highest level of protection possible**

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

**1.1.2.2. Classes of protection appropriate to different levels of risk**

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

**1.2. Innocuousness of PPE**

**1.2.1. Absence of risks and other inherent nuisance factors**

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

**1.2.1.1. Suitable constituent materials**

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

**1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

**1.2.1.3. Maximum permessible user impediment**

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

**1.3 Comfort and effectiveness**

**1.3.1. Adaptation of PPE to user morphology**

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

**1.3.2. Lightness and design strength**

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

**1.4. Information supplied by the manufacturer**

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination





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## 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

**2.1. PPE incorporating adjustment systems**

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

**2.3. PPE for the face, eyes and respiratory system**

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

**2.4. PPE subject to ageing**

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

**2.6. PPE for use in potentially explosive atmospheres**

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

**2.8. PPE for intervention in very dangerous situations**

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

**2.9. PPE incorporating components which can be adjusted or removed by the user**

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

**2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety**

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

**3.10.2. Protection against cutaneous and ocular contact**

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.



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CERTIFICATION

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

## Conforming to EN 149:2001 + A1:2009 Standard Requirements

*Article* 5

**Classification :** Particle Filtering Half Mask
Total Inward Leakage: Classification – FFP2

*Article* 7.4

**Packing :** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage.

*Article* 7.5

**Material :** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports; It is understood withstand handling and wear over the period for which the particle filtering half mask is designed to be used, suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer.

*Article* 7.6

**Cleaning and Disinfection :** Particle filtering half mask is not designed to be as re-usable.

*Article* 7.7

**Practical Performance :** 39 (A.R), 40 (A.R)

| Assessed Elements | Positive | Negative | Requirements in accordance with EN 149:2001 + A1:2009 and Result |
|---|---|---|---|
| 1.The face piece fitting | 2 | 0 | Positive results should be obtained from the performance tests related to the implementation under real conditions. **No imperfections** |
| 2.Head harness comfort | 2 | 0 | |
| 3.Security of fastenings | 2 | 0 | |
| 4.Speech clearness | 2 | 0 | |
| 5.Field of vision | 2 | 0 | |
| 6.Materials compatibility with skin | 2 | 0 | |

**Conditioning :** (A.R.) As Received, original

*Article* 7.8

**Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

*Article* 7.9.1

**Total Inward Leakage:**

| Test Subject | No.of sample | Condition | 1.Walk | Head left /right | Head up /down | Speech | 2. Walk | Average |
|---|---|---|---|---|---|---|---|---|
| 1 | 32 | A.R | 4,99 | 5,21 | 4,79 | 5,12 | 4,72 | 4,97 |
| 2 | 33 | A.R | 4,96 | 5,39 | 4,88 | 5,49 | 4,78 | 5,10 |
| 3 | 34 | A.R | 4,91 | 5,62 | 4,96 | 5,74 | 4,91 | 5,23 |
| 4 | 35 | A.R | 4,78 | 5,56 | 4,61 | 5,43 | 4,67 | 5,01 |
| 5 | 36 | A.R | 4,83 | 5,61 | 4,66 | 5,63 | 4,78 | 5,10 |
| 6 | 16 | T.C. | 5,10 | 5,42 | 5,09 | 5,30 | 5,14 | 5,21 |
| 7 | 17 | T.C. | 5,24 | 4,79 | 5,21 | 5,41 | 5,13 | 5,16 |
| 8 | 18 | T.C. | 5,19 | 4,36 | 5,16 | 5,34 | 5,17 | 5,04 |
| 9 | 19 | T.C. | 5,23 | 5,56 | 5,28 | 5,52 | 5,23 | 5,36 |
| 10 | 20 | T.C. | 5,20 | 5,66 | 5,26 | 5,24 | 5,17 | 5,31 |
| | | | | | | | | |
| Average | | | 5,04 | 5,32 | 5.00 | 5,42 | 4,97 | 5,15 |
| Min | | | 4,78 | 4,36 | 4,61 | 5,12 | 4,67 | 4,97 |
| Max | | | 5,24 | 5,62 | 5,28 | 5,74 | 5,23 | 5,36 |

**Conditioning :** (A.R.) As Received, original
(T.C.) Temperature conditioning

Results P (%) Leakage Value

**Results meet with FFP2 requirements**

*Article* 7.9.2

**Penetration of filter material:** Sodium Chloride Testing

| Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 23 | 3,94 | FFP1 ≤ 20 %<br>FFP2 ≤ 6 %<br>FFP3 ≤ 1 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class **(FFP1, FFP2)** |
| (A.R.) | 24 | 3,88 | | |
| (A.R.) | 25 | 3,79 | | |
| (S.W.) | 1 | 4,16 | | |
| (S.W.) | 2 | 4,22 | | |
| (S.W.) | 3 | 3,95 | | |
| (M.S. T.C.) | 7 | 4,26 | | |
| (M.S. T.C.) | 8 | 4,35 | | |
| (M.S. T.C.) | 9 | 4,42 | | |

