

KN95

The introduction of KN95 Mask

(Name): KN95, KN95 protective mask

(Size): 16*10.5cm (Standard): GB2626-2006

(Colour box size): 22*12*13cm (50pcs)

(Carton size): 62*46*55cm (2000pcs)

(Box weight): 0.39KG

(Carton gross weight): 14.8KG (2000pcs)



Four layers: 1: non-woven fabric 2: hot air cotton 3: e-PTFE 4: non-woven fabric. We can customize 5 layers mask according to customer's requirements.

But price will be different as materials cost goes up.



- Product real photo



- materials analysis



(manual and QC pass)

Runbo

Model: AAF2001
FFP2 NR
CE2834

USER INSTRUCTIONS

- 1 Failure to follow all instructions and limitations could seriously reduce the effectiveness of this particle filtering half mask and could lead to disease, injury or death.
- 2 A properly selected respirator is essential, before occupational use, the wearer must be trained by the employer in the correct use of the respirator in accordance with applicable safety and health standards.
- 3 This particle filtering half mask does not supply oxygen. Use it in adequately ventilated and where containing sufficient oxygen to support life.
- 4 Discard the respirator and replace with a new one if:
 - a. Excessive clogging of the particle filtering half mask causes breathing difficulty.
 - b. The particle filtering half mask becomes damaged.
 - c. Leave the contaminated area if dizziness, irritation or other distress occurs.

USE LIMITATIONS

- 1 Do not use the respirator or 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 contaminants.
 - c. For protection against gases or vapors.
 - d. Contaminants or their concentrations are unknown or immediately dangerous to life or health.
 - e. For sandblasting, paint spray operations and pesticides.
 - f. In explosive atmospheres.
- 2 Do not modify or remove the particle filtering half mask.
- 3 Do not use the particle filtering half mask with facial hair or any other conditions that may prevent a good face seal, the requirements for leakage will be achieved.
- 4 Particle filtering half mask need to be inspected prior to each use to ensure there are no tears in the breathing zone other than punctures around staples and no damage has occurred. Damaged holes resulting from ripped or torn filter materials around staple punctures are considered damage.
- 5 This respirator helps protect against certain particulate contaminants but does not eliminate exposure to the risk of contracting disease or infection. Misuse may result in sickness or death.
- 5 This particle filtering half mask marked "NR" shall not be used for more than one shift.
- 7 This particle filtering half mask is not suitable for users who have an ear that has been damaged.

FITTING INSTRUCTION

- 1 Place fingers inside the particle filtering half mask. Bend the nose clip around fingers to form nose shape.
- 2 Hold the particle filtering half mask in position over the nose and mouth, pull the head harness behind the ears.
- 3 Use both hands, form the nose clip around the nose and snuff the head harness to ensure a positive face seal.
- 4 Seal check:
 - a. To test the fit of the particle filtering half mask without an exhalation valve, cup both hands over particle filtering half mask and inhale sharply.
 - b. If air flow is felt on the nose area, readjust and tighten the nose clip.
 - c. If air flow is felt around the edges of the respirator, adjust the particle half particle filtering half mask head harness to achieve a better fit.
- 5 Change the particle filtering half mask immediately if breathing becomes difficult or particle filtering half mask becomes damaged or distorted.
- 6 Change the particle filtering half mask if proper face seal cannot be achieved.
- 7 Carefully observe these instructions as an important step in safe respirator use.



Particle filtering half mask meet the requirements of Regulation (EU) 2016/425. They have been tested according to EN 136:2011+A1:2016 FFP2 NR, Module B (EU type-approval Certification) and Module D Certification have been issued by CCGS Certification Services Limited, Block 1 Blockhouse Corporate Park, Bellville Road, Blockhouse, Dublin 15, D15 AXP1, Ireland (NB 2034).

Manufacturer: Anshun Health And Medical Technology Co., Ltd.
Address: 68 building industry science and technology park, Hudu street, Zhusi city, Duzhou province, China

QC PASS

Name: Particle Filtering Half Mask

EU standards: EN149:2001+A1:2009

Batch number: Same as production date

Date: _____

QC: _____

Validity: 12 months

Anshun Health And Medical Technology Co., Ltd.

PYSSEL
WWW.PYSSEL.FI

Papinvirrantie 38
68600, Pietarsaari
FINLAND

+358 (0)41 435 5191
info@pyssel.fi
1868857-9



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

ANSHUN HEALTH AND MEDICAL TECHNOLOGY CO.,LTD.

**E6 building industry science and technology park,xixiu district
Anshun CITY, GUIZHOU, 561099, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

HEALREG SERVICE INC

Owner/Operator Number: 10063945

Device Listing#: See annex

HEALREG SERVICE INC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. HEALREG SERVICE INC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. HEALREG SERVICE INC assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.



Chief engineer

Issued: March 24, 2020

Expiration Date: December 31, 2020



Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10063945

Listing No.	Code	Device Name	Proprietary Names	Activities
D377424	MSH	Respirator, surgical	Disposable protective mask AKF2002 N95 mask, AKF2002-26, AKF2002-Y, AKF2006, AKF2008, AKF2005, AKF-2001, AKF2001-C, AKF2001-Y, KN90, KN100, KN95, AKF-KN90, AKF-KN100, AKF-KN95, AKF9801	Manufacturer Contract Manufacturer Remanufacturer Foreign Exporter

END OF THE ANNEX

Chief engineer

Issued: March 24, 2020

Expiration Date: December 31, 2020

● CE application



Manufacturer's name: **Anshun Health And Medical Technology Co., Ltd.**
Address: E6 Building Industry Science and Technology Park,
Xixiu District, Anshun City, Guizhou Province, China
Date: 30.03.2020
CCQS Project Reference: CE-PC-200323-024

Confirmation Letter

To whom it may concern:

This is to confirm that **Anshun Health And Medical Technology Co., Ltd.**, Address: **E6 Building Industry Science and Technology Park, Xixiu District, Anshun City, Guizhou Province, China** has entered into the service agreement **CE-PC-200323-024** with CCQS Certification Services Limited, with regards to the application of Module B EU Type Examination Certification and Module D Production Monitoring for **Particle filtering half mask**, Model: **AKF2002** within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III.

