DIWAMEDICAL

DIWAMEDICAL
FFP2 NR Maske
(5-lagig) mit Ohrenbändern

Technisches Datenblatt

DIWAMEDICAL FFP2 NR Maske (5-lagig) mit Ohrenbändern

Produkt-Bezeichnung	Filtering Half Mask KPM-3
Artikelnummer	MSK-20118
EAN	6931513238632
Angewandte Norm	DIN EN 149:2001 + A1:2009 -- Atemschutzgeräte (filtrierende Halbmasken zum Schutz gegen Partikel)
Klasse	FFP2 = AGW(*) 10-fach (Nicht gegen: Partikel krebserzeugender oder radioaktiver Stoffe, luftgetragene biologische Arbeitsstoffe der Risikogruppe 3 sowie Enzyme) NR = nicht wiederverwendbar (non reusable) / nur für eine Arbeitsschicht nutzbar
Verwendung	Schutz gegen feste und flüssige Partikeln mindergiftiger bzw. gesundheitsschädlicher Stoffe, ohne Ausatemventil
Material	Innen- und Außenschicht: Vliesstoff, Hot Air Cotton Partikelfilter: Melt Blown Vlies Bänderung: Textilgummiband Nasenbügel: Polyethylen (PE) / verstärkt
Farbe	Weiß
Größe	16 x 10,5 cm
Verpackung	1200 Stück / Karton
Unterverpackung	40 Stück / Box
Kennzeichnung	Markenzeichen des Herstellers (Logo) Produkt-Bezeichnung mit Angabe der Schutzstufe Gültige Norm Gebrauchsanleitung CE-Kennzeichnung mit Kenn-Nummer des Prüfinstitutes (4-stellig) Informationen zur Prüfstelle und zum Hersteller Konditionen für die Lagerung

(*)Nach der Gefahrstoffverordnung (GefStoffV) ist der Arbeitsplatzgrenzwert (AGW) der Grenzwert für die zeitlich gewichtete durchschnittliche Konzentration eines Stoffes in der Luft am Arbeitsplatz in Bezug auf einen gegebenen Referenzzeitraum. Er gibt an, bis zu welcher Konzentration eines Stoffs akute oder chronische schädliche Auswirkungen auf die Gesundheit von Beschäftigten im Allgemeinen nicht zu erwarten sind

Technische Informationen nach DIN EN 149:2001 + A1:2009

Tests	FFP2
Gesamte nach innen gerichtete Leckage	≤8 %
Durchlass des Filtermediums	≤6 %
Atemwiderstand Einatmung 30 l/min	≤ 0,7 mbar
Atemwiderstand Einatmung 95 l/min	≤ 2,4 mbar
Atemwiderstand Ausatmung 160 l/min	≤ 3,0 mbar

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Kärntner Sparkasse
IBAN: AT04 2070 6044 0087 6738
BIC: KSPKAT2KXXX

Hersteller

Fujian Leephick Pharmaceutical Industry Co.,Ltd
Wirtschafts- und Technologieentwicklungszone, Stadt Longyan, Provinz Fujian,
China, 364012

Notifizierte Stelle

Universal Certification and Surveillance Service Trade Ltd. Ltd.
Necip Fazil Bulvori Keyop Sitesi E2 Blok Nr.: 44/84
Yukon Dudullu Ümraniye-Istanbul NB:2163

Importeur

H.M.S. Handel Marketing Service GmbH
Gartenstraße 99
AT-9851 Lieserbrücke

Einsatzbereiche

FFP2 Masken schützen gegen gesundheitsschädliche Partikel auf Wasser- und Ölbasis, nicht jedoch gegen krebserzeugende Stoffe, radioaktive Partikel, luftgetragene biologische Arbeitsstoff e der Risikogruppe 3 und Enzyme.
Die Gesamtleckage (Undichtigkeit) beträgt maximal 8%, mindestens 94% der Schadstoff e werden aus der Luft gefiltert.
Typische Anwendungen für eine FFP2-Maske sind beispielsweise der Umgang mit Weichholz, Glasfasern, Metall, Kunststoffen (nicht PVC) und Ölnebel. Außerdem schützen sie vor:

