SAUBAG / KINGFA katalogs

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A: Brivibas gatve 401C, Riga, LV-1024, Latvia
KINGFA

1. BLUE SURGICAL/MEDICAL FACE MASK WITH EAR-LOOPS AND NOSE CLIP, EN 14683 TYPE IIR

Product Specification – KF-B P01 (R)

- Type IIR (≥98% BFE, Splash resistant)
- Lightweight; 3,5 grams
- 3-ply with pleating
- Earloops with spandex
- Adjustable nose-part with flexible clip
- Color: blue outwards facing
- 175*95 [mm], for adults

Packing Information

Dispenser pack **50 pieces / dispenser pack**

Shipping box **2 500 pieces / shipping box (50 dispenser packs)**

Package type	Material	Dimensions [mm]	Weight [gram]
Dispenser pack	LDPE Carton with inner PE plastic bag	190*100*80	216 ± 10
Shipping box	Corrugated cardboard with inner PE plastic bag	525*395*420	11 970 ± 500

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Regulation & Technical Information

Manufacturer & Origin: Guangdong KINGFA SCI.&TECH. Co., Ltd., China

Class characteristics: Class I (not sterile or measuring via Annex IX Rule X)

The product is certified to meet the Essential requirements and relevant provisions of EC Directive:
Medical Devices Directive 93/42/EEC

Product Structure and Composition

This product consists of PP nonwoven fabric, PP melt-blown fabric, nose clip, and ear loops.

Standard(s)/Directive(s):

The following Standards are applied to the product and its packaging as well as the productions facility. The language and instructions for the product is in English.

Product standard	EN 14683: 2019+AC: 2019 (Type IIR)
Biological evaluation	EN ISO 10993-1: 2009/AC:2010
Biological evaluation	EN ISO 10993-5: 2009
Biological evaluation	EN ISO 10993-10: 2010
Product standard, risk evaluation	EN ISO 14971: 2012
Medical devices, symbols	EN ISO 15223-1: 2016
Medical devices, information supply	EN 1041: 2008
Medical devices, quality management	EN ISO 13485: 2016
Quality management	EN ISO 9001: 2015

Product Performance

Bacterial filtration efficiency (BFE):	≥ 98%
Differential pressure (Delta-P):	< 60Pa/cm^2
Splash resistance pressure (kPa):	≥ 16 kPa (120 mmHg)
Microbial cleanliness:	≤ 30 cfu/g

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Precautions

This product is a non-sterile type mask.

This product's validity period is 2 years. Please use within validity period.

Do not use the product if you are allergic to it.

The product is disposable and cannot be reused or recycled. After use, it shall be immediately destroyed or thrown into a special treatment box.

Please check the integrity of the package before use. Do not use the product if the package is damaged.

Incorrect wearing of this product may cause breathing difficulties.

Used masks are considered highly contaminated, it is essential that:

a) The body of the mask is not touched by the fingers/hands of the wearer;

b) Hands are disinfected (full hand disinfection) after mask removal;

c) A mask is worn covering the nose and mouth of the wearer, at no time a mask is hanging around the neck of the wearer.

Storage and transportation conditions

The packaged medical mask shall be stored in a room with normal temperature and relative humidity of no more than 80%, no corrosive gas, good ventilation, and fire, rat and insect prevention facilities. During transportation, keep away from moisture, light and heat.

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Instructions for use

1. Open the sealed package and take out the mask.
2. Attach the mask to the face and nose horizontally, with the nose dip pointing upwards.
3. Place the fingertips of both hands on the nose clip, from the middle position, with the fingers to press inward, and gradually move to the sides to make the nose clip of the mask fit the shape of the nose.
4. Pull the ear loops, while wearing the mask, on the ears.
5. Spread the pleated creases and extend the mask.

Intended use

The disposable medical mask is intended to be used for clinical medical personnel to wear it during invasive environment, covering the user's mouth, nose and jaw, providing a physical barrier to prevent the direct penetration of pathogens, microorganisms, body fluid, particles, etc.