If in any doubt about the integrity of this letter, please contact CCQS by email to verify.

Yours Faithfully.



CCQS Certification Services Limited
Block 1, Blanchardstown Corporate Park, Ballycoolin Rd.,
Blanchardstown, Dublin 15, D15 AKK1 Ireland
Tel: +353 (0) 1 588 6920
Email info@ccqs.co.ie
Registered in Ireland as a Limited Company No.623897

Approved by
Ireland Government
as a Notified Body for
CE Marking No.2834

Anshun Health And Medical Technology Co.,Ltd

Company profile

GB2626-2006, EN149, EN14683,CE, FDA



Anshun Health And Medical Technology Co.,Ltd is located in E6 building industry science and technology park, xixiu district, Anshun city, Guizhou province, China. The area of our factory is about 3200 m². We produce KN95 Personal Protective Mask, Medical Surgical Mask, Disposable Face Mask. And we have acquired China Medical Device License and local standard GB2626-2006, FDA registration, CE certification: EN149, EN14683:2019 certificate.

PYSSEL
WWW.PYSSEL.FI

Papinvirrantie 38
68600, Pietarsaari
FINLAND

+358 (0)41 435 5191
info@pyssel.fi
1868857-9



PYSSEL
WWW.PYSSEL.FI

Papinvirrantie 38
68600, Pietarsaari
FINLAND

+358 (0)41 435 5191
info@pyssel.fi
1868857-9

No. FZ2006531



中国认可
国际互认
检测
TESTING
CNAS L0153



TEST REPORT

Commissioned by Anshun Health And Medical Technology Co., Ltd.

Factory Anshun Health And Medical Technology Co., Ltd.

Name of Sample KN95 Disposable protective mask AKF2002-26

Type, Specification /

Testing Purpose Commission



广东产品质量监督检验研究院

GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

PYSSEL
WWW.PYSSEL.FI

Papinvirrantie 38
68600, Pietarsaari
FINLAND

+358 (0)41 435 5191
info@pysse.fi
1868857-9

No. FZ2006531



TEST REPORT

Security Code: SMX2241

Name of Sample	KN95 Disposable protective mask ANF2002-26		Sample number	YFZ20/006531
	Sending	sampling		
Trade mark	---		Type, Specification	---
Commissioned by	Anshun Health And Medical Technology Co., Ltd.		Testing Purpose	Commission
Address of client	E6 building industry science and technology park, xixiu district, anshun city, Guizhou province, China.		Product No./batch No	---
Factory	Anshun Health And Medical Technology Co., Ltd.		Sampling list No	---
Inspected unit	---		Date of manufacture	---
Sampling unit	---		Quantity of sample	35 (个) 35 (Pieces)
Location of sampling	---		Basic quantity of sampling	---
Date of sampling	---		Location of testing	Laboratory
Date of receiving	2020 03 23		Date of testing	2020 03 23 2020 03 28
Testing reference	GB 2626-2006 GB 2626-2006 Respiratory protective equipment. Non-powered air-purifying particle respirator			
Judging reference	---			
Remarks	Test results are attached as below.  (检验检测专用章) 签发日期: 2020年03月28日 表示此项空白。(Q1)			
Notes	"—" in the report indicates that this item is not applicable, and "P" in the report indicates that this item is blank.			

胡双

王

张城

PYSSEL
WWW.PYSSEL.FI

Papinvirrantie 38
68600, Pietarsaari
FINLAND

+358 (0)41 435 5191
info@pysssel.fi
1868857-9

测 报

TEST REPORT

No	Test items[Unit]	Standard terms	Standard requirements	Result		Conclusion	Notes
1	Filtering efficiency [%]	5.3	KN95 $\geq$ 95.0	Unpretreated	98.8	合格 Pass	/
					98.5		
					99.0		
					98.5		
					99.2		
					99.0		
					98.6		
					98.4		
					98.8		
					99.0		
			Pretreated	99.5			
				98.8			
				98.6			
				99.4			
				99.0			
			Detection of oily particles Temperature: (25±5)℃ Humidity: (30±10)%		Measured temperature: 24℃ Measured Humidity: 34%		
2	Inhale resistance[Pa]	5.5	Total inhale resistance $\leq$ 150	Unpretreated	123.7	合格 Pass	/
					122.1		
				Pretreated	117.6		
					116.4		
3	Exhalation resistance[Pa]	5.5	Total exhalation resistance $\leq$ 250	Unpretreated	115.0	合格 Pass	/
					114.3		
				Pretreated	112.0		
					111.7		

测 报

TEST REPORT

第 3 页 共 5 页

No	Test items[Unit]	Standard terms	Standard requirements	Result		Conclusion	Notes
4	Headband	5.9	Each headband, buckle and other adjustment parts of the disposable mask should not slip or break when it bears a tensile force of 10N for 10s.	Unpretreated	No slippage or fracture	Pass	/
				Pretreated	No slippage or fracture		