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 $dm^3.sn^{-1}$



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*Article* 7.9.2

**Penetration of filter material: :** Paraffin Oil Testing

| Condition | No. of Sample | Paraffin Oil Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 26 | 4,20 | | |
| (A.R.) | 27 | 4,26 | | |
| (A.R.) | 28 | 4,13 | FFP1 ≤ 20 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class **(FFP1, FFP2)** |
| (S.W.) | 4 | 3,96 | | |
| (S.W.) | 5 | 3,94 | FFP2 ≤ 6 % | |
| (S.W.) | 6 | 3,86 | | |
| (M.S. T.C.) | 10 | 4,15 | FFP3 ≤ 1 % | |
| (M.S. T.C.) | 11 | 4,08 | | |
| (M.S. T.C.) | 12 | 4,17 | | |

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

*Article* 7.10

**Compatibility with skin:** In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

*Article* 7.11

**Flammability :**

| Condition | No. of Sample | Visual inspection | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 37 | 1,4 | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | **Passed** |
| (A.R.) | 38 | 1,3 | | |
| (T.C.) | 21 | 1,2 | | Filtering half masks fulfill requirements of the standard |
| (T.C.) | 22 | 1,2 | | |

**Conditioning :** (A.R.) As Received, original
(T.C.) Temperature Conditioning

*Article* 7.12

**Carbon dioxide content of the inhalation air:**

| Condition | No. of Sample | $CO_2$ content of the inhalation air [%] by volume | An average $CO_2$ content of the inhalation air | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|---|
| (A.R.) | 41 | 0,86 | 0,87 | $CO_2$ content of the inhalation air shall not exceed an average of 1,0% by volume | **Passed** |
| (A.R.) | 42 | 0,82 | | | |
| (A.R.) | 43 | 0,93 | | | Filtering half masks fulfill requirements of the standard |

**Conditioning :** (A.R.) As Received, original

*Article* 7.13

**Head harness:** In Practical Performance report, No adverse effects have been reported for holding the mask of the head harness firmly in position, for total inward leakage properties.

*Article* 7.14

**Field of vision :** In Practical Performance report, No adverse effects were reported for the field of vision features.

*Article* 7.16

**Breathing Resistance:** Inhalation

| Condition | Inhalation Resistance (mbar) | | | | | |
|---|---|---|---|---|---|---|
| | No. of Sample | Flow Rate 30 L/min | Requirements in accordance with EN 149:2001 + A1:2009 | Flow Rate 95 L/min | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
| (A.R.) | 29 | 0,5 | FFP1 ≤ 0,6 | 1,3 | FFP1 ≤ 2,1 | **Passed** |
| (A.R.) | 30 | 0,5 | | 1,1 | | |
| (A.R.) | 31 | 0,4 | | 1,3 | | |
| (S.W.) | 1 | 0,5 | FFP2 ≤ 0,7 | 1,4 | FFP2 ≤ 2,4 | |
| (S.W.) | 2 | 0,5 | | 1,3 | | |
| (S.W.) | 3 | 0,6 | FFP3 ≤ 1,0 | 1,5 | FFP3 ≤ 3,0 | |
| (T.C.) | 13 | 0,6 | | 1,6 | | |
| (T.C.) | 14 | 0,5 | | 1,3 | | |
| (T.C.) | 15 | 0,5 | | 1,3 | | |

**Conditioning :** (A.R.) As Received, original
(S.W.) Simulated wearing treatment
(T.C.) Temperature Conditioning



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*Article* 7.16

**Breathing Resistance** : Exhalation

| No. of Sample | Condition | Flow rate | Facing directly | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
|---|---|---|---|---|---|---|---|---|---|
| 29 | As received | 160l/min | 2,1 | 2,0 | 2,0 | 2,0 | 2,0 | FFP1 ≤ 3,0<br>FFP2 ≤ 3,0<br>FFP3 ≤ 3,0 | Passed |
| 30 | | | 2,0 | 2,1 | 2,1 | 2,0 | 1,9 | | |
| 31 | | | 2,0 | 2,1 | 2,0 | 2,1 | 2,3 | | |
| 1 | Simulated wearing treatment | | 2,2 | 2,2 | 2,0 | 2,0 | 2,0 | | |
| 2 | | | 2,0 | 2,2 | 1,9 | 2,0 | 2,0 | | |
| 3 | | | 2,0 | 2,3 | 2,0 | 2,2 | 2,1 | | |
| 13 | Temperature conditioned | | 2,0 | 2,1 | 2,2 | 1,9 | 2,1 | | |
| 14 | | | 2,1 | 2,2 | 2,1 | 2,2 | 2,2 | | |
| 15 | | | 2,0 | 2,1 | 1,9 | 2,0 | 2,0 | | |

**Conditioning :** (A.R.) As Received, original
(S.W.) Simulated wearing treatment
(T.C.) Temperature Conditioning

| | |
|---|---|
| *Article* 7.17.2 | **Clogging :** This test is not applied to Particle Filtering Half Mask which is not reusable.<br>***(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*** |
| *Article* 7.17.3 | **Penetration of filter material:** This test is not applied to Particle Filtering Half Mask which is not reusable. |
| *Article* 7.18 | **Demountable Parts:** There are no demountable parts on the product. |
| *Article* 9 | **Marking – Packaging:** Necessary markings are available on the product and its packaging. |
| *Article* 10 | **Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instruction) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. |

| PREPARED BY | APPROVED BY |
|---|---|
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