Barcode – Dispenser pack

6 973163 400052

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DECLARATION OF CONFORMITY

Manufacturer:	Guangdong KINGFA SCI.&TECH. Co., Ltd.
Address of manufacturer:	NO,28. Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product:	Disposable Medical Mask
Model Ref.:	KF-B P01(R)
Class characteristics:	Class Ⅰ (not sterile or measuring via Annex Ⅸ Rule Ⅹ)
UMDNS-Code:	12458

The product is certified to meet the Essential requirements and relevant provisions of EC Directive: **Medical Devices Directive 93/42/EEC**

Standard(s)/Directive(s):	EN 14683: 2019+AC: 2019(Type IIR) EN ISO 10993-1: 2009/AC:2010 EN ISO 10993-5: 2009 EN ISO 10993-10: 2010 EN ISO 14971: 2012 EN ISO 15223-1: 2016 EN 1041: 2008
Conformity assessment procedure:	EC Declaration of Conformity (Annex II) + Technical Files)
EC representative:	Share Info Consultant Service LLC Repräsentanzbüro
Address:	Heerdter Lohweg 83, 40549 Düsseldorf

This DoC is valid from 27 Apr., 2020.
Authorized by:

CE

Signature
General manager
Place: Qingyuan, China
Date: Apr. 27, 2020

广东金发科技有限公司

GUANGDONG KINGFA SCI. & TECH. CO., LTD

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

GuangDong Kingfa Science and Technology Co., Ltd.
No.28, Delong Road, Qingcheng Dist.
Qingyuan City
511545 Guangdong
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Disposable Medical Face Masks (non-sterile)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-07-13
Certificate Registration No.:	SX 60150441 0001
An audit was performed. Report No.:	17054679 002
This Certificate is valid until:	2023-07-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 2020-07-13

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1430282**

Certificate Holder: **GuangDong Kingfa Science and Technology Co., Ltd.**
Unified Social Credit Code: 91441802077867032A
Registration Address: No. 28, Delong Road, Qingcheng Dist. Shijiao Town, Qingyuan City, 511545 Guangdong, P. R. China
Operation Address: same as above

Scope: Design and Manufacturing of Modified Plastics;
Design and Manufacturing of Masks and Non-Powered Air-Purifying Particle Respirator

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-19 until 2023-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-06-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF MEMBER OF MUTUAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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A: Brivibas gatve 401C, Riga, LV-1024, Latvia

2. PARTICLE FILTERING HALF MASK, FFP3 NR, EN 149:2001 + A1:2009

Product Specification – KF-G F03V

- Type FFP3 NR (Non re-usable)
- Adjustable headband straps
- Cup shaped with mask cushion
- Exhalation valve
- Adjustable nose-part with flexible clip
- Color: white
- 150*130 [mm], for adults

Packing Information

Carton **10 pieces / carton box**

Shipping box **300 pieces / shipping box (30 cartons boxes)**

Package type	Material	Dimensions [mm]	Weight [gram]
Carton box	LDPE Carton with inner PE plastic bags, 10	200*125*170	291 ± 10
Shipping box	Corrugated cardboard with inner PE plastic bag	650*415*530	10 304 ± 300

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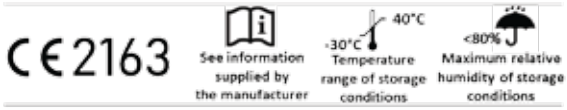
A: Brivibas gatve 401C, Riga, LV-1024, Latvia

Regulation & Technical Information

Manufacturer & Origin: Guangdong KINGFA SCI.&TECH. Co., Ltd., China

The product is certified to meet the essential requirements and relevant provisions of: **Regulation (EU) 2016/425 on personal protective equipment**. The product bears the marking CE2163 according to the Notified Body (NB) 'Universal Certification and Surveillance Service Trade Ltd. Co., Notified Body 2163'.



Product Structure and Composition

This product's main components consist of needle punched nonwoven fabric (82%) and PP melt-blown fabric (18%) The product also consists of, nose clip, headband straps, mask cushion, and exhalation valve.

Standard(s)/Directive(s):

The following Standards are applied to the product and production facility. The language and instructions for the product is in English.

Product standard	EN 149: 2001+A1: 2009
Medical devices, quality management	EN ISO 13485: 2016
Quality management	EN ISO 9001: 2015

Product Performance

The product meets the product performance as stipulated by 'FFP3 NR' requirements according to EN 149:2001 + A1:2009.

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A: Brivibas gatve 401C, Riga, LV-1024, Latvia

Warnings

Before using the masks, first verify that it is suitable for the intended use. The wearer must be adequately trained prior to use and ensuring the masks are proper fit.

The mask is disposable and cannot be reused.

Using the masks with facial hair will cause leakage problem, if the facial hair is not covered, it is unlikely to achieve a seal.

Discard and replace the mask if it becomes damaged or have higher breathing resistance.

