BRDS
TEAMTEX

FFP2 Masken
Zertifikate

MEDICAL


ARCOM
FFP2 NR
FILTERING HALF MASK
NON-STERILE
BAKTERIEN-FREI
SINGLE USE ONLY
NUR EINZELNUTZUNG
EU: 2016/425
EN149: 2001 + A1: 2009 FFP2 NR
20
STÜCK
PIECE
·Pollen prevention
·Allergy free
·Dustpro of
·Sanitary materials grade
·Filter particulates
·Pollenprävention
·Allergiefrei
·Staubdicht
·Sanitäre Materialien Qualität
·Partikel filtern
AC9504
CE 2163
FFP2 NR
EN149:2001+A1:2009
HEYUAN ARCOM
Model:AC9504
CE 2163


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AC9504
CE 2163
FFP2 NR
EN149:2001+A1:2009
HEYUAN ARCOM
Model:AC9504
CE 2163


ARCOM™
FFP2 NR
FILTERING HALF MASK
-30°C
+40°C


ARCOM™
FFP2 NR
FILTERING HALF MASK
[redacted]
Heyuan Arcom Medical Devices Co.,Ltd
Yingke Avenue, Linjiang Indusrial Park, Linjiang Town,
Jiangdong New District, Heyuan City, Guangdong, China

ENGLISH

[Product Name]:Filtering half mask
[Mode[]:AC9504
[EU Executive Standard]:EN 149:2001+A1:2009 FFP2 NR
[Specification]:15.5cm*10.5cm
[Materials]:42.6% non-woven fabric,28.6% hot air cotton,28.6% melt blown fabric
[Production Date]:See the date on the Product Certification.
[Shelf life]:3 years
[Scope of Application]:It is applicable to public health places,families,factoriesor general places.
[Funciton]:It is used to cover the user' s mouth,nose and jaw.It is used to wear and block the exhalation or ejection of pollutants form the mouth and nasal cavity in common environment.

1.Warning:
a.Risk may be expect if the product is used in any surgical setting or wheresignificant exposure to liquid,bodily or other hazardous fluids;Inhalation exposure is high;or use in the presence of a high intensity heat source of flammable gas.
b.The product is not for use in the anoxic environment and under waterenvironment.
c.This product is not a respirator.
d.The mask does not eliminatethe risk of contracting any disease or infection.
e.Failure toproperly use and maintain this product could result in illness.
f.Please use within the validity period.
g.Do not use if the package is damaged.
2.This product is valid for 3 years.Please use it within the validity period.
3.Storage conditions:
a.The product should be stored in the relative humidity of no mor than 80%,no corrosive gas or well ventilated indoor conditions
b.The product shall not be too compressed during transportation in case the packing is damaged.

Correct Way of Wearing

- Place the nose clip over the mask.Put the mask over your chin.
- After pulling the ear belt to the ear,adjust position as comfortable as possible.
- From the middle of nose clip to both sides,press while moving untilthe nose clip fit the bridge of the nose.
- Check mask and face cohesion.

GERMAN

[Produktname]:Halbmaske filtern
[Modell]:AC9504
[EU Executive Standard]:EN 149:2001+A1:2009 FFP2 NR
[Spezifikation]:15.5cm* 10.5 cm
[Materialien]:42,8% Vliesstoff, 28.6% Heißluftbaumwolle, 28.6% schmelzgeblasenes Gewebe
[Produktionsdatum]:Siehe das Datum auf der Produktzertifizierung.
[Lebensdauer]:3 Jahre
[Anwendungsbereich]:Es gilt für öffentliche Gesundheitsplätze, Familien, Fabriken oder allgemeine Orte.
[Funciton]:Es wird verwendet, um den Mund, die Nase und Kinn zu bedecken, um das Ausatmen oder Auswerfen von Schadstoffen aus dem Mund und der Nasenhöhle in der gemeinsamen Umgebung zu tragen und zu blockieren.