- giftigem Staub
- atemwegsreizenden Flüssigkeiten
- atemwegsreizenden Feststoff en
- Bakterien der Risikogruppe 2
- Viren der Risikogruppe 2

Zusatzinformationen zu den Einsatzbereichen, dem Verwendungszweck und der Risikobewertung

- Missachtung dieser Anweisungen oder falsche Anwendung können die Wirksamkeit der Maske reduzieren bzw. Erkrankungen oder dauerhaft e Schäden zur Folge haben.
- Zur Auswahl der richtigen Maske konsultieren Sie eine entsprechende Sicherheitsfachkraft.
- Die Maske ist nur für den einmaligen Gebrauch bestimmt.
- Arbeiten Sie mit der Maske nur, wenn sie richtig sitzt.
- Die Maske soll ausschließlich zum Schutz gegen feste und flüssige Partikel (Feinstäube) eingesetzt werden. Kein Schutz vor Gasen, Giftstoffen, Dämpfen, Lösungsmitteln oder Sauerstoffarmut.
- Kein Einsatz, wenn Art und/oder Konzentration des Gefahrstoff es unbekannt sind.
- Kein Schutz bei Leckage, z.B. wenn sich Gesichtshaare im Bereich der Dichtlinie befinden (Bartträger). Keine Nutzung in explosionsgefährdeter Umgebung.
- Anwendung nur in ausreichend belüfteter Umgebung (Atmosphäre nicht weniger als 19,5% Sauerstoff).
- Maske nur im Original, ohne Veränderungen benutzen.
- Auswechseln der Maske bei Beschädigungen und starker Verschmutzung (hoher Atemwiderstand).
- Sofortiger Abbruch der Arbeit und Verlassen des Arbeitsplatzes bei Übelkeit, Schwindel oder Atemnot.

Aufsetzanleitung

1. Waschen und desinfizieren Sie Ihre Hände, bevor Sie die Maske entfalten.
2. Achten Sie darauf, dass der Nasenbügel nach oben ausgerichtet ist.
3. Setzen Sie nun die Maske auf und ziehen Sie die elastischen Gummibänder hinter die Ohren.
4. Richten Sie die Maske richtig aus, sodass die Maske vollständig Ihre Nase und Mund abdeckt und die Maske eng anliegt.
5. Passen Sie den Nasenbügel Ihrer Nasenkontur an.

Lagerung und Transport

Die Filtering Half Mask KPM-3 haben ab dem Herstelldatum eine Lagerdauer von 3 Jahren. Das Ende der Lagerdauer ist auf dem beiliegenden Produktzertifikat angegeben. Überprüfen Sie vor der ersten Verwendung immer, ob das Produkt die angegebene Lagerdauer (Haltbarkeitsdatum) überschritten hat.
Das Produkt muss in einer sauberen und trockenen Umgebung innerhalb eines Temperaturbereichs von -20°C bis +38°C und bei einer relativen Luftfeuchtigkeit von < 80 % gelagert werden. Vor direkter Sonneneinstrahlung schützen. Die Maske in der Originalverpackung lagern.

Konformitätsbewertung

Die partikelfiltrierende Halbmaske erfüllt die Anforderungen der europäischen Richtlinie (EU) 2016/425. Baumusterprüfung und Konformitätsbewertungsverfahren erfolgten unter Beteiligung folgender notifizierter Stelle: Universal Certification and Surveillance Service Trade Ltd. Ltd., Necip Fazil Bulvori Keyop Sitesi E2 Blok Nr.: 44/84 Yukon Dudullu Ümraniye-Istanbul NB:2163

Produktbilder

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-931

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

Fujian Leephick Pharmaceutical Industry Co., Ltd.
Economic & Technology Development Zone, Longyan City, Fujian Province, 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

Model: KPM-3
Filtering half mask
Classification: FFP2 NR

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 **03/07/2020** 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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2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-931/01

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

Fujian Leephick Pharmaceutical Industry Co., Ltd.
Economic & Technology Development Zone, Longyan City, Fujian Province, 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.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
KPM-3	FFP2 NR	2163-PPE-931	03.07.2020	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 **03/07/2020** and will be valid for one year, until **02/07/2021** 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

Verify the validity with the QR code

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 03.07.2020 / 2163-KKD-931

Manufacturer: Fujian Leephick Pharmaceutical Industry Co., Ltd.
Address: Economic & Technology Development Zone, Longyan City, Fujian Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Guojian Testing Technology Co., Ltd. accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-10118 for the product identified below, dated 24.06.2020 with Serial Id [2020] WSZ FHL NO.6667 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 28 June, 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

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 issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask
Classification: FFP2 NR
Brand Name: - **Model:** KPM-3

UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

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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.

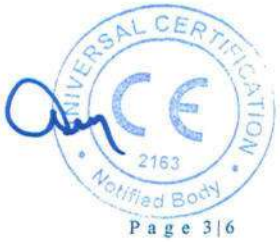
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

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.
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. 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
2.Head harness comfort	2	0	Positive results are obtained from the test subjects **No imperfections**
3.Security of fastenings	2	0	
5.Field of vision	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 Lekage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the condcution 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. It was reported that; All 50 exercise measurement results are smaller or equal to 11%, the values varies between 0,4 % and 2,1 %. All 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 1,0 % and 1,6 %. **According to the reported results, the product meets the limits for FFP1, FFP2 and FFP3 classifications.**
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.)	-	0.1	FFP1 ≤ 20 % FFP2 ≤ 6 % 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 **FFP1, FFP2 and FFP3** classes.
(A.R.)	-	0.1		
(A.R.)	-	0.1		
(S.W.)	-	0.1		
(S.W.)	-	0.2		
(S.W.)	-	0.1		
(M.S. T.C.)	-	0.3		
(M.S. T.C.)	-	0.2		
(M.S. T.C.)	-	0.2		

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.)	-	0.3	FFP1 ≤ 20 % FFP2 ≤ 6 % 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 **FFP1 and FFP2** classes.
(A.R.)	-	0.3		
(A.R.)	-	0.3		
(S.W.)	-	0.4		
(S.W.)	-	0.3		
(S.W.)	-	0.4		
(M.S. T.C.)	-	2.6		
(M.S. T.C.)	-	2.8		
(M.S. T.C.)	-	2.6		

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.)	-	Burn for 0.1s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed** Filtering half masks fulfill requirements of the standard
(A.R.)	-	Burn for 0.1s		
(T.C.)	-	Burn for 0.1s		
(T.C.)	-	Burn for 0.1s		

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.)	-	0.7125	0.71 [%]	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed** Filtering half masks fulfil requirements of the standard
(A.R.)	-	0.7135			
(A.R.)	-	0.7145			

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

Article 7.13

Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

Article 7.14

Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

Article 7.15

Exhalation Valve(s): The model under inspection have no valves.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 simulated wearing treatment conditioned complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

Passed.

UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

Article 7.17	**Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. ***(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)***
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 manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the 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. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing KPM-3. The product marking in the Article 9 of the technical file 28 June, 2020 Version 01 date and revision control indicates that the mask will carry information about the name of the manufacturer (Leephick Pharmaceutical), 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 sample by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model KPM-3 drawing exists in the technical file of the manufacturer, 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
Osman CAMCI PPE Expert	**Suat KAÇMAZ** Director

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UNIVERSAL
Zertifikat

NB 2163

KONFORMITÄTSERKLÄRUNG

Zertifikat Nr. 2163-PPE-931/01

Atemschutzgeräte, filtrierende Halbmasken zum Schutz gegen Partikeln hergestellt von

Fujian Leephick Pharmaceutical Industry Co., Ltd.
Economic & Technology Development Zone, Longyan City, Fujian Province, China

erfüllt weiterhin die Anforderungen von

EN 149:2001 + A1:2009
Atemschutzgeräte, filtrierende Halbmasken zum Schutz gegen Partikeln
Anforderungen, Prüfung, Kennzeichnung

Basierend auf der Auswertung von Prüfberichten und internen Qualitätskontroll-Auditberichten nach EN 149 + A1:2009 Persönliche Schutzausrüstung Verordnung (EU) 2016/425 Anhang VII (Modul C2).

Diese Bescheinigung besagt, dass die unten genannten hergestellten Produkte mit dem genehmigten EU-Prüfungsmodell übereinstimmen und die Anforderungen der Verordnung erfüllen.

Produktdefinition

Modell	Klasse	EU-Überprüfungszertifikat		
		Seriennummer	Datum	Ausgabenummer Benannte Stelle
KPM-3	FFP2 NR	2163-PPE-931	03.07.2020	2163

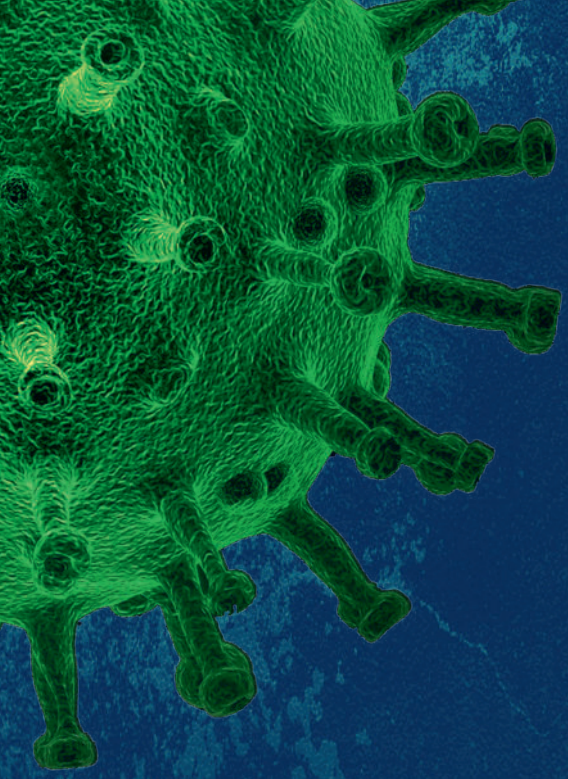
Hierdurch ist der Hersteller berechtigt, die Nummer der benannten Stelle (2163) zu verwenden und kann das CE-Zeichen, wie unten gezeigt, auf den oben genannten Produktmodellen der Kategorie III anbringen:

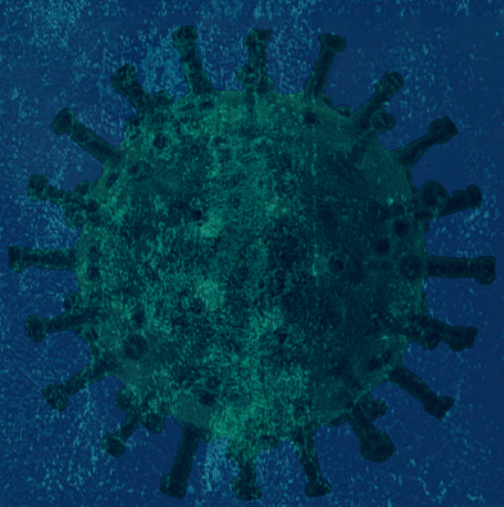
- Ausstellung einer entsprechenden EU-Konformitätserklärung gemäß Verordnung (EU) 2016/425 des Europäischen Parlaments und des Rates vom 9. März 2016 über persönliche Schutzausrüstungen, Anhang 9.
- Ergreifung aller erforderlichen Maßnahmen, damit der Fertigungsprozess und seine Überwachung die Homogenität der Produktion und die Konformität der hergestellten PSA mit dem in der EU-Baumusterprüfbescheinigung beschriebenen Baumuster gewährleisten.

Dieses Zertifikat wird am 03.07.2020 ausgestellt und ist ein Jahr lang (bis zum 02.07.2021) gültig, wenn der Hersteller keine wesentlichen Änderungen an den Produktdesigns und Herstellungsprozessen vornimmt, die die Produktleistung hinsichtlich der wesentlichen Gesundheits- und Sicherheitsanforderungen beeinflussen.

FUJIAN LEEPACK PHARMACEUTICAL INDUSTRY CO., LTD. 福建省力菲克药业有限公司

2163





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