Don’t use the mask in heavily polluted environment, oxygen-deficient environment, fire environment and underwater work.

Patients with heart disease or other disease should discard it if wearing is uncomfortable.

Masks marked NR shall not be used for more than one shift.

This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this respirator when oxygen concentration is less than 19,5%.

Do not use in explosive atmospheres.

It is strictly prohibited to use after the package is damaged

Storage and Transportation Conditions

Keep masks in the package away from direct sunlight or contaminants until use. Ambient temperature between -30°C to +40°C, and relative humidity <80%, no corrosive gas, good ventilation. During the transportation, keep away from moisture, light and heat. The mask should not be removed from its package until it is required for use, and should be discarded after use. The product’s shelf life is 2 years

User Instructions

1. To protect your health and to prevent serious injury or death, it is important to read all the instructions provided with the enclosed product. Please read all warnings printed on the packaging box.
2. The mask needs to be inspected prior to each use to assure there are no holes in the breathing zone other than punctures around and staples and no damage has occurred.

1	2	3	4
Hold the particle half mask in position over the nose and mouth.	Pull the upper headband over the head positioning it just above the ears. Pull lower headband over the head and fit around the back of the neck. Tie the headband on the fixed position of head harness adjusting button.	Ensure the nose clip is securely molded around the nose, resting the ends against the cheek to obtain a good seal.	To check for proper fit, cup both hands over the mask and exhale vigorously. If air leaks around the nose, tighten the nose clip, if air leaks around the edge, reposition the head harness for better fit. Repeat adjustments until the mask is sealed properly.

Limitation

Do not use the mask to enter or stay in a contaminated area under the following circumstances:

a) Atmosphere contains less than 19.5% oxygen.
b) If you smell or taste contaminant.
c) For protection against gases or vapors.
d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
e) For sandblasting, spray-paint operations and asbestos treatment.
f) In explosive atmospheres.

Barcode – Dispenser pack

6 973163 400700

Ellips Innovation AB
Org no. 556809-0459
Address: Box 47003
100 74 Stockholm, Sweden

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A: Brivibas gatve 401C, Riga, LV-1024, Latvia
KINGFA

KINGFA

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	GUANGDONG KINGFA SCI.&TECH. CO., LTD. NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product name	Particle Filtering half mask
Model/ Serial No.	KF-G F03V FFP3 NR
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	UNIVERSAL- NB 2163 Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ü mraniye /İSTANBUL / TÜRKİYE
Certificate number (Module B)	2163-PPE-1538
Notified body for conformity to type based on internal prodution control plus surpervised product checks at random intervals (Module C2)	UNIVERSAL- NB 2163 Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ü mraniye / İSTANBUL / TÜRKİYE
Certificate number(Module C2)	2163-PPE-1538/01

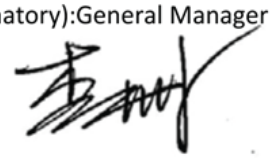
We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

Signed for and on behalf of:GUANGDONG KINGFA SCI.&TECH. CO., LTD.

(date of signature):2020-10-21

(title of signatory):General Manager

(signature):



UNIVERSAL

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CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1538

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

Guangdong Kingfa Sci.&Tech. Co., Ltd.
28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong 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: KF-G F03V
Filtering half mask
Classification: FFP3 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 **05/10/2020** 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

Verify the validity with the QR code

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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CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1538/01

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

Guangdong Kingfa Sci. &Tech. Co., Ltd
28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City,
Guangdong 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
KF-G F03V	FFP3 NR	2163-PPE-1538	05.10.2020	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 **20/10/2020** and will be valid for one year, until **19/10/2021** 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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

GuangDong Kingfa Science and Technology Co., Ltd.
No.28, Delong Road, Qingcheng Dist.
Qingyuan City
511545 Guangdong
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Disposable Medical Face Masks (non-sterile)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-07-13
Certificate Registration No.:	SX 60150441 0001
An audit was performed. Report No.:	17054679 002
This Certificate is valid until:	2023-07-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 2020-07-13

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1430282**

Certificate Holder: **GuangDong Kingfa Science and Technology Co., Ltd.**
Unified Social Credit Code: 91441802077867032A
Registration Address: No. 28, Delong Road, Qingcheng Dist. Shijiao Town, Qingyuan City, 511545 Guangdong, P. R. China
Operation Address: same as above

Scope: Design and Manufacturing of Modified Plastics;
Design and Manufacturing of Masks and Non-Powered Air-Purifying Particle Respirator