1.Warnung:
a.Risiko kann erwartet werden, wenn das Produkt in einer chirurgischen Umgebung verwendet wird oder wenn eine signifikante Exposition gegenüber flüssigen, körperlichen oder anderen gefährlichen Fluiden;inhalationsexposition hoch ist;oder in Gegenwart einer hochintensiven Wärmequelle von brennbarem Gas verwendet wird.
b.Das Produkt ist nicht für den Einsatz in der anoxischen Umgebung und unter Wasser.
c.Dieses Produkt ist kein Beatmungsgerät.
d.Die Maske eliminiert nicht das Risiko einer Krankheit oder Infektion.
e.Die nichtordnungsgemäße Verwendung und Wartung dieses Produkts kann zu einer Erkrankung führen.
f.Bitte innerhalb der Gültigkeitsdauer verwenden.
g.Bitte nicht verwenden, wenn das Paket beschädigt ist.
2.Dieses Produkt ist gültig Tor 3 Jahre. Bitte nutzen Sie diese innerhalb der Gültigkeitsdauer.
3.Lagerbedingungen:
a.Das Produkt sollte in der relativen Luftfeuchtigkeit von nicht mor als 80%, kein korrosives Gas oder gut belüfteten Innenbedingungen gelagert werden
b.Das Produkt darf während des Transports nicht zu komprimiert werden, wenn die Verpackung beschädigt wird.

Korrekte Art des Tragens

- Legen Sie den Nasenclip über die Maske. Setzen Sie die Maske über Ihr Kinn.
- Nach dem Ziehen des Ohrriemens an das Ohr, stellen Sie die Position so bequem wie möglich.
- Von der Mitte des Nasenclips zu beiden Seiten drücken, drücken Sie während der Bewegung, bis die Nase Clip passen die Brücke der Nase.
- Maske und Gesichtszusammenhalt überprüfen.