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-19 until 2023-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-06-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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IAF

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A: Brivibas gatve 401C, Riga, LV-1024, Latvia

3. PARTICLE FILTERING HALF MASK, FFP3 NR, EN 149:2001 + A1:2009

Product Specification – KF-A F11 (RF-TD-3)

- Type FFP3 NR (Non re-usable)
- Adjustable headband straps
- Adjustable nose-part with flexible clip
- Lightweight; 7,7 grams
- Color: white
- 230*120 [mm], for adults

Packing Information

Carton **30 pieces / carton box**

Shipping box **1 080 pieces / shipping box (36 cartons boxes)**

Package type	Material	Dimensions [mm]	Weight [gram]
Carton box	LDPE Carton with inner PE plastic bags, 10	140*120*125	285 ± 10
Shipping box	Corrugated cardboard with inner PE plastic bag	585*375*395	11 440 ± 500

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A: Brivibas gatve 401C, Riga, LV-1024, Latvia

Regulation & Technical Information

Manufacturer & Origin: Guangdong KINGFA SCI.&TECH. Co., Ltd., China

The product is certified to meet the essential requirements and relevant provisions of: **Regulation (EU) 2016/425 on personal protective equipment**. The product bears the marking CE2163 according to the Notified Body (NB) 'Universal Certification and Surveillance Service Trade Ltd. Co., Notified Body 2163'.

Product Structure and Composition

This product's main components consist of PP nonwoven fabric (56%), PP melt-blown fabric (31%), and hot air nonwoven fabric (13%). The product also consists of, nose clip and headband straps.

Standard(s)/Directive(s):

The following Standards are applied to the product and production facility. The language and instructions for the product is in English.

Product standard	EN 149: 2001+A1: 2009
Medical devices, quality management	EN ISO 13485: 2016
Quality management	EN ISO 9001: 2015

Product Performance

The product meets the product performance as stipulated by 'FFP3 NR' requirements according to EN 149:2001 + A1:2009.

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Warnings

This mask marked “NR”, shall not be used for more than one shift.

Never substitute, modify, add, or omit parts in the configuration as specified by the manufacturer.

This mask helps protect against certain particulate contaminants but does not completely eliminate exposure to the risk of contracting disease or infection.

Do not use the particle half mask with facial hair or any other conditions that may prevent a good face-seal, the requirements of leakage will not be achieved.

Discard the mask and replace the mask if:

a) The mask is removed whilst in the contaminated areas.
b) Clogging of the mask causes breathing difficulties.
c) The mask becomes damaged.

Contraindication

People allergic to nonwoven are prohibited to use. Not recommended for use in anoxic and explosive atmospheres.

Storage and Transportation Conditions

Keep masks in the package away from direct sunlight or contaminants until use. Ambient temperature between -30°C to +40°C, and relative humidity <80%, no corrosive gas, good ventilation. During the transportation, keep away from moisture, light and heat. The mask should not be removed from its package until it is required for use, and should be discarded after use. The product’s shelf life is 2 years

User Instructions

1. To protect your health and to prevent serious injury or death, it is important to read all the instructions provided with the enclosed product. Please read all warnings printed on the packaging box.
2. The mask needs to be inspected prior to each use to assure there are no holes in the breathing zone other than punctures around and staples and no damage has occurred.

Hold the particle half mask in position over the nose and mouth.	Pull the upper headband over the head positioning it just above the ears. Pull lower headband over the head and fit around the back of the neck. Tie the headband on the fixed position of head harness adjusting button	Ensure the nose clip is securely molded around the nose, resting the ends against the cheek to obtain a good seal.	To check for proper fit, cup both hands over the mask and exhale vigorously. If air leaks around the nose, tighten the nose clip, if air leaks around the edge, reposition the head harness for better fit. Repeat adjustments until the mask is sealed properly

Limitation

Do not use the mask to enter or stay in a contaminated area under the following circumstances:

a) Atmosphere contains less than 19.5% oxygen.
b) If you smell or taste contaminant.
c) For protection against gases or vapors.
d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
e) For sandblasting, spray-paint operations and asbestos treatment.
f) In explosive atmospheres.

Barcode – Dispenser pack

6 973163 400533

Ellips Innovation AB
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100 74 Stockholm, Sweden

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A: Brivibas gatve 401C, Riga, LV-1024, Latvia
KINGFA

KINGFA

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	GUANGDONG KINGFA SCI.&TECH. CO., LTD. NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product name	Particle Filtering half mask
Model/ Serial No.	KF-A F11(RF-TD-3) FFP3 NR
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	UNIVERSAL- NB 2163 Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ü mraniye /İSTANBUL / TÜRKİYE
Certificate number (Module B)	2163-PPE-1245
Notified body for conformity to type based on internal prodution control plus surpervised product checks at random intervals (Module C2)	UNIVERSAL- NB 2163 Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ü mraniye / İSTANBUL / TÜRKİYE
Certificate number(Module C2)	2163-PPE-1245/01

We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

Signed for and on behalf of:GUANGDONG KINGFA SCI.&TECH. CO., LTD.

(date of signature):2020-8-20

(title of signatory):General Manager

(signature):

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1245

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

Guangdong Kingfa Sci.&Tech. Co., Ltd.
28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong 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: KF-A F11(RF-TD-3)
Filtering half mask
Classification: FFP3 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 **09/08/2020** 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

Verify the validity with the QR code

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1245/01

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

Guangdong Kingfa Sci. &Tech. Co., Ltd.

NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong 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
KF-A F11(RF-TD-3)	FFP3 NR	2163-PPE-1245	09.08.2020	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 **19/08/2020** and will be valid for one year, until **18/08/2021** 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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

GuangDong Kingfa Science and Technology Co., Ltd.
No.28, Delong Road, Qingcheng Dist.
Qingyuan City
511545 Guangdong
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Disposable Medical Face Masks (non-sterile)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-07-13
Certificate Registration No.:	SX 60150441 0001
An audit was performed. Report No.:	17054679 002
This Certificate is valid until:	2023-07-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2020-07-13

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1430282**

Certificate Holder: **GuangDong Kingfa Science and Technology Co., Ltd.**
Unified Social Credit Code: 91441802077867032A
Registration Address: No. 28, Delong Road, Qingcheng Dist. Shijiao Town, Qingyuan City, 511545 Guangdong, P. R. China
Operation Address: same as above

Scope: Design and Manufacturing of Modified Plastics;
Design and Manufacturing of Masks and Non-Powered Air-Purifying Particle Respirator

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-19 until 2023-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-06-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

P: +371 200 200 29 E: info@saubag.com
A: Brivibas gatve 401C, Riga, LV-1024, Latvia

4. PARTICLE FILTERING HALF MASK, FFP2 NR, EN 149:2001 + A1:2009

Product Specification – KF-A F10(SC)

- Type FFP2 NR (Non re-usable)
- Earloops with clip extender
- Lightweight; 6,8 grams
- Adjustable nose-part with flexible clip
- Color: white
- 230*120 [mm], for adults

Packing Information

Carton **30 pieces / carton box**

Shipping box **1 080 pieces / shipping box (36 cartons boxes)**

Package type	Material	Dimensions [mm]	Weight [gram]
Carton box	LDPE Carton with inner PE plastic bags, 3*10	140*120*121	255 ± 10
Shipping box	Corrugated cardboard with inner PE plastic bag	585*375*385	9 180 ± 500

P: +371 200 200 29 E: info@saubag.com
A: Brivibas gatve 401C, Riga, LV-1024, Latvia

Regulation & Technical Information

Manufacturer & Origin: Guangdong KINGFA SCI.&TECH. Co., Ltd., China

The product is certified to meet the essential requirements and relevant provisions of: **Regulation (EU) 2016/425 on personal protective equipment**. The product bears the marking CE0598 according to the Notified Body (NB) 'SGS FIMKO OY, Notified Body 0598'.

Notified Body	SGS Fimko Oy
Notified Body No.	0598
Address	Takomotie 8, FI-00380 Helsinki, Finland

Product Structure and Composition

This product's main components consist of PP nonwoven fabric (52%), PP melt-blown fabric (24%), and spunlaced nonwoven (24%). The product also consists of, nose clip, ear loops and clip extender.

Standard(s)/Directive(s):

The following Standards are applied to the product and production facility. The language and instructions for the product is in English.

Product standard	EN 149: 2001+A1: 2009
Medical devices, quality management	EN ISO 13485: 2016
Quality management	EN ISO 9001: 2015

Product Performance

The product meets the product performance as stipulated by 'FFP2 NR' requirements according to EN 149:2001 + A1:2009.

P: +371 200 200 29 E: info@saubag.com
A: Brivibas gatve 401C, Riga, LV-1024, Latvia

Warnings

This mask marked “NR”, shall not be used for more than one shift.

Never substitute, modify, add, or omit parts in the configuration as specified by the manufacturer.