7438644116242

MADE IN CHINA

ERP代码	产品名称	规格
E030666	雅康FFP2NR防护口罩（英、德文）20个装彩盒	250G单铜+光胶 180*112*90mm

ARCOM

FFP2 NR

FILTERING HALF MASK

NON-STERILE
BAKTERIEN-FREI

SINGLE USE ONLY
NUR EINZELNUTZUNG

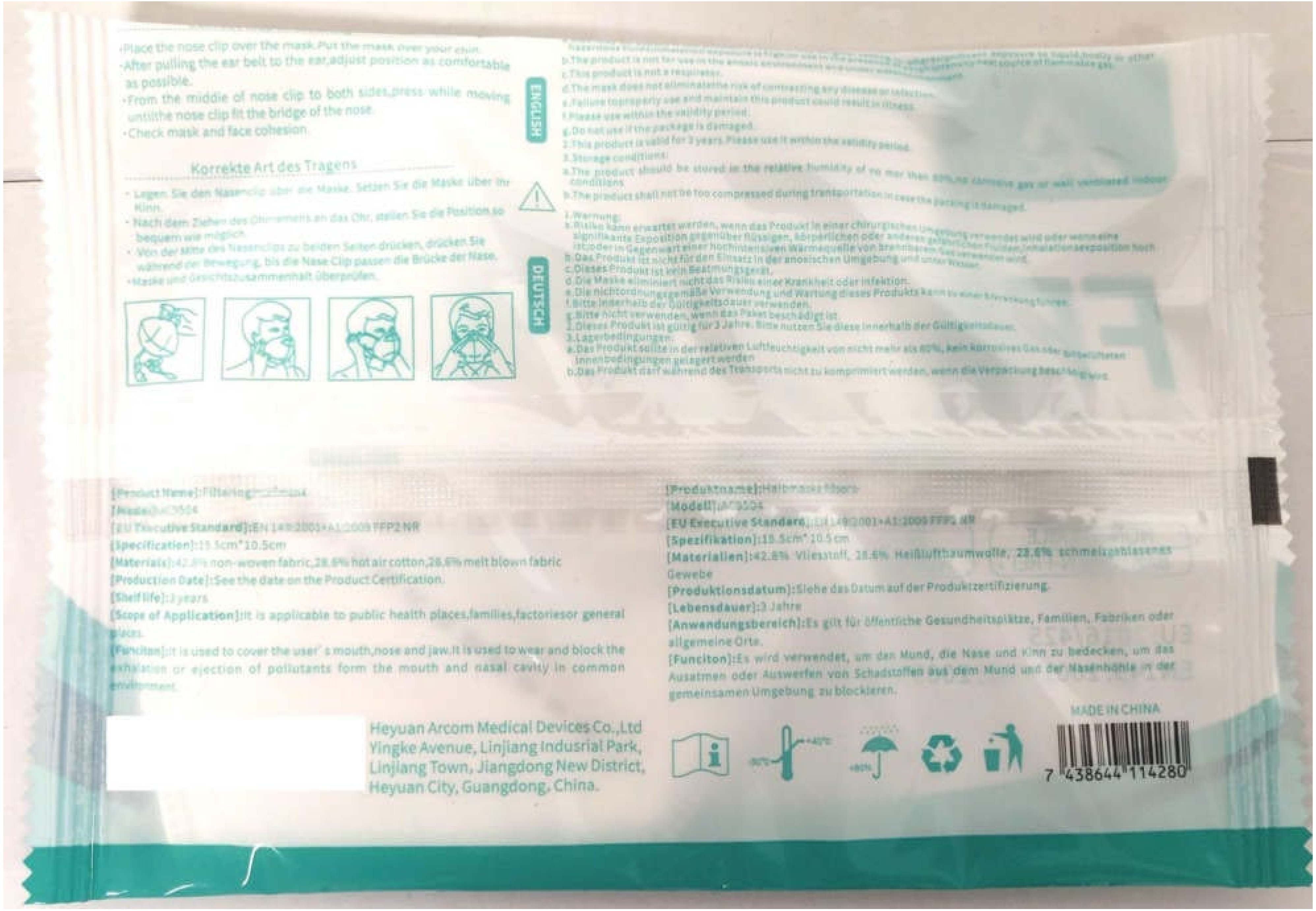
1 STÜCK
PIECE

EU: 2016/425

EN149: 2001 + A1: 2009 FFP2 NR

Model:AC9504

CE 2163

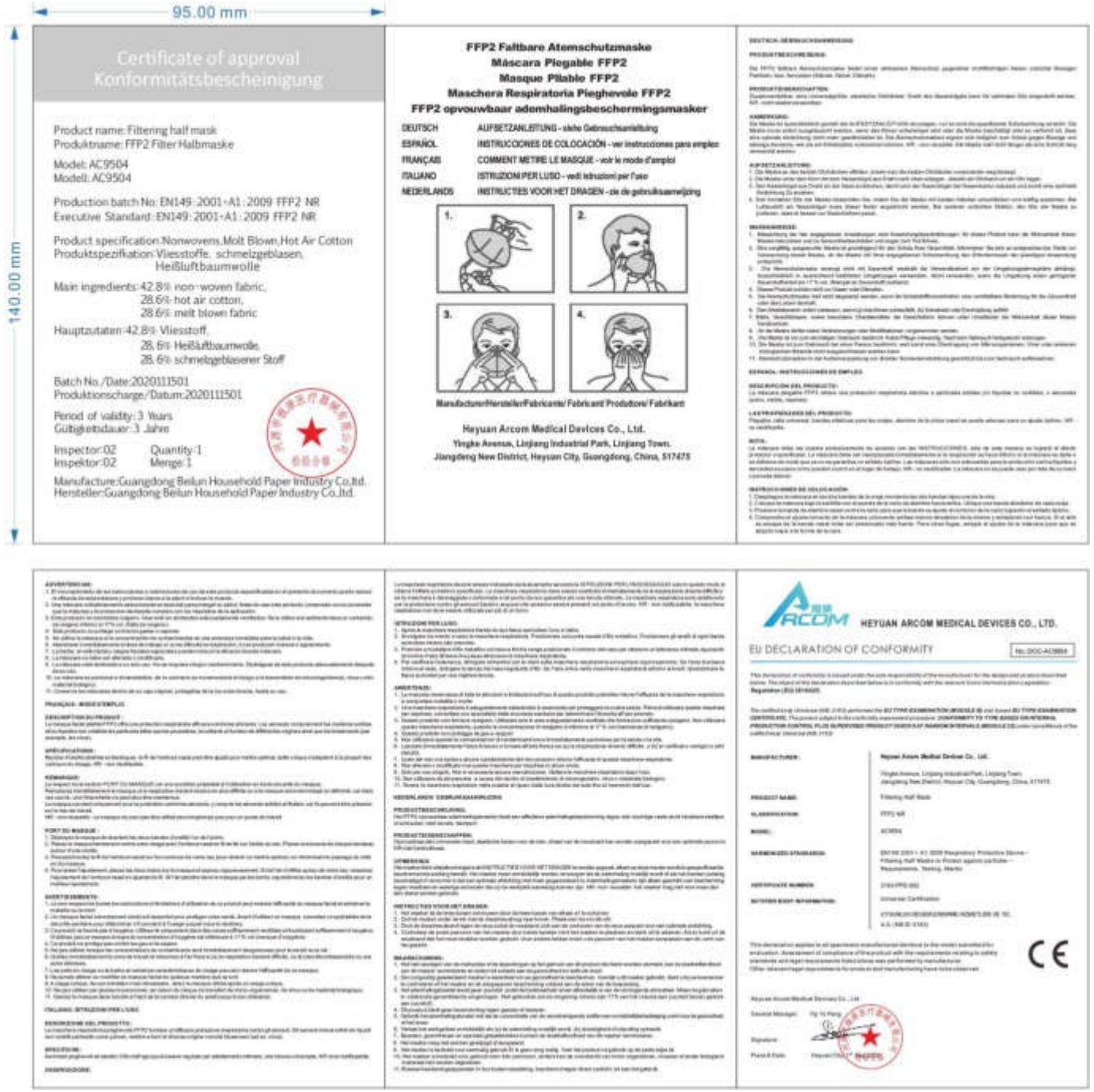


·Place the nose clip over the mask.Put the mask over your chin.
·After pulling the ear belt to the ear,adjust position as comfortable as possible.
·From the middle of nose clip to both sides,press while moving untilthe nose clip fit the bridge of the nose.
·Check mask and face cohesion.
Korrekte Art des Tragens
· Legen Sie den Nasenclip über die Maske. Setzen Sie die Maske über Ihr Kinn.
· Nach dem Ziehen des Ohrriemens an das Ohr, stellen Sie die Position so bequem wie möglich.
· Von der Mitte des Nasenclips zu beiden Seiten drücken, drücken Sie während der Bewegung, bis die Nase Clip passen die Brücke der Nase.
·Maske und Gesichtszusammenhalt überprüfen.
ENGLISH
DEUTSCH
c.This product is not a respirator.
d.The mask does not eliminatethe risk of contracting any disease or infection.
e.Failure toproperly use and maintain this product could result in illness.
f.Please use within the validity period.
g.Do not use if the package is damaged.
2.This product is valid for 3 years.Please use it within the validity period.
3.Storage conditions:
b.The product shall not be too compressed during transportation in case the packing is damaged.
1.Warnung:
c.Dieses Produkt ist kein Beatmungsgerät.
d.Die Maske eliminiert nicht das Risiko einer Krankheit oder Infektion.
f.Bitte innerhalb der Gültigkeitsdauer verwenden.
g.Bitte nicht verwenden, wenn das Paket beschädigt ist.
3.Lagerbedingungen:
[Product Name]:Filtering
[Specification]:15.5cm*10.5cm
[Materials]:42.8% non-woven fabric,28.6% hot air cotton,28.6% melt blown fabric
[Production Date]:See the date on the Product Certification.
[Shelf life]:3 years
[Scope of Application]:It is applicable to public health places,families,factoriesor general places.
[Funciton]:It is used to cover the user' s mouth,nose and jaw.It is used to wear and block the exhalation or ejection of pollutants form the mouth and nasal cavity in common environment.
[Produktname]:Halbmaske
[Modell]:
[Spezifikation]:15.5cm*10.5cm
[Materialien]:42.8% Vliesstoff, 28.6% Heißluftbaumwolle, 28.6% schmelzgeblasenes Gewebe
[Produktionsdatum]:Siehe das Datum auf der Produktzertifizierung.
[Lebensdauer]:3 Jahre
[Anwendungsbereich]:Es gilt für öffentliche Gesundheitsplätze, Familien, Fabriken oder allgemeine Orte.
[Funciton]:Es wird verwendet, um den Mund, die Nase und Kinn zu bedecken, um das Ausatmen oder Auswerfen von Schadstoffen aus dem Mund und der Nasenhöhle in der gemeinsamen Umgebung zu blockieren.
Heyuan Arcom Medical Devices Co.,Ltd
Yingke Avenue, Linjiang Indusrial Park,
Linjiang Town, Jiangdong New District,
Heyuan City, Guangdong, China.
MADE IN CHINA
7 438644 114280

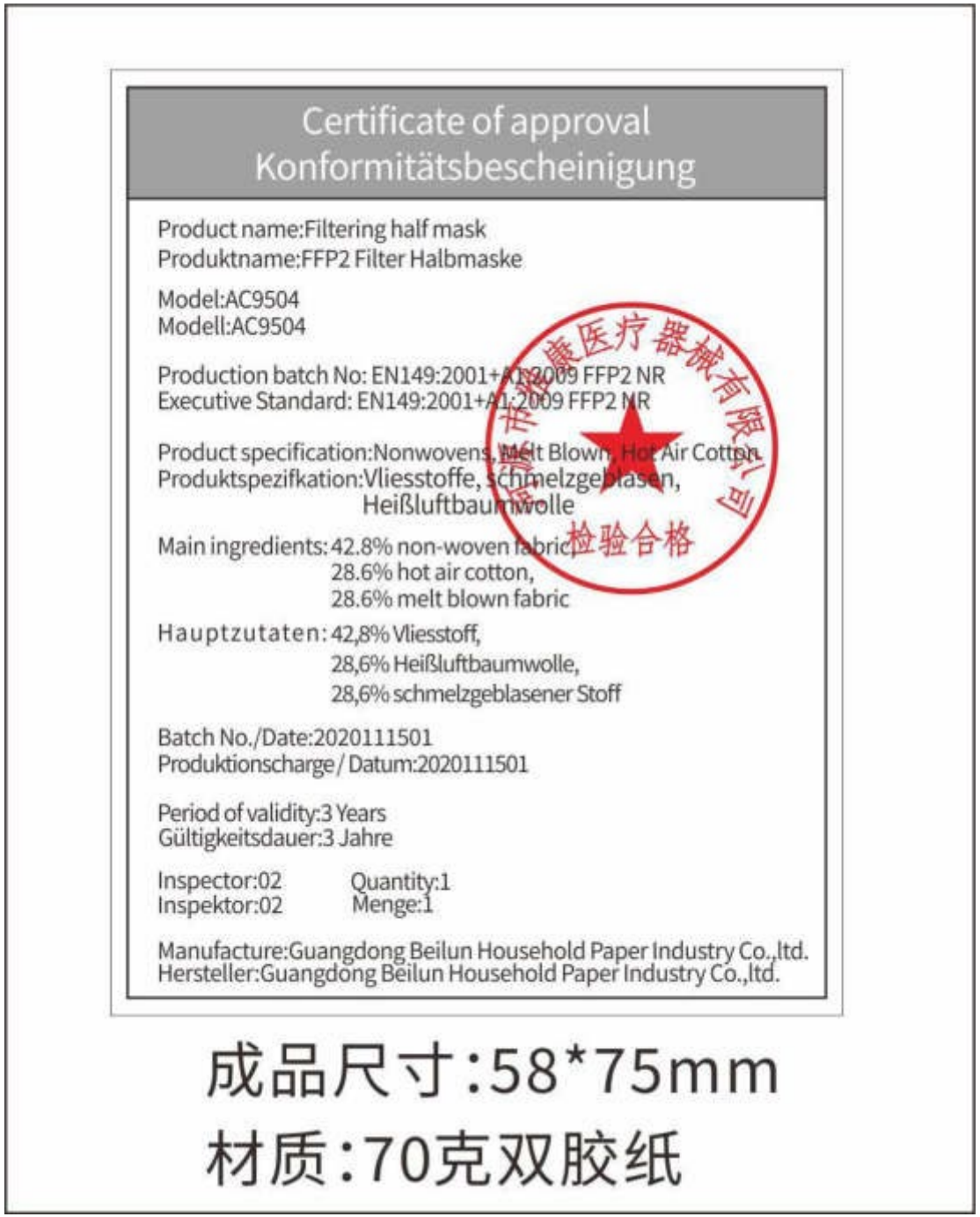
出卷方向 ⟶

ERP代码	产品名称	规格
E020611	雅康FFP2NR防护口罩（英、德文）1个装内包	BOPP/CPP 0.045 宽280*长180mm

- Anleitung / Beipackzettel



- Konformitäts / Fertigungssbescheinigung



Certificate of approval
Konformitätsbescheinigung

Product name:Filtering half mask
Produktname:FFP2 Filter Halbmaske

Model:AC9504
Modell:AC9504

Production batch No: EN149:2001+A1:2009 FFP2 NR
Executive Standard: EN149:2001+A1:2009 FFP2 NR

Product specification:Nonwovens, Melt Blown, Hot Air Cotton
Produktspezifkation:Vliesstoffe, schmelzgeblasen, Heißluftbaumwolle

Main ingredients: 42.8% non-woven fabric
28.6% hot air cotton,
28.6% melt blown fabric

Hauptzutaten: 42,8% Vliesstoff,
28,6% Heißluftbaumwolle,
28,6% schmelzgeblasener Stoff

Batch No./Date:2020111501
Produktionscharge / Datum:2020111501

Period of validity:3 Years
Gültigkeitsdauer:3 Jahre

Inspector:02 Quantity:1
Inspektor:02 Menge:1

Manufacture:Guangdong Beilun Household Paper Industry Co.,ltd.
Hersteller:Guangdong Beilun Household Paper Industry Co.,ltd.

检验合格

成品尺寸:58*75mm

材质:70克双胶纸

- EU_Konformitaetserklärung

HEYUAN ARCOM MEDICAL DEVICES CO., LTD.

EU DECLARATION OF CONFORMITY

No.: DOC-AC9504

This declaration of conformity is issued under the sole responsibility of the manufacturer for the designated product described below. The object of the declaration described below is in conformity with the relevant Union Harmonization Legislation: **Regulation (EU) 2016/425**.

The notified body **Universal** *(NB: 2163) performed the* **EU TYPE-EXAMINATION (MODULE B)** *and issued* **EU TYPE-EXAMINATION CERTIFICATE**. *The product subject to the conformity assessment procedure:* **CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)** *under surveillance of the notified body* **Universal** *(NB: 2163)*

MANUFACTURER:	**Heyuan Arcom Medical Devices Co., Ltd.** Yingke Avenue, Linjiang Industrial Park, Linjiang Town, Jiangdong New District, Heyuan City, Guangdong, China, 517475
PRODUCT NAME:	**Filtering Half Mask**
CLASSIFICATION:	**FFP2 NR**
MODEL:	**AC9504**
HARMONIZED STANDARDS:	**EN149:2001+A1:2009 Respiratory Protective Device – Filtering Half Masks to Protect against particles – Requirements, Testing, Markin**
CERTIFICATE NUMBER:	**2163-PPE-892**
NOTIFIED BODY INFORMATION:	Universal Certification UYGUNLUK DEĞERLENDİRME HİZMETLERİ VE TİC. A.Ş. (NB ID: 2163)

This declaration applies to all specimens manufactured identical to the model submitted for evaluation. Assessment of compliance of the product with the requirements relating to safety standards and legal requirements listed above was performed by manufacturer.
Other relevant legal requirements for product and manufacturing have to be observed.

CE

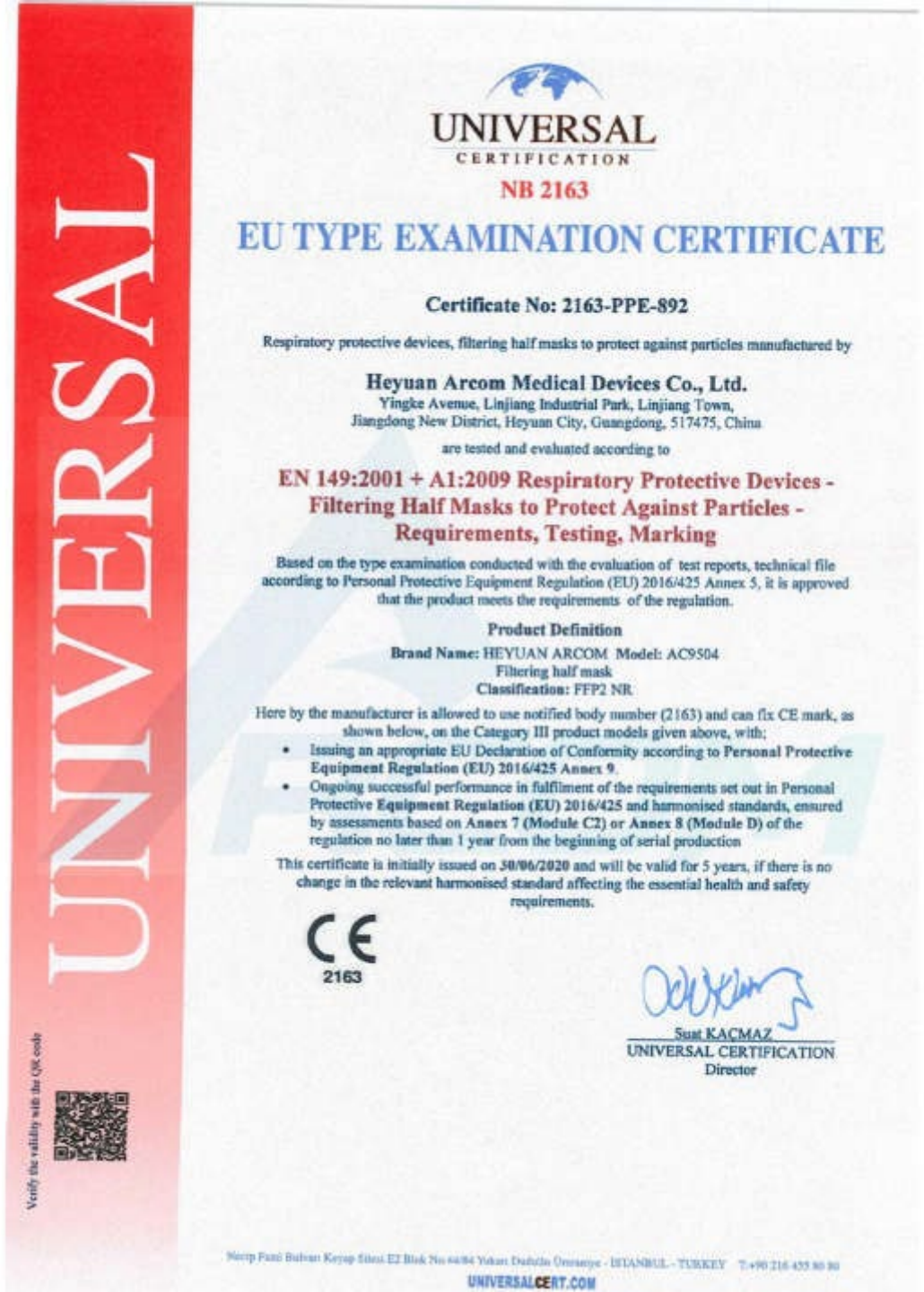
Heyuan Arcom Medical Devices Co., Ltd.

General Manager: Yip Yu Pang

Signature:

Place & Date: Heyuan City, 1st Sep 2020

- Baumusterpruefbescheinigung



UNIVERSAL

Verify the validity with the QR code

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-892

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

Heyuan Arcom Medical Devices Co., Ltd.
Yingke Avenue, Linjiang Industrial Park, Linjiang Town,
Jiangdong New District, Heyuan City, Guangdong, 517475, 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: HEYUAN ARCOM Model: AC9504
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 **30/06/2020** 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

Necip Fazıl Bulvarı Keyap Ofisi E2 Blok No 6a/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80

UNIVERSALCERT.COM

- PPE Modul C2

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE–892/01

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

Heyuan Arcom Medical Devices Co., Ltd.
Yingke Avenue, Linjiang Industrial Park, Linjiang Town, Jiangdong New District, Heyuan City, Guangdong, 517475, 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
HEYUAN ARCOM / AC9504	FFP2 NR	2163-PPE–892	30.06.2020	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 **30/06/2020** and will be valid for one year, until **29/06/2021** 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

Nerip Fuat Bulvarı Kayışı Sitesi B2 Blok No:44/84 Yukarı Dudullu Umraniye - İSTANBUL - TURKEY T:+90 216 455 82 80

UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 30.06.2020 / 2163-KKD-892

Manufacturer: Heyuan Arcom Medical Devices Co., Ltd.

Address: Yingke Avenue, Linjiang Industrial Park, Linjiang Town, Jiangdong New District, Heyuan City, Guangdong, 517475, 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 20.06.2020 with Serial Id WSZ FHL F0749 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 24 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.

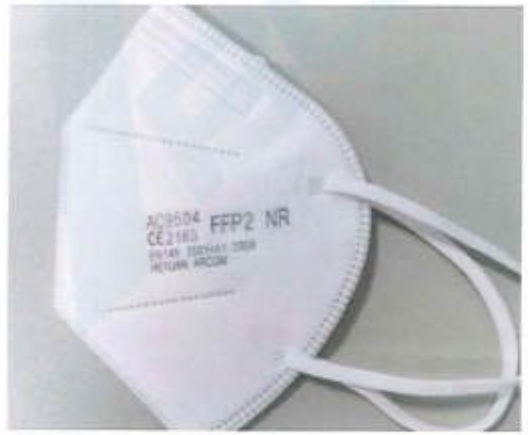
The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipement Regulation and found to be appropriate.

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

Trademark: HEYUAN ARCOM **Model:** AC9504



UNIVERSAL
CERTIFICATION

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 possible level. The test results with human subjects did not report any problem with the ergonomics of the product.

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. The manufacturer declares in his technical file that according to the results of risk analysis and the material properties they use in the manufacturing, the product has no hazardous content for health.

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. The material selection is processed in the technical manufacturing process and documented.

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 is evaluated and reported in the test report.

1.2.1.3. Maximum permissible user impediment

Any impediment 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 question;
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

UNIVERSAL
CERTIFICATION

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 these 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. The product is for single use and tested with simulated wearing conditioning.

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 these 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

Confirming 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 temperature conditioning. No resistance 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 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 exercises 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 imperfections reported during total inward tests about the comfort, field of vision and fastening means. **Conditioning :** (A.R.) As Received, original

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
2.Head harness assembly	2	0	Positive results are obtained from the test subjects No imperfections
3.Security of fastenings	2	0	
5.Field of vision	2	0	

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 exercises 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 exercises are available in the test report. It was reported that; At least 46 out of the 50 exercise measurement results are smaller or equal to 11%, the values varies between 4.2 % and 6.0 %. At least 8 out of the 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 4.9 % and 5.7 %. **According to the reported results, the product meets the limits for FFP1 and FFP2 classification.**
Article 7.9.2	**Penetration of filter material:** Sodium Chloride Testing

Condition	No. of Samples	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0.1		
(A.R.)	-	0.2		
(A.R.)	-	0.1	FFP1 ≤ 20 %	Filtering half masks fulfil the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2, FFP3** classes.
(S.W.)	-	0.2		
(S.W.)	-	0.1	FFP2 ≤ 6 %	
(S.W.)	-	0.1		
(M.S. T.C.)	-	0.3	FFP1 ≤ 1 %	
(M.S. T.C.)	-	0.1		
(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 dm³ 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.)	-	0.5	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** classes.
(A.R.)	-	0.6		
(A.R.)	-	0.7		
(S.W.)	-	0.7		
(S.W.)	-	0.6		
(S.W.)	-	0.6		
(M.S. T.C.)	-	2.9		
(M.S. T.C.)	-	3.2		
(M.S. T.C.)	-	3.1		

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.)	-	0.1 s	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.)	-	0.1 s		
(T.C.)	-	0.1 s		
(T.C.)	-	0.1 s		

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.)	-	0.6925	0.69 [%]	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.)	-	0.6953			
(A.R.)	-	0.6943			

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 temperature 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. The measurement details for each single mask tested are available in the test report.

Passed.

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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 date 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 AC9504. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (HEYUAN ARCOM) 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 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 AC9504 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 commercially available package.

PREPARED BY	APPROVED BY
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AC9504 FFP2 NR
CE 2163
EN149:2001+A1:2009
HEYUAN ARCOM

- Masterkarton FRONT

ARCOM™

- Pollen prevention
- Allergy free
- Dustpro of
- Sanitary materials grade
- Filter particulates

- Pollenprävention
- Allergiefrei
- Staubdicht
- Sanitäre Materialien Qualität
- Partikel filtern

FFP2 NR

FILTERING HALF MASK

NON-STERILE
BAKTERIEN-FREI

SINGLE USE ONLY
NUR EINZELNUTZUNG

EU: 2016/425

EN149: 2001 + A1: 2009 FFP2 NR

1000 STÜCK PIECE

Model:AC9504

CE 2163


ARCOM™
FFP2 NR
FILTERING HALF MASK
-30°C
+40°C
Heyuan Arcom Medical Devices Co.,Ltd
Yingke Avenue, Linjiang Indusrial Park, Linjiang Town,
Jiangdong New District, Heyuan City, Guangdong, China.


ARCOM™
PRODUCT NAME: Filtering Half Mask
MODEL: A C 9 5 0 4
MEAS: 65*50*37.2
QTY : 1000 PCS
N.W: 9.5kg
G.W: 11.2kg
MADE IN CHINA
5

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