This mask helps protect against certain particulate contaminants but does not completely eliminate exposure to the risk of contracting disease or infection.

Do not use the particle half mask with facial hair or any other conditions that may prevent a good face-seal, the requirements of leakage will not be achieved.

Discard the mask and replace the mask if:

a) The mask is removed whilst in the contaminated areas
b) Clogging of the mask causes breathing difficulties
c) The mask becomes damaged

Contraindication

People allergic to nonwoven are prohibited to use. Not recommended for use in anoxic and explosive atmospheres.

Storage and Transportation Conditions

Keep masks in the package away from direct sunlight or contaminants until use. Ambient temperature between -30°C to +40°C, and relative humidity <80%, no corrosive gas, good ventilation. During the transportation, keep away from moisture, light and heat. The mask should not be removed from its package until it is required for use, and should be discarded after use. The product’s shelf life is 2 years

User Instructions

1. To protect your health and to prevent serious injury or death, it is important to read all the instructions provided with the enclosed product. Please read all warnings printed on the packaging box.
2. The mask needs to be inspected prior to each use to assure there are no holes in the breathing zone other than punctures around and staples and no damage has occurred.

1	2	3	4
Press the respirator firmly against your face with the nose clip on the bridge of your nose	Attach the hook to the ear loop of the other side. Position ear loops and hook behind the back of the head to ensure a good seal of the mask to the face	Extend the mask to cover mouth and chin. Using both hands' fingertips, mold the nose clip to fit the shape of your nose	Cup both hands over the mask and exhale vigorously. If air leaks from the bridge of your nose, please remold nose clip following step 3; if air escapes at the sides of mask, adjust ear loops until it fits properly.

Limitation

Do not use the mask to enter or stay in a contaminated area under the following circumstances:

a) Atmosphere contains less than 19.5% oxygen.
b) If you smell or taste contaminant.
c) For protection against gases or vapors.
d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
e) For sandblasting, spray-paint operations and asbestos treatment.
f) In explosive atmospheres.

Barcode – Dispenser pack

6 973163 400328

Ellips Innovation AB
Org no. 556809-0459
Address: Box 47003
100 74 Stockholm, Sweden

SAUBAG

P: +371 200 200 29 E: info@saubag.com
A: Brivibas gatve 401C, Riga, LV-1024, Latvia

KINGFA

KINGFA

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	GUANGDONG KINGFA SCI.&TECH. CO., LTD. NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product name	Particle Filtering half mask
Model/ Serial No.	KF-A F10(SC) FFP2 NR
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	UNIVERSAL- NB 2163 Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye / İSTANBUL / TÜRKİYE
Certificate number (Module B)	2163-PPE-884
Notified body for EU type-examination (Module D)	SGS FIMKO OY - NB 0598 Takomotie 8, FI-00380 Helsinki, Finland
Certificate number(Module D)	Certificate CN20/42082

We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

Signed for and on behalf of:GUANGDONG KINGFA SCI.&TECH. CO., LTD.

(date of signature):2020-6-30

(title of signatory):General Manager

(signature):

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-884

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

Guangdong Kingfa Sci.&Tech. Co., Ltd.

28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong 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

Brand Name: KINGFA **Model:** KF-A F10(SC)
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 **29/06/2020** 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

Verify the validity with the QR code

SGS

Certificate CN20/42082

The management system of

Guangdong KINGFA SCI. &TECH. Co., Ltd.

No.28, Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, 511545, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Manufacture of FFP1/FFP2 Protective Respirator (Note: all products marked CE0598 must have a valid EU Type Examination Certificates issued under Module B or a valid EC type examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.)

This certificate is valid from 10 June 2020 until 9 June 2023 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 May 2023
Issue 1. Certified since 10 June 2020

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Page 1 of 1

TÜVRheinland®

Certificate

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hereby certifies that the organization

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EN ISO 13485:2016

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This Certificate is valid until:	2023-07-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 2020-07-13

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1430282**

Certificate Holder: **GuangDong Kingfa Science and Technology Co., Ltd.**
Unified Social Credit Code: 91441802077867032A
Registration Address: No. 28, Delong Road, Qingcheng Dist. Shijiao Town, Qingyuan City, 511545 Guangdong, P. R. China
Operation Address: same as above

Scope: Design and Manufacturing of Modified Plastics;
Design and Manufacturing of Masks and Non-Powered Air-Purifying Particle Respirator

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-19 until 2023-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-06-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln