

KEHOLL

Ciencia y tecnología al servicio de la salud

Fabricante y distribuidor
de mascarillas FFP2 y FFP3



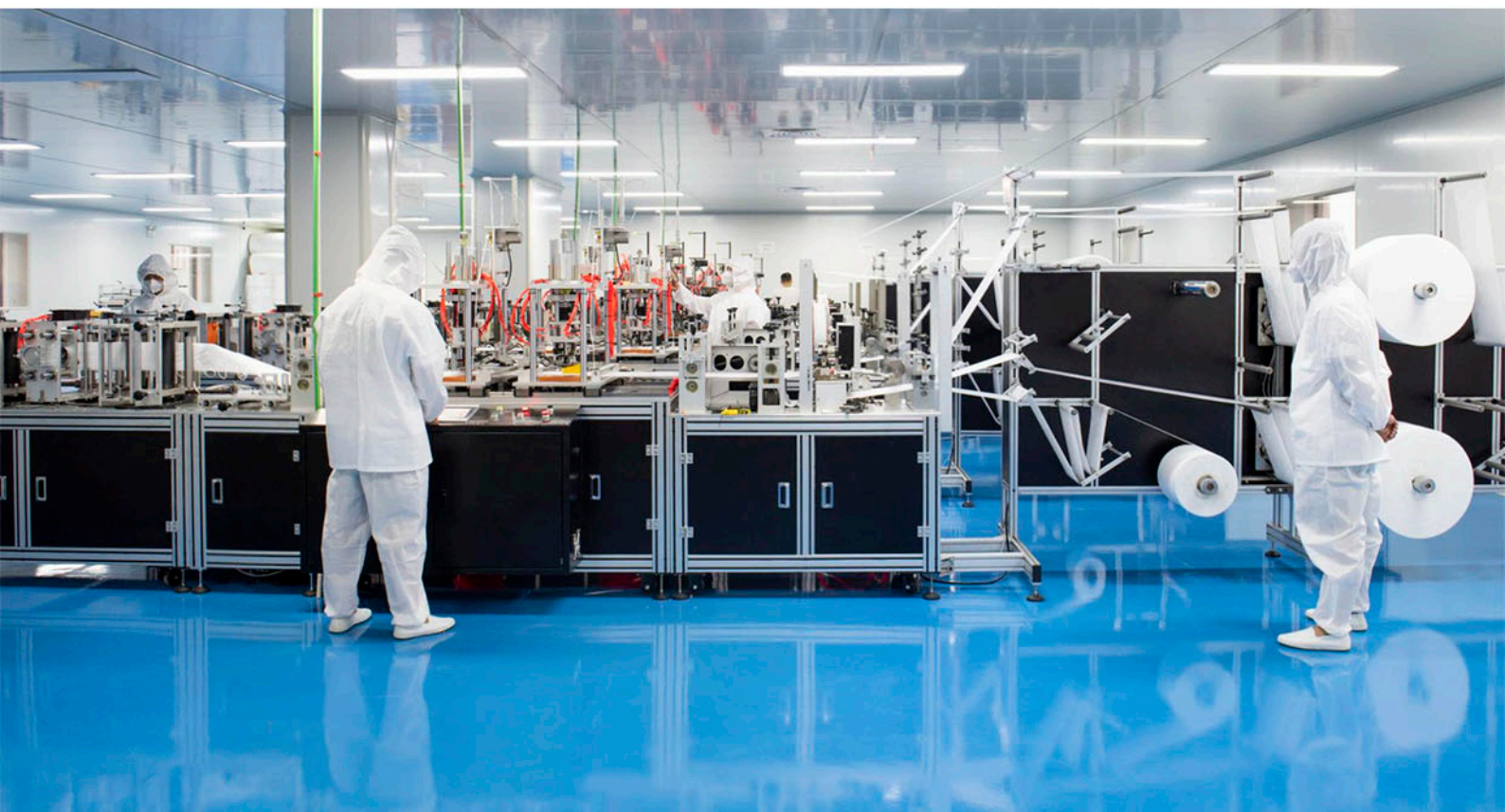
Zhejiang Min'an Medical Products Co. Ltd.

Está ubicada en la Zona Industrial Tingshi, Provincia de Zhejiang.

Es una empresa dedicada a la producción de mascarillas protectoras médicas. Zhejiang Min'an Medical siempre se ha comprometido a crear una empresa dinámica, poderosa y atractiva para crear un mayor valor para los clientes.

El objetivo es fabricar mascarillas FFP2 y FFP3 de alta calidad para ser usadas por personas en todo el país y en todo el mundo, crear productos con una excelente calidad de fabricación como contribución a la economía y la sociedad.

La marca KEHOLL se centra en la investigación, el desarrollo, la producción y la venta de máscaras FFP2 y FFP3, y ha proporcionado una gran cantidad de mascarillas de alta calidad a muchas provincias y ciudades de todo el país y a muchos países del mundo.



Vallepharma Andaluz S.L.U.

Está ubicada en la ciudad de Barcelona, Catalonia, España.

Es una empresa dedicada a la importación y representación de productos principalmente de China.

Representando la marca KEHOLL en exclusividad para España y Europa y con el objetivo de distribuir mascarillas FFP2 y FFP3 de alta calidad y con los precios más competitivos.



营业执照

(副本)

统一社会信用代码
91330381MA2HCGBJ0T(1/1)

名称 浙江民安医疗用品有限公司

类型 有限责任公司(自然人投资或控股)

法定代表人 蔡少海

经营范围 一般项目: 医护人员防护用品生产(I类医疗器械); 医护人员防护用品批发; 卫生用品和一次性使用医疗用品销售; 口罩批发; 日用口罩(非医用)生产; 日用口罩(非医用)销售; 第一类医疗器械生产; 第一类医疗器械销售; 第二类医疗器械销售; 特种劳动防护用品生产; 特种劳动防护用品销售; 除依法须经批准的项目外, 凭营业执照依法自主开展经营活动)。许可项目: 医用口罩生产; 卫生用品和一次性使用医疗用品生产; 医护人员防护用品生产(II类医疗器械); 货物进出口; 技术进出口(依法须经批准的项目, 经相关部门批准后方可开展经营活动, 具体经营项目以审批结果为准)。

注册资本 叁仟万元整

成立日期 2020年04月27日

营业期限 2020年04月27日至2050年04月26日

住所 浙江省温州市瑞安市汀田街道汀田工业区(瑞安市时友织带厂第三层东首)

登记机关 瑞安市市场监督管理局

2020年04月27日

国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过国家信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

Business License (COPY)

Unified Social Credit Code
91330381MA2HCGBJ0T(1/1)

Name: Zhejiang Min'an Medical Supplies Co., Ltd.

Registered Capital: Thirty Million Yuan

Type: Limited Liability Company (investment or holdings by a natural person)

Establish Date: April 27, 2020

Legal Representative: Cai Shaohai

Business Term: from April 27, 2020 to April 26, 2050

Address: Tingtian Industrial Zone Tingtian Street Ruian City

Wenzhou City Zhejiang Province

{The eastern of the 3rd floor of Ruian Shiyou Ribbon Factory}

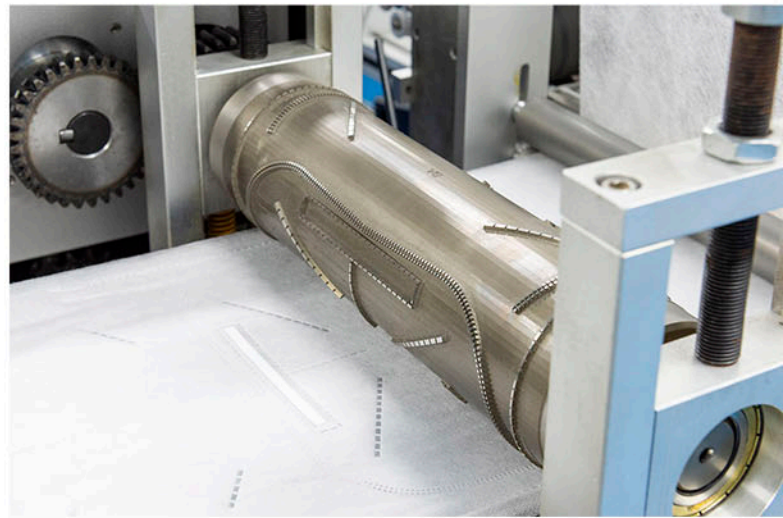
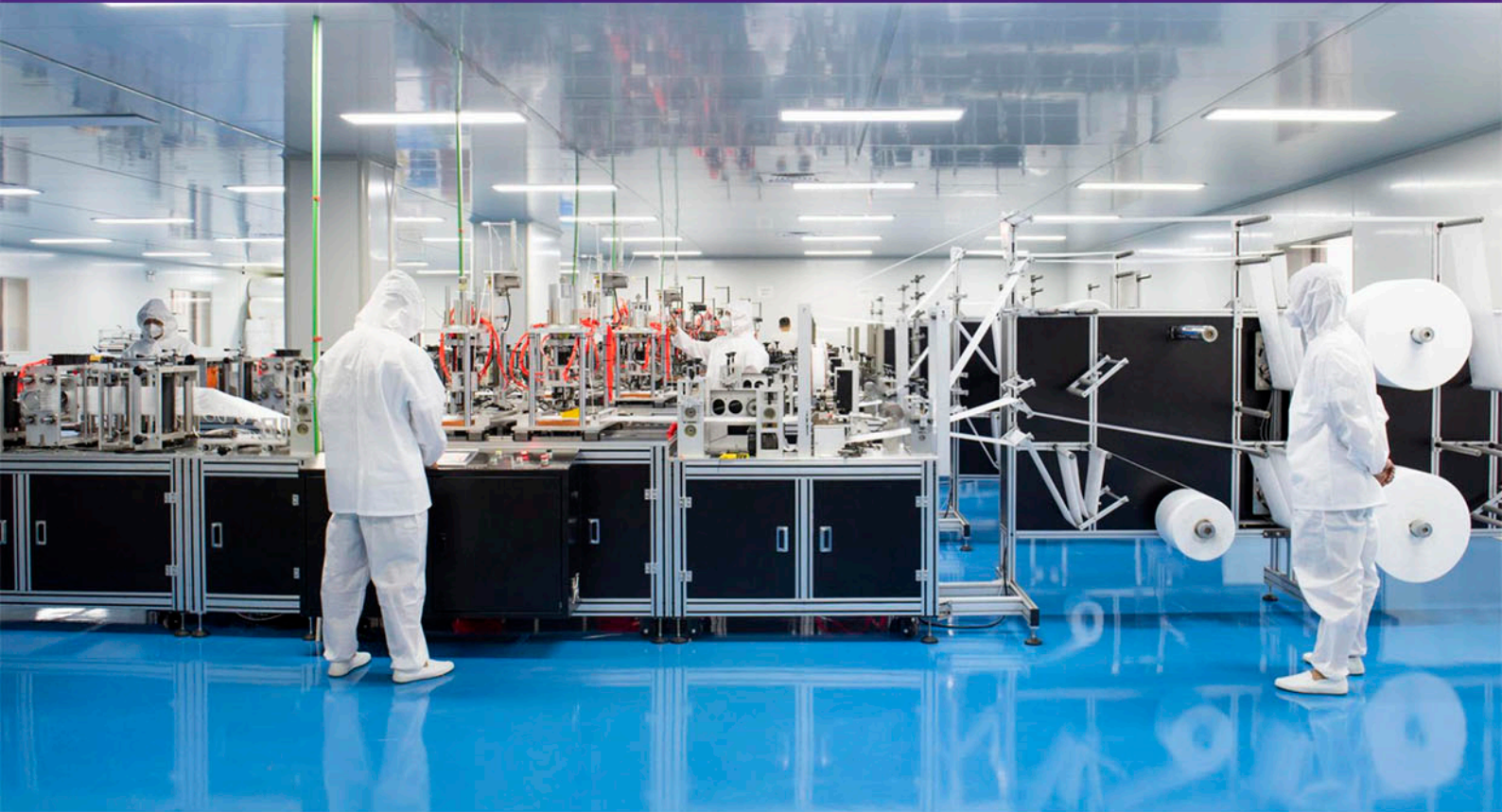
Business Scope: General Item: Production of protective equipment for medical staff (class I medical equipment); Wholesale of protective equipment for medical staff; Sales of sanitary and disposable medical supplies; Wholesale of surgical masks; Production of daily use masks (non-medical); Sales of daily masks (non-medical); Production of Class I medical equipment; Sales of Class I medical equipment; Sales of Class II medical equipment; Production of protective equipment for special labor; Sales of protective equipment for special labor (Carry out business activities independently according to the law by business license, except for items subject to approval according to law). Licensed items: Production of surgical mask; Production of sanitary and disposable medical supplies; Production of protective equipment for medical staff (class II medical equipment); Import and export of goods; Import and export of technology (for items subject to approval according to law, business activities can only be carried out after the approval of relevant departments, and the specific business item shall be subject to the approval results).

Registration Authority: Ruian Market Supervision Administration 3303810078252
April 27, 2020

Website of National Enterprise Credit Information Publicity System: <http://www.gsxt.gov.cn>

The market entities shall submit and public the annual report through the national credit publicity system on January 1, 2016 and June 30 of each year.

Supervised by State Administration for Market Regulation.



KEHOLL™ FFP2 NR
EN149:2001+A1:2009

Filtering Half Mask

FILTRACIÓN TASA **≥95%**

MASCARILLA RESPIRATORIA

CE 2163

FILTERABILITY ≥ 95%

- Estructura de cinco niveles
- adherirse a la cara, corte sólido
- corte sólido
- ajuste de 360° a la piel
- tela no tejida súper suave interior



Model: MA-001

Effectively block dust, bacteria and other particles
Bloquea eficazmente el polvo, las bacterias y otras partículas

20 PCS PIEZAS



KEHOLL™ FFP2 NR
EN149:2001+A1:2009

Filtering Half Mask

FILTRACIÓN TASA **≥95%**

MASCARILLA RESPIRATORIA

CE 2163

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Model: MA-001

Effectively block dust, bacteria and other particles
Bloquea eficazmente el polvo, las bacterias y otras partículas

20 PCS PIEZAS



FFP2 NR MASCARILLA RESPIRATORIA

**Nombre del producto:**

Filtering half mask (non medical)

Modelo:

MA-001

Norma:

EN149:2001+A1:2009

Marcado:

CE 2163

Componentes - Características:

No tejido

Fabric 42%

Melt-blown fabric 29%

Hot air cotton 29%

Capas:

5 capas

Filtrado:

≥95%

Dimensiones:

160x105 mm. (+/- 3mm.)

Condiciones de almacenaje:

<50 °C humedad <80%

Garantía:

2 años

Fabricante:

Manufacturer: Zhejiang Min'an Medical Supplies Co., Ltd.

Importador:

Vallepharma Andaluz S.L.U.

**Colores disponibles:**

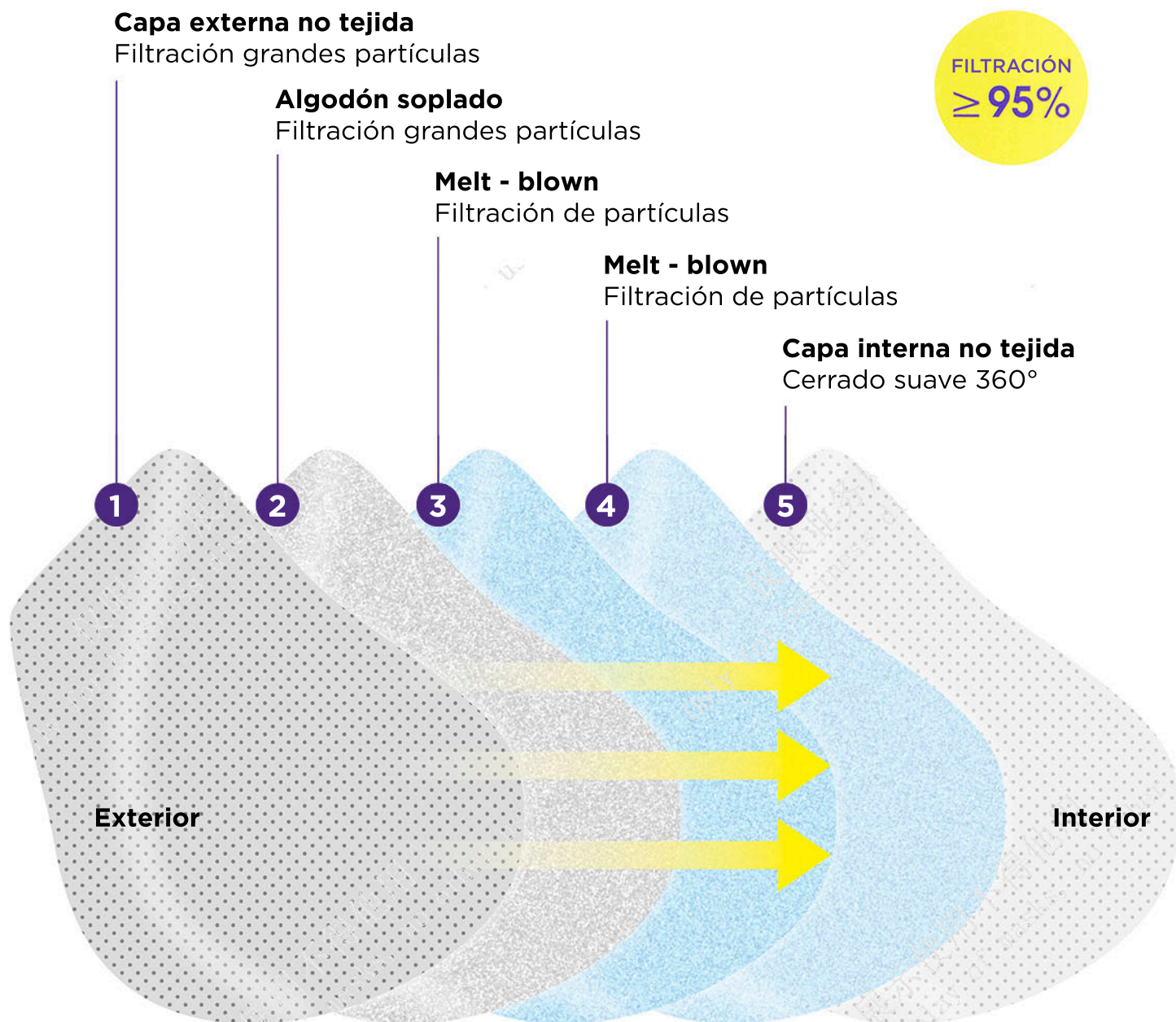
Blanco

Negro

FFP2 NR MASCARILLA RESPIRATORIA

- Ajuste a la cara
- Corte sólido
- Ajuste de 360° a la piel
- Tela no tejida interior super suave
- Estructura de 5 capas
- Bloquea efectivamente el polvo, las bacterias y otras partículas
- Tasa de filtración $\geq 95\%$

FFP2 NR - Mascarilla Respiratoria



KEHOLL™

Filtering Half Mask

FILTRACIÓN TASA

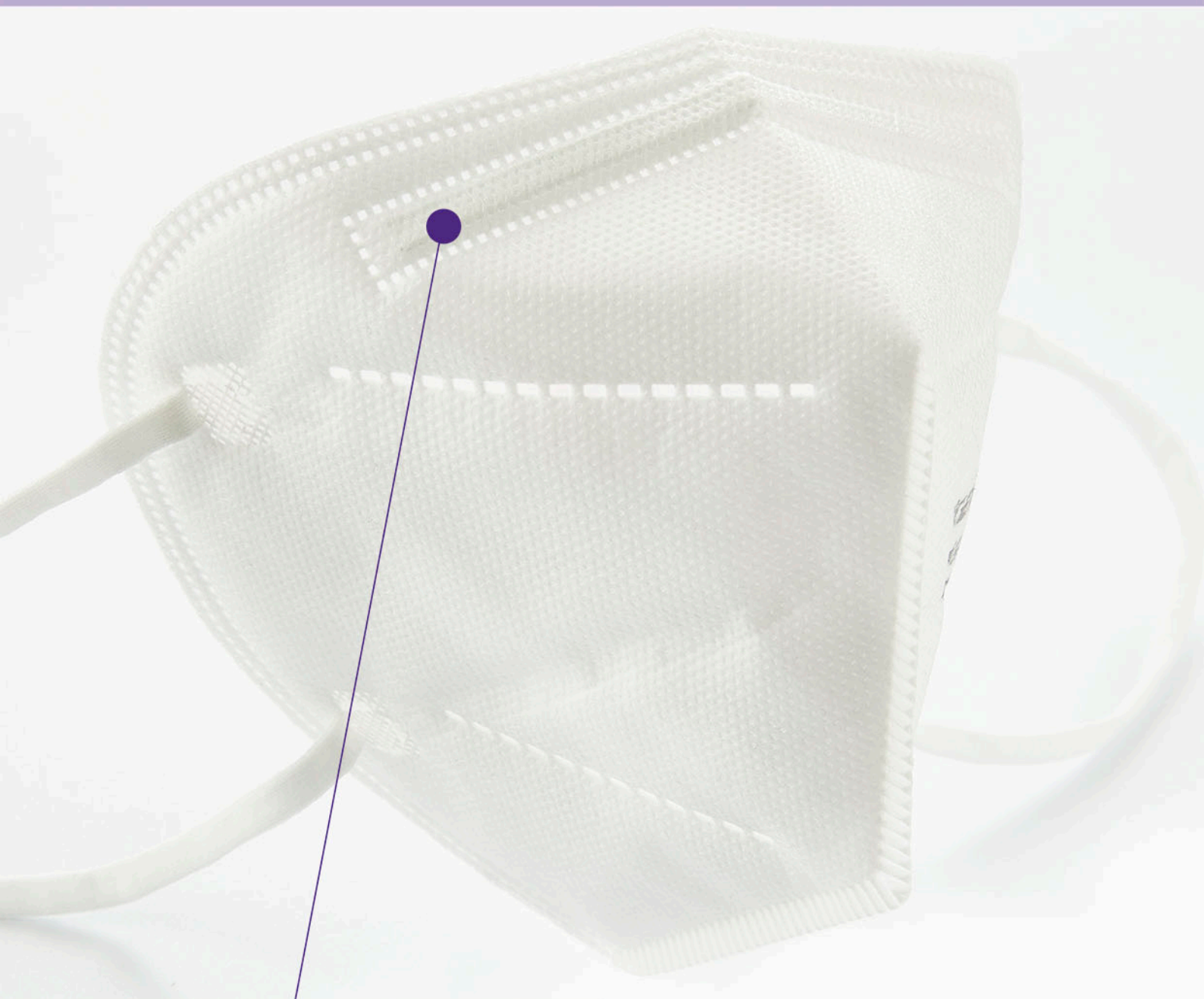
≥95%

FFP2 NR

EN149:2001 + A1:2009

CE 2163

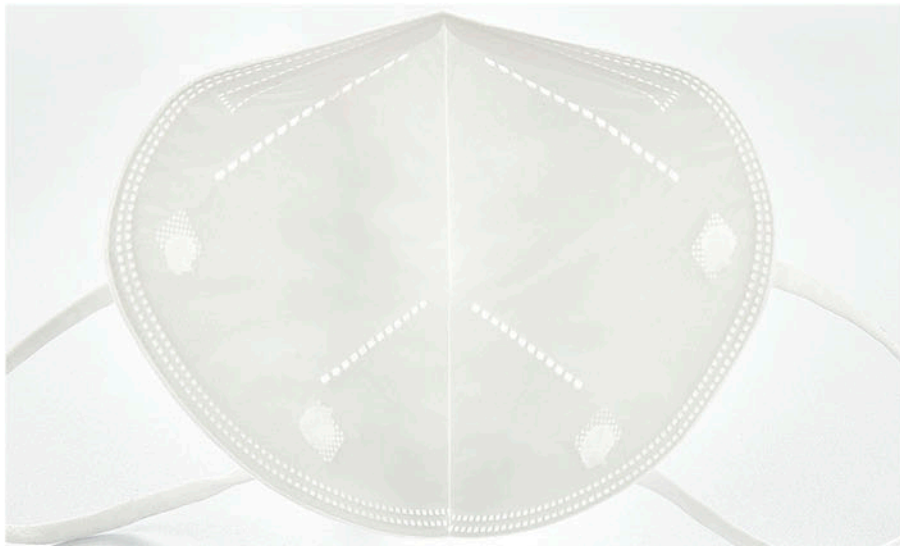
MASCARILLA RESPIRATORIA

FFP2 NR MASCARILLA RESPIRATORIA**Clip de nariz incorporado**

Integrado en el cuerpo
de la mascarilla



FFP2 NR - Mascarilla Respiratoria



Corte sólido

Ajuste perfecto



Clip de nariz

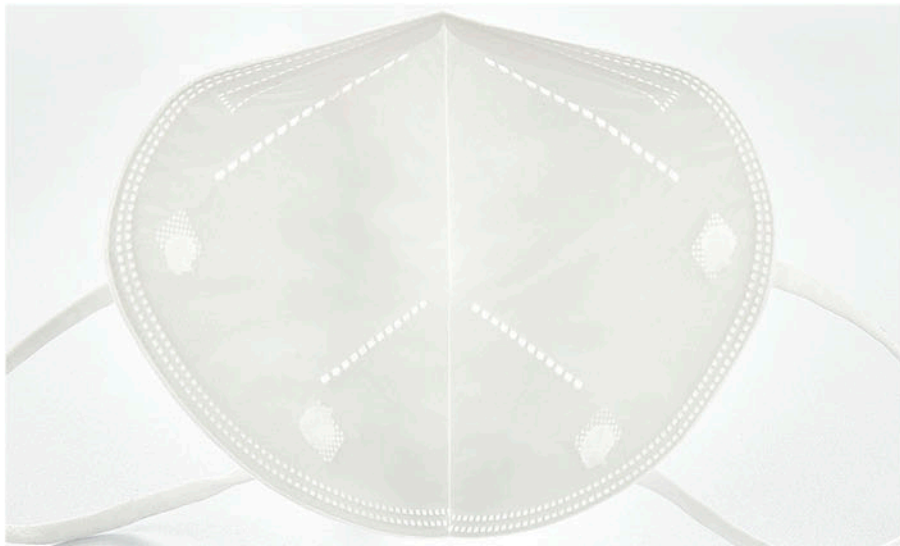
Integrado en el cuerpo
de la mascarilla



No tejido

Textura super suave

FFP2 NR - Mascarilla Respiratoria



Uniones

Tecnología de ultrasonica



Bandas

Elásticas y suaves



Terminaciones

Alta calidad en todos los detalles

KEHOLL

Ajuste de 360° a la cara

FFP2 NR - Mascarilla Respiratoria



FFP2 NR - Mascarilla Respiratoria



1 pieza



1 pieza



Caja 20 piezas



Caja 20 piezas

FFP2 NR - Mascarilla Respiratoria



200 piezas



200 piezas



Packs 1000 piezas

KEHOLL

合格证

PRODUCT CERTIFICATE

中国制造

MADE IN CHINA

产品名称 Produce name	一次性KN95立体口罩 (非医用) Disposable KN95 stereo mask (non-medical)		
产品品牌 Brand	KEHOLL	产品型号 Model	KN95
产品规格 Specifications	160mmX105mm (±3mm)		
生产日期/批次 Production date/batch	见包装 See packaging	有效期 Expiry Date	二年 Two years
执行标准 Executive standard	GB2626-2006	检验员 Inspection	合格001 Qualified001

● 主要材料：42%无纺布、29%热风棉、29%熔喷布

Material: 42%Non-woven fabric; 29%hotair cotton; 29% meltblown fabric

● 适用范围：本产品不得用于发热门诊隔离病房（区）、隔离留观病房（区）手术室、隔离重症监护室等区域

Scope of application: This product shall not be used in isolation ward (area), isolation observation ward (area) operating room, isolation intensive care unit, etc

● 生产厂商：浙江民安医疗用品有限公司

Manufacturer: Zhejiang Min'an Medical Supplies Co., Ltd.

● 生产地址：浙江省温州市瑞安市汀田街道汀田工业区

Address: Tingtian Industrial Zone Tingtian Street Ruian City Wenzhou City Zhejiang Province

检验专用章

本产品为非医疗器械 仅供应急使用

This products is non-medical equipment for urgent use only



营 业 执 照

(副 本)

统一社会信用代码
91330381MA2HCGBJ0T(1/1)

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息

名 称 浙江民安医疗用品有限公司 注册 资 本 叁仟万元整

类 型 有限责任公司(自然人投资或控股) 成 立 日 期 2020年04月27日

法定代表人 蔡少海 营 业 期 限 2020年04月27日至2050年04月26日

经 营 范 围 一般项目: 医护人员防护用品生产(I类医疗器械); 医护人员防护用品批发; 卫生用品和一次性使用医疗用品销售; 口罩批发; 日用口罩(非医用)生产; 日用口罩(非医用)销售; 第一类医疗器械生产; 第一类医疗器械销售; 第二类医疗器械销售; 特种劳动防护用品生产; 特种劳动防护用品销售(除依法须经批准的项目外,凭营业执照依法自主开展经营活动)。许可项目: 医用口罩生产; 卫生用品和一次性使用医疗用品生产; 医护人员防护用品生产(II类医疗器械); 货物进出口; 技术进出口(依法须经批准的项目,经相关部门批准后方可开展经营活动,具体经营项目以审批结果为准)。

住 所 浙江省温州市瑞安市汀田街道汀田工业区(瑞安市时友织带厂第三层东首)

登 记 机 关

2020 年 04 月 27 日

国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过国家信用公示系统报送公示年度报告。

国家市场监督管理总局监制

Business License (COPY)

Unified Social Credit Code
91330381MA2HCGBJ0T(1/1)

Name: Zhejiang Min'an Medical Supplies Co., Ltd. Registered Capital: Thirty Million Yuan
Type: Limited Liability Company (investment or holdings by a natural person) Establish Date: April 27, 2020
Legal Representative: Cai Shaohai Business Term: from April 27, 2020 to April 26, 2050
Address: Tingtian Industrial Zone Tingtian Street Ruian City
Wenzhou City Zhejiang Province
(The eastern of the 3rd floor of Ruian Shiyong Ribbon Factory)

Business Scope: General Item: Production of protective equipment for medical staff (class I medical equipment); Wholesale of protective equipment for medical staff; Sales of sanitary and disposable medical supplies; Wholesale of surgical masks; Production of daily use masks (non-medical); Sales of daily masks (non-medical); Production of Class I medical equipment; Sales of Class I medical equipment; Sales of Class II medical equipment; Production of protective equipment for special labor; Sales of protective equipment for special labor (Carry out business activities independently according to the law by business license, except for items subject to approval according to law). Licensed items: Production of surgical mask; Production of sanitary and disposable medical supplies; Production of protective equipment for medical staff (class II medical equipment); Import and export of goods; Import and export of technology (for items subject to approval according to law, business activities can only be carried out after the approval of relevant departments, and the specific business item shall be subject to the approval results).

Registration Authority: Ruian Market Supervision Administration 3303810078252
April 27, 2020

Website of National Enterprise Credit Information Publicity System: <http://www.gsxt.gov.cn>

The market entities shall submit and public the annual report through the national credit publicity system on January 1, 2016 and June 30 of each year.

Supervised by State Administration for Market Regulation.

UNIVERSAL
CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1127

Respiratory protective devices, filtering half masks to protect against particles manufactured by
Zhejiang Miran Medical Supplies Co., Ltd.
Tinglian Industrial Zone, Tinglian Street Ruan City, Wenzhou City, Zhejiang 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: KEHOLL Models: MA-001
Filtering half mask
Classification: FFP2 NR

Hereby 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 **22/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.




Sant KACMAZ
UNIVERSAL CERTIFICATION
Director

Necip Fazıl Bulvarı Keypaz Sitesi E2 Blok No: 44/4 Yıkari Düşük Ücretli - İSTANBUL - TÜRKİYE T: +90 216 455 80 80
UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION
NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1127/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by
Zhejiang Miran Medical Supplies Co., Ltd.
Tinglian Industrial Zone, Tinglian Street Ruan City, Wenzhou City, Zhejiang 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 149:2001 + 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
KEHOLL / MA-001	FFP2 NR	2163-PPE-1127	22.07.2020	2163

Hereby 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 **22/07/2020** and will be valid for one year, until **21/07/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.




Sant KACMAZ
UNIVERSAL CERTIFICATION
Director

Necip Fazıl Bulvarı Keypaz Sitesi E2 Blok No: 44/4 Yıkari Düşük Ücretli - İSTANBUL - TÜRKİYE T: +90 216 455 80 80
UNIVERSALCERT.COM



TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 22.07.2020 / 2163-KKD-1127

Manufacturer: Zhejiang Minan Medical Supplies Co., Ltd.
Address: Tingtian Industrial Zone, Tingtian Street Ruian City, Wenzhou City, Zhejiang Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Quality Supervision And Inspection Center For Special Safety Protection Products accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-7891 for the product identified below, dated 14.07.2020 with Serial Id STFWT202015854 based on EN 149:2001 + A1:2009 standard and the technical file dated 20 July, 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 Personal Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask
Classification: FFP2 NR
Brand Name: KEHOLL Model: MA-001



UFR-M3 12.12.2018 Rev-01

UNIVERSAL CERTIFICATION VE GÖZETİM HİZMETLERİ LTD. ŞTİ. Katip Tunca Mahallesi, Paşaport Bulvarı, 22 Blok, No:4484 Y. Dudağı - Çarşı - İSTANBUL, T: +90 216 453 80 80 F: +90 216 453 80 80 info@universalcert.com



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.

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 not 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 hazards

PPE must be so designed and manufactured as to exclude risks and other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

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

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

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

1.2.1.3. Maximum 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:

- In addition to the name and address of the manufacturer and/or his authorized representative established in the Community
- 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;
- Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- Suitable PPE accessories and the characteristics of appropriate spare parts;
- The classes of protection appropriate to different levels of risk and the corresponding limits of use;
- The obsolescence deadline or period of obsolescence of PPE or certain of its components;
- The type of packaging suitable for transport;
- The significance of any markings (see 2.12);
- Where appropriate the references of the Directives applied in accordance with Article 6(1) (b);
- 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.



UFR-M3 12.12.2018 Rev-01

UNIVERSAL CERTIFICATION VE GÖZETİM HİZMETLERİ LTD. ŞTİ. Katip Tunca Mahallesi, Paşaport Bulvarı, 22 Blok, No:4484 Y. Dudağı - Çarşı - İSTANBUL, T: +90 216 453 80 80 F: +90 216 453 80 80 info@universalcert.com



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

2.1. PPE incorporating adjustment systems

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

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised. The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

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

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

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging. If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

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

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced spark 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 remain perfectly legible throughout the foreseeable useful 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 at least part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging 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

Conforming to EN 149:2001 + A1:2009 Standard and other Standards

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	Packaging: Particle filtering half masks are packaged in groups, then from concentrations 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 over which the particle filtering half mask is designed to be used, is suffered mechanical failure of the facepiece or straps, any material from the filter media reduced 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 effect to the health and safety of users. Based on the test results, the masks did not collapse when subjected to simulated wearing and temperature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.																																																		
Article 7.6	Cleaning and Disinfection: Particle filtering half mask is not designed to be reusable. No cleaning or disinfection procedure provided by the manufacturer.																																																		
Article 7.7	Practical Performance (use): The test report indicates that the human subjects did not face any difficulty in performing the exercises while they were wearing by the sample masks, in walking, in work simulation tests. The wearers did not report any failure by means of head harness / straps / facepiece comfort, security of fit/seal and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fanning issues. <table> <tr> <th>Assessment Elements</th><th>Positive</th><th>Negative</th><th>Requirements in accordance with EN 149:2001 + A1:2009 and Results</th></tr> <tr> <td>2 Ideal Situation comfort</td><td>2</td><td>0</td><td>Positive results are obtained from the test subjects</td></tr> <tr> <td>3 Security of fit/seal</td><td>2</td><td>0</td><td>No imperfections</td></tr> <tr> <td>5 % of vision</td><td>2</td><td>0</td><td></td></tr> </table> Conditioning: (N.R.) As Received, original	Assessment Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Results	2 Ideal Situation comfort	2	0	Positive results are obtained from the test subjects	3 Security of fit/seal	2	0	No imperfections	5 % of vision	2	0																																			
Assessment Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Results																																																
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3 Security of fit/seal	2	0	No imperfections																																																
5 % 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 exercise are available in the test report. It was reported that: 47 out of 50 exercise measurement results are smaller or equal to 11%, the values varies between 4.4 % and 12.3 %. 9 out of 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 6.7 % and 10.6 %. According to the reported results, the product meets the limits for FFP1 and FFP2 classifications.																																																		
Article 7.9.2	Penetration of filter material: Sodium Chloride Testing <table> <tr> <th>Condition</th><th>No. of Sample</th><th>Sodium Chloride Testing 95 L/min max (%)</th><th>Requirements in accordance with EN 149:2001 + A1:2009</th><th>Result</th></tr> <tr> <td>(A.R.)</td><td>19</td><td>1.68</td><td></td><td></td></tr> <tr> <td>(A.R.)</td><td>20</td><td>1.55</td><td></td><td></td></tr> <tr> <td>(A.R.)</td><td>21</td><td>1.68</td><td>FFP1 ≤ 20 %</td><td>Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 p.16 in 7.9.2 in range of the FFP1 and FFP2 classes.</td></tr> <tr> <td>(S.W.)</td><td>22</td><td>1.80</td><td>FFP2 ≤ 6 %</td><td></td></tr> <tr> <td>(S.W.)</td><td>23</td><td>1.99</td><td></td><td></td></tr> <tr> <td>(S.W.)</td><td>24</td><td>2.21</td><td></td><td></td></tr> <tr> <td>(M.S.T.C.)</td><td>25</td><td>2.30</td><td>FFP3 ≤ 1 %</td><td></td></tr> <tr> <td>(M.S.T.C.)</td><td>26</td><td>2.35</td><td></td><td></td></tr> <tr> <td>(M.S.T.C.)</td><td>27</td><td>2.73</td><td></td><td></td></tr> </table> 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/min	Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	(A.R.)	19	1.68			(A.R.)	20	1.55			(A.R.)	21	1.68	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 p.16 in 7.9.2 in range of the FFP1 and FFP2 classes.	(S.W.)	22	1.80	FFP2 ≤ 6 %		(S.W.)	23	1.99			(S.W.)	24	2.21			(M.S.T.C.)	25	2.30	FFP3 ≤ 1 %		(M.S.T.C.)	26	2.35			(M.S.T.C.)	27	2.73		
Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result																																															
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(M.S.T.C.)	27	2.73																																																	

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	Penetration of filter material: ParaFin Oil Testing					
Article 7.9.2	Condition	No. of Sample	ParaFin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	
	(A.R.)	24	3.81	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard [EN 149:2001 + A1:2009] shown in 7.9.2 in range of the FFP1 and FFP2 classes.	
	(A.R.)	25	3.95			
	(A.R.)	30	4.02	FFP2 ≤ 6 %		
	(S.W.)	31	4.15			
	(S.W.)	32	4.32	FFP3 ≤ 1 %		
	(S.W.)	33	4.86			
	(M.S.T.C.)	34	5.10			
	(M.S.T.C.)	35	5.22			
	(M.S.T.C.)	36	5.35			
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	Flame Impaction	Requirements in accordance with EN 149:2001 + A1:2009	Result	
	(A.R.)	-	Burn for 0.6s	Filtering half mask shall not burn or not continue to burn for more than 5s after removal from the flame	Passed	
	(A.R.)	-	Burn for 0.6s			
	(T.C.)	-	Burn for 0.6s			
	(T.C.)	-	Burn for 0.6s			
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	Result	
	(A.R.)	-	0.49	Requirements in accordance with EN 149:2001 + A1:2009	Passed	
	(A.R.)	-	0.50			
	(A.R.)	-	0.51	CO ₂ content of the inhalation air shall not exceed an average of 1.0% by volume		
Conditioning: (A.R.) As Received, original						
Article 7.13	Headbands: In Practical Performance and TIL test reports no adverse effects have been reported for donning and removal of the mask also the results of these tests indicate 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 worn.					
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.					
	Passed.					

Article 7.17	Chugging: This test is not applied to Particle Filtering Half Mask which is not reusable. (For single shift use devices, the chugging test is optional test. For reusable devices test is mandatory.)
Article 7.18	Detachable Parts: There are no detachable parts on the product.
Article 8	Testing: All tests conducted according to Clause 8 of this standard is available in Certificate and are evaluated in this report for qualification and classification of the mask.
Article 9	Marking - Packaging: Necessary markings are available on the product packaging (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of reusability, the reference to EN 149:2001 + A1:2009 standard, the end date of shelf life, using and storage instructions and pictograms and symbols 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 (s.w.) also evaluated for marking requirements, drawing MA-001. The mask template (drawing) indicates that the mask will carry information about the trademark (KEHOLL) of the manufacturer, type of mask, the reference to EN 149:2001 + A1:2009 standard and classification including the reusability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assembly. Over the tested sample, the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model MA-001 drawing exists in the technical file of the manufacturer. Annex 9.1 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, use, care, cleaning and storage limitations, storage and meanings of symbols / pictograms are defined. User instruction document is in the technical file. For it to be appropriate, Annex 8. The manufacturer shall include this documented user information text in every smaller, commercially available package.

PREPARED BY	APPROVED BY
Osman CANCI PPE Expert	Suat KACMAZ Director



中国商品条码系统成员证书

GS1 China Membership License

物编注册字第 883454 号
Certificate No

成员名称:

Prefix Licensee's Name

浙江民安医疗用品有限公司

注册地址:

Registration Address

浙江省温州市瑞安市汀田街道汀田工业区(瑞安市时友织带厂第三层东首)



QR码



汉信码

厂商识别代码:

GS1 Company Prefix (GCP)

697349264

厂商识别代码可用于生成下述标识代码:

GS1 Company Prefix is used to create the following GS1 Identification Keys:

全球贸易项目代码 (GTIN)

全球位置码 (GLN)

系列货运包装箱代码 (SSCC)

全球型号代码 (GMN)

全球可回收资产代码 (GRAI)

全球单个资产代码 (GIAI)

全球服务关系代码 (GSRN)

全球文件类型代码 (GDTI)

全球货物托运标识代码 (GINC) 全球货物装运标识代码 (GSIN)

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6973492640013

机构全球位置码:

Legal Entity Global Location Number (GLN)

2020年06月12日

2022年06月12日

有效期:

至12/06/2020

12/06/2022

This License shall become effective as of

(d/m/y) and remain valid until

(d/m/y)

NO. 0203528



中國物品編碼中心



对外贸易经营者备案登记表

统一社会信用代码: 91330381MA2HCGBJ0T

备案登记表编号: 04386236

进出口企业代码: -----

经营者中文名称	浙江民安医疗用品有限公司		
经营者英文名称	ZHEJIANG MINAN MEDICAL SUPPLIES CO.,LTD.		
组织机构代码	-----	经营者类型 (由备案登记机关填写)	有限责任公司
住 所	浙江省温州市瑞安市汀田街道汀田工业区(瑞安市时友织带厂第三层东首)		
经营场所(中文)	浙江省温州市瑞安市汀田街道汀田工业区(瑞安市时友织带厂第三层东首)		
经营场所(英文)	(EAST, FLOOR 3, RUIAN SHIYOU RIBBON FACTORY), TINGTIAN INDUSTRIAL ZONE, TINGTIAN STREET, RUIAN CITY, WENZHOU CITY, ZHEJIANG PROVINCE		
联系电话	13758755551	联系传真	0577-66501867
邮政编码	325206	电子邮箱	1002055551@qq.com
工商登记注册日期	2020-4-27	工商登记注册号	-----

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	蔡少海	有效证件号	330325197906242957
注册资金	叁仟万元		(折美元)

依法办理工商登记的外国(地区)企业或个体工商户(独资经营者)还须填写以下内容

企业法定代表人/ 个体工商户负责人姓名		有效证件号	
企业资产/个人财产			(折美元)

备注 海关注册编码: 331596197X 报检备案号码: 3351200687	外管备案号码: 330381201791087
---	-------------------------

填表前请认真阅读背面的条款,并由企业法定代表人或个体工商户负责人签字、盖章。



Application form of customs union



杭州尚纬检测技术服务有限公司
Hangzhou Suhway Testing Technology Service Co., Ltd.

海关联盟 CU-TR(EAC)认证申请表
Application form of Customs Union

制造商信息 Manufacturer	
名称(中英文) Name(In Chinese and English)	浙江民安医疗用品有限公司 Zhejiang Minan Medical Supplies Co., Ltd.
地址(中英文) Add(In Chinese and English)	浙江省温州市瑞安市汀田街道汀田工业区 Tingtian Industrial Zone, Tingtian Street, Ruian City, Wenzhou, Zhejiang
电话 Telephone	0577-66501867
传真 Fax	0577-66501867
邮箱 E-mail	2766369910@qq.com
联系人 Contact	蔡少海 Cai Shaohai
网址 Website	
是否有 ISO 体系证书 Have the ISO certificate or not	
认证类型(单批次/一年/三年/五年) Type of certification(Batch/1/3/5 years)	
国外申请人信息 Applicant(如果该项无法提供, 可不填)	
名称(俄文)Name(In Russia)	
地址(俄文)Address(In Russia)	
电话 Telephone	
传真 Fax	
邮箱 E-mail	
联系人(俄文)Contact(In Russia)	
营业执照(扫描件) Business License(Scan)	
产品信息 Product information	
名称(中英文) Name (In Chinese and English)	
产品用途 Purpose	
产品型号 Types	
海关编码 HS code	
技术参数(可以附件形式) Technical parameter	
产品图片(可以附件形式)Product photo	
现有第三方检测报告及证书(如果有)	



地址: 浙江省杭州市下沙经济技术开发区经四支路138号浙商创业园3D311-3D313室
电话: 0571-86759463
传真: 0571-86759413
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检测
TESTING
CNAS L3780检 验 报 告
TEST REPORT

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国纺委字第 W202016600 号

报 告 编 号

REPORT NO.

产 品 名 称

KN95 口罩

NAME OF SAMPLE

委 托 单 位

浙江民安医疗用品有限公司

C U S T O M E R

检 验 类 别

委托检验

TEST CATEGORY

浙江省轻工业品质量检验研究院

(浙江省纺织测试研究院)

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心(浙江)

National Textiles and Garment Quality Supervision inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心(浙江)

检验报告

国纺委字第 W202016600 号

第 1 页 共 3 页

委托单位名称 Name of Customer	浙江民安医疗用品有限公司	地址 Address	---
生产单位 Manufacturer	---	地址 Address	---
样品信息 Sample information	样品名称 Name of sample: KN95 口罩 样品特性 Characteristics: 白色 商标 Trademark: --- 规格/号型 Specification/model: KN95 等级 Level: KN95 安全技术类别 Category of safety specification: --- 样品款号/货号 Art. No.: ---		
以上为客户信息 (Above-mentioned information by Customer-supplied)			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	40 只
送检日期 Receiving Date of Sample	2020-05-08	检测类别 Test Category	委托检验
判定依据 Rating Requirements	GB 2626-2006		
检测结论/Test Summary: 实测结果详见附页。			
批准日期/Date of Approval: 2020-05-18			
备注 Remarks			

签 发:
Approved by

批准日期/Date of Approval: 2020-05-18

检验报告

国纺委字第 W202016600 号

第 2 页 共 3 页

序号	检测项目	检测方法	单位	标准要求 (KN95)	实测值	单项评价	结果备注
1	过滤效率 (盐性介质)	GB 2626-2006 6.3	%	≥95.0	97.3	符合	---
2	呼吸阻力	GB 2626-2006 6.5 6.6	Pa	≤350	170	符合	---
			Pa	≤250	150		

检验报告

国纺委字第 W202016600 号

第 3 页 共 3 页

样品图片



—以下空白—

声明

- 一、本机构保证检测的公正性、独立性和诚实性，对检测结果负责，对委托方所提供的检测样品保密和保护所有权。
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DECLARATION

1. Our organization guarantees impartiality, independence and honesty of inspection, and is responsible for the results of inspection, keeping the samples supplied by the entrusting party confidential and at the same time protecting the ownership of the samples supplied.
2. The test report will be deemed invalid without signatures of the inspector/reviewer and authorized personnel, and the red special inspection stamp of our organization.
3. The test report will be invalid if it is altered. Copies of the report are invalid without the red special inspection stamp of our organization.
4. The test results shown in this report are applicable only to the samples provided by customers.
5. All the pages of the report are integral parts of the report. Our organization will not be responsible for any misunderstanding or other results caused by using separate page(s) of the report.
6. If there is any dissent of the report, the entrusting party shall notify our organization timely. For the mandatory inspection given by governmental administration departments, and dissent about the sample being tested or test results on the report should be dealt with in accordance with national regulations.

浙江省轻工业产品质量检验研究院及附设的检验中心
The Affiliated Inspection Centers

浙江省轻工业产品质量检验研究院
Zhejiang Light Industrial Products Inspection and Research Institute
国家纺织服装产品质量监督检验中心 (浙江)
National Textiles and Garment Quality Supervision Inspection Center (Zhejiang)
地址: 浙江省杭州市江干区下沙路 300 号 6 号楼
Address: Building No.6, 300 XiaSha Road, Hangzhou, Zhejiang

联系电话: 0571-85122669
Telephone: 0571-85122669
E-Mail: 1137597994@qq.com

国家家具产品质量监督检验中心 (浙江)
National Center for Quality Supervision Inspection of Furniture (Zhejiang)
浙江省室内安全及家具产品质量检验中心
Zhejiang Center of Quality Test for Indoor Safety and Furniture Products
地址: 浙江省杭州市余杭区良渚街道经一路 1 号良渚大学科技园 4 号楼
Address: Building 4 LiangZhu University Science and Technology Park, No.1, JingYi Rd., Yuhang District, Hangzhou, Zhejiang

联系电话: 0571-89009556
Telephone: 0571-89009556
E-Mail: 2047699564@qq.com

浙江省轻工及五金产品质量检验中心
Zhejiang Center of Quality Test for Light Industry and Hardware Products
浙江省体育用品质量检验中心
Zhejiang Center of Quality Test for Sports Products
地址: 浙江省杭州市西湖区天目山路 222 号 3 号楼
浙江省杭州市余杭区良渚街道经一路 1 号良渚大学科技园 3 号楼
Address: No. 222 Tianmushan Rd., Hangzhou, Zhejiang
Building 3 LiangZhu University Science and Technology Park, No.1, JingYi Rd., Hangzhou, Zhejiang

联系电话: 0571-89001107
Telephone: 0571-89001107
E-Mail: wujtest@126.com

国家锁具产品质量监督检验中心 (浙江)
National Center for Quality Supervision Inspection of Lock (Zhejiang)
浙江省锁具产品质量检验中心
Zhejiang Center of Quality Test for Lock Products
地址: 浙江省杭州市塘栖路 24 号
Address: No. 24 Tangmiao Rd., Hangzhou, Zhejiang

联系电话: 0571-85027738
Telephone: 0571-85027738
E-Mail: Locktest@126.com

网上业务受理/报告查询: <http://www.zjtj.cn>
Online Business Reception/Report Inquires: <http://www.zjtj.cn>

投诉电话: 0571-85023552
Complaint Tel: 0571-85023552



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检验报告

TEST REPORT



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浙江省轻工业品质量检验研究院

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心(浙江)

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

 Zhejiang Light Industrial Products Inspection and Research Institute
 National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

Test report

Number:W202016600E

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Name of Customer	Zhejiang Minan Medical Supplies Co., Ltd	Address	Tinglian Industrial Zone, Tinglian Street, Ruian City, Wenzhou, Zhejiang
Manufacturer	---	Address	---
Sample information	Name of sample: KN95 MASK Characteristics of sample: White Trademark of sample: --- Specification/model: KN95 Level: KN95 Category of safety specification: --- Art. No.: ---		
Above-mentioned information by Customer-supplied			
The sent way of sample	Courier	Sample quantity	40 pieces
Receiving Date of Sample	2020/05/08	Test Category	Entrusted inspection
Date of Testing	2020-05-08- 2020-05-17		
Rating/Requirements	GB 2626-2006		
Test Summary: See the attached page for the results.			
Date of Approval: 2020-05-18 			
Remarks			

Approved by:

Test report

Number:W202016600E

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ITEM	STANDARD (KN95)	RESULT	RATING
1. FILTER EFFICIENCY (SALT MEDIUM) (GB 2626-2006 6.3)(%)			
-	≥95.0	97.3	PASS
2. RESPIRATORY RESISTANCE (GB 2626-2006 6.5 & 6.6)(Pa)			
-INSPIRATORY RESISTANCE	≤350	170	PASS
-EXPIRATORY RESISTANCE	≤250	150	PASS

Picture(s) of sample



—End of report—

DECLARATION

- Our organization guarantees impartiality, independence and honesty of inspection, and is responsible for the results of inspection, keeping the samples supplied by the entrusting party confidential and at the same time protecting the ownership of the samples supplied.
- The test report will be deemed invalid without signatures of the inspector/reviewer and authorized personnel, and the red special inspection stamp of our organization.
- The test report will be invalid if it is altered. Copies of the report are invalid without the red special inspection stamp of our organization.
- The test results shown in this report are applicable only to the samples provided by customers.
- All the pages of the report are integral parts of the report. Our organization will not be responsible for any misunderstanding or other results caused by using separate page(s) of the report.
- If there is any dissent of the report, the entrusting party shall notify our organization timely. For the mandatory inspection given by governmental administration departments, a dissent about the sample being tested or test results on the report should be dealt with in accordance with national regulations.

浙江省轻工产品质量检验研究院及附设的检验中心
The Affiliated Inspection Centers

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Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心 (浙江)

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地址: 浙江省杭州市江干区下沙路300号6号楼

Address: Building No.6, 300 XiaSha Road, Hangzhou, Zhejiang

联系电话: 0571-85122669

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E-Mail: 1137907994@qq.com

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地址: 浙江省杭州市余杭区良渚街道钱二一路1号良渚大学科技园4号楼

Address: Building 4 LiangZhu University Science and Technology Park, No.1, JingYi Rd, Yuhang District, Hangzhou, Zhejiang

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Zhejiang Center of Quality Test for Sports Products

地址: 浙江省杭州市西湖区天目山路222号3号楼

浙江省杭州市余杭区良渚街道钱二一路1号良渚大学科技园3号楼

Address: No.222 Tianmushan Rd., Hangzhou, Zhejiang

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浙江省锁具产品质量检验中心

Zhejiang Center of Quality Test for Lock Products

地址: 浙江省杭州市塘栖路24号

Address: No.24 Tangqiao Rd., Hangzhou, Zhejiang

联系电话: 0571-85027738

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检测
CNAS17901

检验检测报告

TEST REPORT



STFWT202014076

产品名称

Product Name

口罩 Mask

委托单位

Trust Unit

浙江民安医疗用品有限公司
Zhejiang Minan Medical Supplies

生产单位

Manufacturer

浙江民安医疗用品有限公司
Zhejiang Minan Medical Supplies

检验检测类别

Test Category

委托送样检验

江苏省特殊安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检验检测报告

Test Report

STFWT202014076

共 5 页 第 1 页
Page 1 of 5

产品名称 Product Name	口罩 Mask	规格型号 Specification Type	—
		商 标 Trademark	—
委托单位 Trust Unit	浙江民安医疗用品有限公司 Zhejiang Minan Medical Supplies Co., Ltd.	电 话 Tel	—
生产单位 Manufacturer	浙江民安医疗用品有限公司 Zhejiang Minan Medical Supplies Co., Ltd.	样品等级 Sample Grade	KN95
样品数量 Sample Quantity	40 只	送样日期 Sample Receiving Date	2020-05-19
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	—
样品状态 Samples Conditions	符合检测要求		
检验检测判定依据 Document and Decide Accordance	GB 2626-2006《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 GB 2626-2006 标准规定的 KN95 级要求。		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。本报告仅对来样负责。		

批准:
Approver

顾海燕

审核:
Examiner

吴高亮

主 检:
Major tester

蔡燕文

检 验 检 测 结 果
Testing Results

STFWT202014076

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Page 2 of 5

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment																					
1	一般要求 (结构)	—	a) 应不易产生结构性破损, 部件的设计、组成和安装不应给使用者构成任何危险; b) 头带的设计应可调, 便于佩戴和摘除, 应能将面罩牢固地固定在脸上, 且佩戴时不应出现明显的压迫或压痛现象; c) 应尽可能具有较小的死腔和较大的视野; d) 随弃式面罩的结构应能保证与面部的密合, 且应在使用寿命期内不出现变形。	a) 不易产生结构性破损, 部件的设计、组成和安装未对使用者构成任何危险; b) 头带的设计可调, 便于佩戴和摘除, 能将面罩牢固地固定在脸上, 且佩戴时未出现明显的压迫或压痛现象; c) 具有较小的死腔和较大的视野; d) 随弃式面罩的结构能保证与面部的密合, 且在使用寿命期内不出现变形。	合格																					
2	外观检查	—	样品表面不应破损、变形和有明显的其它缺陷, 部件材料和结构应能够耐受正常使用条件及可能遇到的温度、湿度和机械冲击, 头带应可调。	符合要求	合格																					
3	呼吸阻力	Pa	每个样品的总吸气阻力应不大于 350, 总呼气阻力应不大于 250	<table><tr><th colspan="2">试样编号</th><th>实测值</th></tr><tr><td rowspan="4">总吸气阻力</td><td>未预处理</td><td>1[#] 142.9</td></tr><tr><td>预处理</td><td>2[#] 146.4</td></tr><tr><td>预处理</td><td>5[#] 147.3</td></tr><tr><td>预处理</td><td>6[#] 148.3</td></tr><tr><td rowspan="4">总呼气阻力</td><td>未预处理</td><td>3[#] 122.6</td></tr><tr><td>预处理</td><td>4[#] 124.9</td></tr><tr><td>预处理</td><td>7[#] 127.6</td></tr><tr><td>预处理</td><td>8[#] 126.4</td></tr></table>	试样编号		实测值	总吸气阻力	未预处理	1 [#] 142.9	预处理	2 [#] 146.4	预处理	5 [#] 147.3	预处理	6 [#] 148.3	总呼气阻力	未预处理	3 [#] 122.6	预处理	4 [#] 124.9	预处理	7 [#] 127.6	预处理	8 [#] 126.4	合格
试样编号		实测值																								
总吸气阻力	未预处理	1 [#] 142.9																								
	预处理	2 [#] 146.4																								
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	预处理	7 [#] 127.6																								
	预处理	8 [#] 126.4																								

检 验 检 测 结 果
Testing Results

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序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment			
4	过滤效率% (NaCl 颗粒物)	—	KN90: ≥90.0 KN95: ≥95.0 KN100: ≥99.97	试样编号	实测值	合 格		
				未预 处理	9 [#]		初始	98.2
							加载	97.6
					10 [#]		初始	98.3
							加载	97.7
					11 [#]		初始	98.3
							加载	97.7
				12 [#]	初始		98.6	
					加载		98.0	
				13 [#]	初始		98.4	
					加载		97.7	
				14 [#]	初始		98.4	
					加载		97.7	
				15 [#]	初始		98.5	
					加载		97.8	
				16 [#]	初始		98.4	
					加载		97.7	
				17 [#]	初始		98.4	
					加载		97.7	
				18 [#]	初始		98.3	
					加载		97.6	
				温度 湿度 处理	19 [#]		初始	98.0
					20 [#]		初始	97.9
							加载	97.3
21 [#]	初始	98.2						
	加载	97.6						
22 [#]	初始	97.8						
	加载	97.3						
23 [#]	初始	97.6						
加载	97.0							

检验检测结果
Testing Results

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序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
5	头带	—	面罩的每条头带、带扣及其他调节部件在承受 10N 拉力且持续 10s 时, 不应出现滑脱或断裂。	未预处理: 1"面罩的每条头带、带扣及其他调节部件在承受 10N 拉力且持续 10s 后, 未出现滑脱或断裂。 预处理后: 5"面罩的每条头带、带扣及其他调节部件在承受 10N 拉力且持续 10s 后, 未出现滑脱或断裂。	合格
6	视野	—	下方视野 $\geq 60^\circ$	63°	合格
7	死腔	—	二氧化碳体积分数应不大于 1%	二氧化碳体积分数为 0.5%	合格
8	呼气阀盖	—	面罩的呼气阀盖在承受 10N 拉力且持续 10s 时, 不应出现滑脱或断裂。	无呼气阀, 不测此项。	—
9	呼气阀气密性	—	各样品均不得出现下述情况之一: a) 排气流速已经达到 500mL/min 时, 系统负压达不到 1180Pa; b) 呼气阀恢复至常压时间小于 20s。	无呼气阀, 不测此项。	—
10	可燃性	—	暴露于火焰的各部件在从火焰移开后, 不应燃烧; 如果燃烧, 燃烧时间不应超过 5s。	未预处理: 1"、2"试样暴露于火焰的各部件在从火焰移开后, 未燃烧。 预处理后: 3"、4"试样暴露于火焰的各部件在从火焰移开后, 未燃烧。	合格
11	连接和连接部件	—	可更换式过滤元件与面罩之间, 呼吸导管与过滤元件及面罩之间的所有连接和连接部件, 在承受 10N 轴向拉力且持续 10s 时, 不应出现滑脱、断裂或变形。	随弃式面罩, 不测此项。	—

检验检测结果
Testing Results

STFWT202014076

共 5 页 第 5 页
Page 5 of 5

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results							单项评价 Individual Judgment		
12	泄漏性/%	—	以每个动作的 TIL 为评价基础时 (即 10 人 $\times$ 5 个动作), 50 个动作中至少有 46 个动作的 TIL KN90 < 13 KN95 < 11 KN100 < 5 以人的总体 TIL 为评价基础时, 10 个受试者中至少有 8 个人的总体 TIL KN90 < 10 KN95 < 8 KN100 < 2	试样号	TIL					总体 TIL	合格		
					头部静止	左右转动	抬头低头	大声阅读	头部静止				
					31 ^a	4.9	9.1	9.0	9.2			4.7	7.4
					32 ^a	5.8	6.6	2.3	6.7			2.0	4.7
					33 ^a	3.8	7.7	4.3	7.9			8.2	6.4
				未预处理	34 ^a	6.2	6.3	6.1	2.2	1.5		4.5	
					35 ^a	5.0	8.9	5.1	9.0	8.9		7.4	
					36 ^a	9.2	5.0	8.6	5.1	9.3		7.4	
					37 ^a	7.5	11.8	7.9	11.4	11.5		10.0	
					38 ^a	3.9	7.8	8.0	7.9	3.6		6.2	
				预处理	39 ^a	7.8	8.2	8.0	3.8	3.2		6.2	
					40 ^a	4.2	8.5	4.5	8.2	8.4		6.7	
					50 个动作中, 有 47 个动作的 TIL 小于 11%								
					10 个试验者中, 有 9 个人的 TIL 小于 8%								

样品图片



以下空白

注 意 事 项

- 1、检验检测报告无“检验检测报告专用章”或检验检测单位公章无效。
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地址：江苏省泰州市高港区临港经济园临港大道 166 号

Add: Lingang Road 166, Lingang Economic Park , Gaogang, Taizhou.Jiangsu

电话 (Tel): 0523-86989959

0523-86989939

邮编 (Post): 225300

网址 (Web): www.jstfzx.com

邮箱 (E-mail): 1735889887@qq.com

监督电话 (Complain Tel): 0523-86989901


**Test Report
(SVHC)**

No. NGBHG2002086701 Date: 29 May 2020 Page 1 of 18

 ZHEJIANG MINAN MEDICAL SUPPLIES CO., LTD.
TINGTIAN INDUSTRIAL ZONE, TINGTIAN STREET, RUIAN CITY, WENZHOU, ZHEJIANG

The following sample(s) was/were submitted and identified on behalf of the clients as: MASK

SGS Job No.: NBRHL2005006908MD - NB
 Style No.: MA-001
 Date of Sample Received: 25 May 2020
 Testing Period: 25 May 2020 - 29 May 2020
 Test Requested: As requested by client, SVHC screening is performed according to:
 (i) Two hundred and five (205) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before Jan 18, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH.
 (ii) Five (5) substances in the Public Consultation List of potential Substances of Very High Concern (SVHC) published by European Chemicals Agency (ECHA) on Mar 3, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH.

Test Results: Please refer to next page(s).

Summary:

According to the specified scope and evaluation screening, the test results of SVHC are $\leq 0.1\%$ (w/w) in the submitted sample.	PASS
---	------

 Signed for and on behalf of:
SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch

Lris Xiao
 Iris Xiao
 Approved Signatory


**Test Report
(SVHC)**

No. NGBHG2002086701 Date: 29 May 2020 Page 3 of 18

Data Sheet (SDS) against the SVHC to comply with the supply chain communication obligation under Regulation (EC) No 1907/2006, in which:

- a substance that is classified as hazardous under the CLP Regulation (EC) No 1272/2008;
- a mixture that is classified as hazardous under the CLP Regulation (EC) No 1272/2008, when it contains a substance with concentration equal to, or greater than the classification limit as set in Regulation (EC) No 1272/2008; or
- a mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008, but contains either:
 - (a) a substance posing human health or environmental hazards in an individual concentration of $\geq 1\%$ by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures) or $\geq 0.2\%$ by volume for gaseous mixtures; or
 - (b) a substance that is PBT or PbP in an individual concentration of $\geq 0.1\%$ by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures); or
 - (c) a substance on the SVHC candidate list (for reasons other than those listed above), in an individual concentration of $\geq 0.1\%$ by weight for non-gaseous mixtures; or
 - (d) a substance for which there are Europe-wide workplace exposure limits.

3. If a SVHC is found over the reporting limit, client is suggested to identify the component which contains the SVHC and the exact concentration of the SVHC by requesting further quantitative analysis from the laboratory.

Test Sample:
Sample Description:

Specimen No.	SGS Sample ID	Description
SN1	NG520-020867-001	White fabric body + White elastic part + White plastic part on nose clip

Test Method:

SGS In-House method-NBCHEM-TOP-138, NBCHEM-TOP-124. Analyzed by ICP-OES, UV-VIS, GC-MS, HPLC-DAD/MS and Colorimetric Method.


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Remark:

1. The chemical analysis of specified SVHC is performed by means of currently available analytical techniques against the following SVHC related documents published by ECHA: <http://echa.europa.eu/web/guest/candidate-list-table>. These lists are under evaluation by ECHA and may subject to change in the future.
2. REACH obligation:
 - 2.1 Concerning article(s):
Communication:
Article 33 of Regulation (EC) No 1907/2006 requires supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance in the Candidate List.

Notification:

In accordance with Regulation (EC) No 1907/2006, any EU producer or importer of articles shall notify ECHA, in accordance with paragraph 4 of Article 7, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1) of the Regulation. If (a) the substance in the Candidate List is present in those articles in quantities totaling over one tonne per producer or importer per year; and (b) the substance in the Candidate List is present in those articles above a concentration of 0.1% weight by weight (w/w).

SGS adopts the ruling of the Court of Justice of the European Union on the definition of an article under REACH unless indicated otherwise. Detail explanation is available at the following link:

<http://www.sgs.com/-/media/global/documents/technical-documents/technical-bulletins/sgs-consultation-statement-on-svhc-in-articles-ad-en-16-06.pdf?la=en>

2.2 Concerning material(s):

Test results in this report are based on the tested sample. This report refers to testing result of tested sample submitted as homogeneous material(s). In case such material is being used to compose an article, the results indicated in this report may not represent SVHC concentration in such article. If this report refers to testing result of composite material group by equal weight proportion, the material in each composite test group may come from more than one article.

If the sample is a substance or mixture, and it directly exports to EU, client has the obligation to comply with the supply chain communication obligation under Article 31 of Regulation (EC) No 1907/2006 and the conditions of Authorization of substance of very high concern included in the Annex XIV of the Regulation (EC) No 1907/2006.

2.3 Concerning substance and preparation:

If a SVHC is found over 0.1% (w/w) and/or the specific concentration limit which is set in Regulation (EC) No 1272/2008 and its amendments, client is suggested to prepare a Safety


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Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Test Result: (Substances in the Consultation List of potential SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in consultation list	-	ND	-

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Notes:

- (1) The table above only shows detected SVHC, and SVHC that below RL are not reported. Please refer to Appendix for the full list of tested SVHC.
- (2) RL = Reporting Limit (Test data will be shown if it $\geq$ RL. RL is not regulatory limit.)
ND = Not detected (lower than RL). ND is denoted on the SVHC substance.
- (3) *CAS No. of diastereoisomers identified (α -HBCDD, β -HBCDD, γ -HBCDD): 134237-50-6, 134237-51-7, 134237-52-8
*CAS No. of Hexahydrodimethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride: 25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9; EC No. of those: 247-094-1, 243-072-0, 256-356-4, 260-666-1.
- (4) * The test result is based on the calculation of selected element(s) and to the worst-case scenario.
** The test result is based on the calculation of selected marker(s) and to the worst-case scenario.
For detail information, please refer to the SGS REACH website:

<http://www.sgs.com/en/Consumer-Goods-Retail-Toys-and-Luggage-Products/Tools/REACH/Management-of-SVHC.aspx>

Calculated concentration of boric compounds are based on the total boron for liquid, powder and paste samples and water extractive boron for other samples by ICP-OES.

RL = 0.005% is evaluated for element (i.e. cobalt, chromium, lead, chromium (VI), aluminum, zirconium, boron, strontium, zinc, antimony, titanium, bismuth and cadmium) (respectively), except molybdenum RL=0.0005%, boron RL=0.0025% (only for Lead) (tetrafluoroborate).

(5) § The substance is proposed for the identification as SVHC only where it contains Michler's ketone (CAS Number: 90-94-8) or Michler's base (CAS Number: 101-61-1) $\geq 0.1\%$ (w/w).

(6) / = Substances in the Consultation List of SVHC

(7) Composite test has been performed in equal proportion for the components/material per client requested. And the result is calculated using the minimum sample weight.

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
II	21	Anthracene oil, anthracene paste, distn. light**	91995-17-4	0.050
II	22	Anthracene oil, anthracene-low**	90640-82-7	0.050
II	23	Diisobutyl phthalate	84-69-5	0.050
II	24	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*	12656-85-8	0.005
II	25	Lead chromate*	7758-97-6	0.005
II	26	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	0.005
II	27	Pitch, coal tar, high temp.**	65996-93-2	0.050
II	28	Tris(2-chloroethyl)phosphate	115-96-8	0.050
III	29	Strontium dichromate*	7789-09-5	0.005
III	30	Boric acid*	10043-35-3, 11113-50-1	0.005
III	31	Sodium tetraborate, anhydrous*	1303-96-4, 1330-43-4, 12179-04-3	0.005
III	32	Potassium chromate*	7789-00-6	0.005
III	33	Potassium dichromate*	7778-50-9	0.005
III	34	Sodium chromate*	7775-11-3	0.005
III	35	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	0.005
III	36	Trichloroethylene	79-01-6	0.050
IV	37	2-Ethoxyethanol	110-80-5	0.050
IV	38	2-Methoxyethanol	109-86-4	0.050
IV	39	Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid*	7738-94-5, 13530-68-2	0.005

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
I	1	4,4'-Diaminodiphenylmethane(MDA)	101-77-9	0.050
I	2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	0.050
I	3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	0.050
I	4	Anthracene	120-12-7	0.050
I	5	Benzyl butyl phthalate (BBP)	85-68-7	0.050
I	6	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.050
I	7	Bis(tributyltin)oxide (TBTO)	56-35-9	0.050
I	8	Cobalt dichloride*	7543-70-9	0.005
I	9	Diarsenic pentoxide*	1303-28-2	0.005
I	10	Diarsenic trioxide*	1327-53-3	0.005
I	11	Dibutyl phthalate (DBP)	84-74-2	0.050
I	12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α -HBCDD, β -HBCDD, γ -HBCDD)*	25637-99-4, 3194-55-6	0.050
I	13	Lead hydrogen arsenate*	7784-40-9	0.005
I	14	Sodium dichromate*	7789-12-0, 10588-01-9	0.005
I	15	Triethyl arsenate*	15608-95-8	0.005
II	16	2,4-Dinitrotoluene	121-14-2	0.050
II	17	Acrylamide	79-06-1	0.050
II	18	Anthracene oil**	90640-80-5	0.050
II	19	Anthracene oil, anthracene paste**	90640-81-6	0.050
II	20	Anthracene oil, anthracene paste, anthracene fraction**	91995-15-2	0.050

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
IV	40	Chromium trioxide*	1323-82-0	0.005
IV	41	Cobalt(II) carbonate*	513-79-1	0.005
IV	42	Cobalt(II) diacetate*	71-48-7	0.005
IV	43	Cobalt(II) dinitrate*	10141-05-6	0.005
IV	44	Cobalt(II) sulphate*	10124-43-3	0.005
V	45	1,2,3-trichloropropane	96-18-4	0.050
V	46	1,2-Benzenedicarboxylic acid, di-C6-2-branched alkyl esters, C7-rich	71888-89-6	0.050
V	47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	66515-42-4	0.050
V	48	1-methoxy-2-pyrrolidone	872-50-4	0.050
V	49	2-ethoxyethyl acetate	111-15-9	0.050
V	50	Hydrazine	7803-57-8, 302-01-2	0.050
V	51	Strontium chromate*	7789-06-2	0.005
VI	52	1,2-Dichloroethane	107-06-2	0.050
VI	53	2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.050
VI	54	2-Methoxyaniline; o-Anisidine	90-04-0	0.050
VI	55	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.050
VI	56	Aluminosilicate Refractory Ceramic Fibres *	650-017-00-8 (Index no.)	0.005
VI	57	Arsenic acid*	7778-33-4	0.005
VI	58	Bis(2-methoxyethyl) ether	111-96-3	0.050
VI	59	Bis(2-methoxyethyl) phthalate	117-82-8	0.050

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VI	60	Calcium arsenate*	7778-44-1	0.005
VI	61	Dichromium tris(chromate) *	24613-89-6	0.005
VI	62	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	0.050
VI	63	Lead diazide, Lead azide*	13424-46-9	0.005
VI	64	Lead dipicrate*	6477-64-1	0.005
VI	65	Lead styphnate*	15245-44-0	0.005
VI	66	N,N-dimethylacetamide	127-19-5	0.050
VI	67	Pentazinc chromate octahydroxide*	49663-84-5	0.005
VI	68	Phenolphthalein	77-09-8	0.050
VI	69	Potassium hydroxyoctaoxidizedichromate*	11103-86-9	0.005
VI	70	Trilead diarsenate*	3687-31-8	0.005
VI	71	Zirconia Aluminosilicate Refractory Ceramic Fibre*	650-017-00-8 (Index no.)	0.005
VII	72	[4-[[4-anilino-1-naphthyl]4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Blue 26)	2580-56-5	0.050
VII	73	[4-[4-(4-bis(dimethylamino)benzylidene)-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)]	548-62-9	0.050
VII	74	1,2-Lis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.050
VII	75	1,2-bis(methoxy)ethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.050
VII	76	4,4'-bis(dimethylamino) benzophenone (Michler's Ketone)	90-94-8	0.050
VII	77	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol	561-41-1	0.050
VII	78	Diboron trioxide*	1303-86-2	0.005

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VII	79	Formamide	75-12-7	0.050
VII	80	Lead (II) bis(methanesulfonate)*	17570-76-2	0.005
VII	81	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	0.050
VII	82	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	2451-62-9	0.050
VII	83	o-Bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4)	6786-83-1	0.050
VII	84	8-TGIC (1,3,5-tris(2S and 2R)-2,3-epoxypropyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	52653-74-6	0.050
VIII	85	[Phthalato (2-)]dioxotrilead*	19011-06-9	0.005
VIII	86	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	84777-00-0	0.050
VIII	87	1,2-Diethoxyethane	629-14-1	0.050
VIII	88	1-Bromo propane	106-94-5	0.050
VIII	89	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazoline	143860-04-2	0.050
VIII	90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	0.050
VIII	91	4,4'-Methylenedi-o-toluidine	838-88-0	0.050
VIII	92	4,4'-Oxydianiline and its salts	101-80-4	0.050
VIII	93	4-Aminoozobenzene	60-09-3	0.050
VIII	94	4-Methyl-m-phenylenediamine	95-80-7	0.050
VIII	95	4-Nonylphenol, branched and linear	-	0.050
VIII	96	6-Methoxy-m-toluidine	120-71-8	0.050
VIII	97	Acetic acid, lead salt, basic*	51404-69-4	0.005

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	98	Biphenyl-4-ylamine	92-67-1	0.050
VIII	99	Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	0.050
VIII	100	Cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride	85-42-7, 13149-00-3, 14166-21-3	0.050
VIII	101	Diazene-1,2-dicarboxanide (C-C'-azodi(formamide))	123-77-3	0.050
VIII	102	Dibutyltin dichloride (DBTC)	683-18-1	0.050
VIII	103	Diethyl sulphate	64-67-5	0.050
VIII	104	Dikopentylphthalate	605-50-5	0.050
VIII	105	Dimethyl sulphate	77-78-1	0.050
VIII	106	Dinoseb	88-85-7	0.050
VIII	107	Dioctylis(stearato)trilead*	12578-12-0	0.005
VIII	108	Fatty acids, C16-18, lead salt*	91031-62-8	0.005
VIII	109	Furan	110-00-9	0.050
VIII	110	Henicosafuoroundecanoic acid	2058-94-8	0.050
VIII	111	Heptacosafuorotetradecanoic acid	376-06-7	0.050
VIII	112	Hexahydro-1-methylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride	*	0.050
VIII	113	Lead bis(tetrafluoroborate)*	13814-96-5	0.005
VIII	114	Lead cyanamidate*	20837-86-9	0.005
VIII	115	Lead dinitrate*	10099-74-8	0.005
VIII	116	Lead monoxide*	1317-36-8	0.005

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	117	Lead oxide sulfate*	12036-76-9	0.005
VIII	118	Lead tetroxide (orange lead)*	1314-41-6	0.005
VIII	119	Lead titanium trioxide*	12060-00-3	0.005
VIII	120	Lead titanium zirconium oxide*	12626-81-2	0.005
VIII	121	Methoxyacetic acid	625-45-6	0.050
VIII	122	Methyloxirane (Propylene oxide)	75-58-9	0.050
VIII	123	N,N-dimethylformamide	68-12-2	0.050
VIII	124	N-Methylacetamide	79-16-3	0.050
VIII	125	N-Pentylisocetylphthalate	776297-69-9	0.050
VIII	126	p-Aminozotoluene	97-56-3	0.050
VIII	127	p-Toluidine	95-53-4	0.050
VIII	128	Pentacosafuorotridecanoic acid	72629-94-8	0.050
VIII	129	Pentalead tetraoxide sulphate*	12065-90-6	0.005
VIII	130	Pyrochlore, antimony lead yellow*	8012-00-8	0.005
VIII	131	Silicic acid, barium salt, lead-doped*	68784-75-8	0.005
VIII	132	Silicic acid, lead salt*	11120-22-2	0.005
VIII	133	Sulfurous acid, lead salt, dibasic*	62220-08-7	0.005
VIII	134	Tetraethyllead*	78-00-2	0.005
VIII	135	Tetralead trioxide sulphate*	12202-17-4	0.005
VIII	136	Tricosafuorododecanoic acid	207-56-1	0.050
VIII	137	Trilead bis(carbonate)dihydroxide (basic lead carbonate)*	1313-46-6	0.005

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XII	156	2-(2H-benzotriazol-2-yl)-4,6-di-tert-butylphenol (UV-328)	25973-55-1	0.050
XII	157	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.050
XII	158	2-ethylhexyl 10-ethyl-4,4-diethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	0.050
XII	159	Cadmium fluoride *	7790-79-6	0.005
XII	160	Cadmium sulphate *	10124-36-4/31119-53-6	0.005
XII	161	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-diethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate & 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyloxy)-2-oxoethylthio]-4-oxyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE & DOTE)	15571-58-1/27191-69-7	0.050
XIII	162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate	6851-51-5/68648-93-1	0.050
XIII	163	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1]; 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] (covering any of the individual isomers α [1] and [2] or any combination thereof)	-	0.050
XIV	164	1,3-propanesultone	1120-71-4	0.050
XIV	165	2,4-di-tert-butyl-4-(2-chlorobenzotriazol-2-yl) phenol (UV-327)	3894-99-1	0.050
XIV	166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl) phenol (UV-329)	38437-37-3	0.050
XIV	167	Nitrobenzene	98-95-3	0.050
XIV	168	Perfluorooctanoic acid and its sodium and ammonium salts	375-95-1/21049-39-8/4149-60-4	0.050
XV	169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.050

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XIX	187	Dodecamethylcyclotetrasiloxane (D6)	540-97-6	0.050
XIX	188	Ethylenediamine(EDA)	107-15-3	0.050
XIX	189	Lead*	7439-92-1	0.005
XIX	190	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.050
XIX	191	Terphenyl, hydrogenated	61788-32-7	0.050
XX	192	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2,2,1]heptan-2-one (3-benzylidene camphor)	15087-24-8	0.050
XX	193	2,2-bis(4'-hydroxyphenyl)-4,4'-ethylpentane	6807-17-6	0.050
XX	194	Benzo[k]fluoranthene	207-08-9	0.050
XX	195	Fluoranthene	206-44-0/93951-69-0	0.050
XX	196	Phenanthrene	85-01-8	0.050
XX	197	Pyrene	129-00-0/1718-52-1	0.050
XXI	198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.050
XXI	199	2-methoxyethyl acetate	110-49-6	0.050
XXI	200	4-tert-butylphenol	98-54-4	0.050
XXI	201	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.050
XXII	202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.050
XXII	203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.050
XXII	204	Diisohexyl phthalate	71850-09-4	0.050

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Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XVI	170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.050
XVI	171	4-Heptylphenol, branched and linear	-	0.050
XVI	172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	3106-42-7/335-76-2/3830-45-3	0.050
XVI	173	p-(1,1-dimethylpropyl)phenol	80-46-6	0.050
XVII	174	Perfluorohexane-1-sulphonic acid and its salts	-	0.050
XVIII	175	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05.10]octadeca-7,15-diene ("Dechlorane Plus™") (covering any of its individual anti- and syn-isomers or any combination thereof)	-	0.050
XVIII	176	Benz[a]anthracene	56-55-3/1718-53-2	0.050
XVIII	177	Cadmium nitrate*	10022-68-1/10325-94-7	0.005
XVIII	178	Cadmium carbonate*	513-78-0	0.005
XVIII	179	Cadmium hydroxide*	21041-95-2	0.005
XVIII	180	Chrysene	218-01-9/1719-03-6	0.050
XVIII	181	Reaction products of 1,3,4-thiadiazolin-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) (with ≥ 0.1% w/w 4-heptylphenol, branched and linear)	-	0.050
XIX	182	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride)	552-30-7	0.050
XIX	183	Benzo[ghi]perylene	191-24-2	0.050
XIX	184	Decamethylcyclopentasiloxane (D5)	541-02-6	0.050
XIX	185	Diisohexyl phthalate (DCHP)	84-61-7	0.050
XIX	186	Disodium octaborate*	12008-41-2	0.005

SGS

Test Report
(SVHC)

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Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	138	Trilead dioxide phosphonate*	12141-20-7	0.005
IX	139	4-Nonylphenol, branched and linear, ethoxylated	-	0.050
IX	140	Ammonium pentadecafluorooctanoate (APFC)**	3825-26-1	0.050
IX	141	Cadmium oxide*	1306-19-0	0.005
IX	142	Cadmium*	7440-43-9	0.005
IX	143	Dipentyl phthalate (DPP)	131-18-0	0.050
IX	144	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.050
X	145	Cadmium sulphate*	1306-23-6	0.005
X	146	Dihexyl phthalate	84-75-3	0.050
X	147	Disodium 3,3'-[[1,1'-biphenyl-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.050
X	148	Disodium 4-amino-3'-[[4'-[[2,4-diaminophenyl]azo] (1,1'-biphenyl)-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.050
X	149	Imidazolidine-2-thione; 2-imidazoline-2-thiol	96-45-7	0.050
X	150	Lead di(acetate)*	301-04-2	0.005
X	151	Triethyl phosphate	25155-23-1	0.050
XI	152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.050
XI	153	Cadmium chloride*	10109-94-2	0.005
XI	154	Sodium perborate; perboric acid, sodium salt*	-	0.005
XI	155	Sodium peroxometaborate*	7832-4-4	0.005

SGS

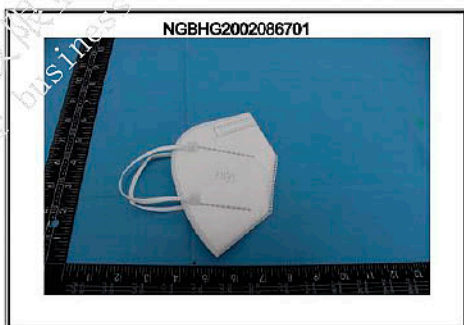
Test Report
(SVHC)

Sample photo:

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SGS authenticate the photo on original report only.

*** End of Report ***

SGS

Test Report
(SVHC)

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Date: 29 May 2020

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Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XXII	205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.050
/	206	1-vinylimidazole	1072-63-5	0.050
/	207	2-methylimidazole	693-98-1	0.050
/	208	Butyl 4-hydroxybenzoate	94-26-8	0.050
/	209	Diethylbis(pentane-2,4-dione O,O')in	22673-19-4	0.050
/	210	Resorcinol	108-46-3	0.050



中国国际出口销售贸易协会

China International Export Sale Trade Association

自由销售证书

CERTIFICATE OF FREE SALE

Certificado de Libre Venta

证书编号: 2020066049

Certificate No.(Número de certificado): 2020066049

产品名称/Product (Nombre del producto):

1、一次性 KN90 立体口罩 (非医用)

Disposable KN90 stereo mask (non-medical)

Máscara estereó KN90 desechable (no médica)

2、KN-95 口罩 (非医用)

KN-95 mask (non-medical)

Máscara KN-95 (no médica)

产品规格型号(Model/Modelo): MA-001 MA-002

产品执行标准 (Product Standards/ Producto estándar): GB 2626-2006

销往国家: 哥伦比亚

Export to (Exportar a): Colombia

出口商: 浙江民安医疗用品有限公司

Exporter(Exportador): Zhejiang Minan Medical Supplies Co., Ltd.

出口商地址: 浙江省温州市瑞安市汀田街道汀田工业区

Address(Dirección): Tingtian Industrial Zone, Tingtian Street, Ruian City, Wenzhou, Zhejiang

制造商: 浙江民安医疗用品有限公司

MANUFACTURER (Fabricante): Zhejiang Minan Medical Supplies Co., Ltd.

制造商地址: 浙江省温州市瑞安市汀田街道汀田工业区

Address(Dirección): Tingtian Industrial Zone, Tingtian Street, Ruian City, Wenzhou, Zhejiang

兹证明上述产品符合中华人民共和国相关标准, 已在中国注册, 准许市场销售, 该产品出口不受限制。

THIS IS TO CERTIFY THAT THE ABOVE PRODUCTS COMPLY WITH THE RELEVANT STANDARDS OF P.R.CHINA, HAVE BEEN REGISTERED AND ARE ALLOWED TO BE SOLD IN CHINA, THE EXPORTATION OF THE PRODUCTS ARE NOT RESTRICTED.

SE CERTIFICA QUE LOS PRODUCTOS ARRIBA CITADOS CUMPLEN CON LAS NORMAS DE LA REPÚBLICA POPULAR CHINA, SE HAN REGISTRADO Y SE PERMITE SU VENTA EN CHINA, LA EXPORTACIÓN DE LOS PRODUCTOS NO ESTÁ LIMITADA.

此证明自签发时起有效期 一 年。

THIS CERTIFICATE IS VALID FOR ONE YEARS FROM THE DATE OF ISSUANCE.

ESTE CERTIFICADO TIENE UNA VALIDEZ DE 1 AÑOS A PARTIR DE LA FECHA DE EMISIÓN.

中国国际出口销售贸易协会

China International Export Sale Trade Association

Asociación comercial de las ventas de exportación internacionales de China

Date: June 22, 2020

Fecha: 22 de Junio de 2020

China International Export Sale Trade Association

<https://www.chinafsc.org>

Registration Number: 59900984-001

E-mail: abc@chinafsc.org



Hong Kong General Chamber of Commerce
香港總商會 1861

Reference Number

5477155

Certificate 證明書

THIS IS TO CERTIFY THAT:

The annexed **CERTIFICATE OF FREE SALE** is submitted to the Chamber for certification: and

Specimens of authorized signature and company chop of the applicant company are recorded in the Chamber.

茲證明：

附件 **CERTIFICATE OF FREE SALE** 已提交予本會作商事證明；及
申請公司的授權人簽署及印章式樣已在本會記錄備案。



Signature of Authorized Officer

Name of Signatory

Mr. Lawrence CHANG Chun-Wa

Date: 26 Jun 2020

Certification Chop

The Hong Kong General Chamber of Commerce

Authorized by the Government of the Hong Kong SAR to
issue Certificates of Origin (Chapter 324 of the laws of HK)

Issuing Office: Mongkok Certification Branch, HKGCC
18/F Hang Seng Mongkok Building, 677 Nathan Road,
Mongkok, Kowloon, Hong Kong



Authentication Code 26339856

<http://cert.chamber.org.hk/verify>

**TEST REPORT**

No. 8621.SH.2102.0020 Date: 02.07, 2021 Page: 1 / 12

Applicant : ZHEJIANG MINAN MEDICAL SUPPLIES CO., LTD.
Address : TINGTIAN INDUSTRIAL ZONE, TINGTIAN STREET, RUIAN CITY,
WENZHOU CITY, ZHEJIANG PROVINCE, CHINA

Below information submitted by the applicant:

Product Name : Filtering half mask, Grey
Model : MA-001
Model may cover : /
Reference info. : /
Manufacturer info. : Zhejiang Minan Medical Supplies Co., Ltd.
Tingtian Industrial Zone, Tingtian Street, Ruian City, Wenzhou City,
Zhejiang Province, China
Supplier info. : /
Buyer info. : /
Country of Destination : /
Country of Origin : /

Sample Received : 02.04, 2021
Test Period : 02.04, 2021 - 02.07, 2021
Test Requirement : Refer to next pages
Test Method : Refer to next pages
Test Result : Refer to next pages
Test Conclusion : Refer to next pages

Signed for and on behalf of
Jordan Wang, General Manager
BU Chemical Compliance
TUV THURINGEN (SHANGHAI) CO., LTD.
Location: Shanghai

TÜV Thüringen CHINA

Attention: please note that every statement made in this report is only valid for the samples tested and reported herein. This report shall not be reproduced except in full, without the written approval of the testing laboratory. Any holder of this document is advised that information contained herein reflects the parties to a transaction from exercising all their rights and obligations under the transaction documents.
http://tuv-thuringen.com.cn/news/12_138 Vision date: 2021.01.01

E-mail: shanghai@tuv-thuringen.de Web: <http://www.tuv-thuringen.com.cn>**TUV Thuringen (Shanghai) Co., Ltd.**

Room C6, Floor 16th Jiangsu Building, No.526 Laoshan Road, Shanghai 200122, P.R.China



TEST REPORT

No. 8621.SH.2102.0020 Date: 02.07, 2021 Page: 2 / 12

TEST RESULTS

As requested by the client, test items as below:

Test Items	Verdict
1. According to European Commission Regulation 1907/2006 (concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC), to test the SVHC content which have been listed in ECHA's SVHC candidate list till Jan.19, 2021 http://echa.europa.eu/web/guest/candidate-list-table - REACH SVHC content in candidate list till 2021.01.19, less than 0.1%	PASS

SAMPLE DESCRIPTION

Sample description : 1# Filtering half mask, Grey

TEST RESULTS

1. REACH SVHC in candidate lists

Test Method: In-house method with reference to EPA: 8270D, 3052, 6010C, 3550C, 8321B, EN14362, DIN EN ISO 17353, IEC 62321, AfPS GS 2019:01 and EN 14582 etc

Abbr.: MDL, means Method Detection Limit; N.D. = Not Detected, means the content is less than MDL.

Seq. Test Item(s)	Units	MDL	Results
			1#
All tested SVHC in candidate lists	---	---	N.D.

Test Parameter& MDL for SVHC listed in candidate lists

Seq.	Test Item(s)	EC. No.	CAS No.	MDL (%)
1	2,4-Dinitrotoluene	204-450-0	121-14-2	0.01
2	2-Ethoxyethanol	203-804-1	110-80-5	0.005
3	2-Methoxyethanol	203-713-7	109-86-4	0.005
4	4,4'- Diaminodiphenylmethane(MDA)	202-974-4	101-77-9	0.005
5	5-tert-butyl-2,4,6-trinitro-m-xylene(musk xylene)	201-329-4	81-15-2	0.005
6	Acrylamide	201-173-7	79-06-1	0.01
7	Alkanes, C ₁₀₋₁₃ , chloro (Short Chain Chlorinated Paraffins)	287-476-5	85535-84-8	0.005
8	Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al ₂ O ₃ and SiO ₂ are present within the following concentration ranges: Al ₂ O ₃ : 43.5 – 47 % w/w, and SiO ₂ : 49.5 – 53.5 % w/w, or Al ₂ O ₃ : 45.5 – 50.5 % w/w, and SiO ₂ : 48.5 – 54 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm)***	---	---	0.01
9	Ammonium dichromate*	232-143-1	7789-09-5	0.01



TÜV Thüringen CHINA

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Room C6, Floor 16th Jiangsu Building, No.526 Laoshan Road, Shanghai 200122, P.R.China



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Seq.	Test Item(s)	EC. No.	CAS No.	MDL (%)
10	Anthracene	204-371-1	120-12-7	0.005
11	Anthracene oil	292-602-7	90640-80-5	0.01
12	Anthracene oil, anthracene paste	292-603-2	90640-81-6	0.01
13	Anthracene oil, anthracene paste, anthracene fraction	295-275-9	91995-15-2	0.01
14	Anthracene oil, anthracene paste; distn. Lights	295-278-5	91995-17-4	0.01
15	Anthracene oil, anthracene-low	292-604-8	90640-82-7	0.01
16	Benzyl butyl phthalate(BBP)	201-622-7	85-68-7	0.005
17	Bis(2-ethylhexyl)phthalate(DEHP)	204-211-0	117-81-7	0.005
18	Bis(tributyltin)oxide(TBTO)**	200-268-0	56-35-9	0.005
19	Boric acid*	233-139-2 / 234-343-4	10043-35-3 / 11113-50-1	0.01
20	Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid	231-801-5 236-881-5	7738-94-5 13530-68-2	0.01
21	Chromium trioxide*	215-607-8	1333-82-0	0.01
22	Cobalt dichloride*	231-589-4	7646-79-9	0.01
23	Cobalt(II) carbonate*	208-169-4	513-79-1	0.01
24	Cobalt(II) diacetate*	200-755-8	71-48-7	0.01
25	Cobalt(II) dinitrate*	233-402-1	10141-05-6	0.01
26	Cobalt(II) sulphate*	233-334-2	10124-43-3	0.01
27	Diarsenic pentaoxide*	215-116-9	1303-28-2	0.01
28	Diarsenic trioxide*	215-481-4	1327-53-3	0.01
29	Dibutyl Phthalate(DBP)	201-557-4	84-74-2	0.005
30	Diisobutyl Phthalate(DIBP)	201-553-2	84-69-5	0.01
31	Disodium tetraborate, anhydrous*	215-540-4	1303-96-4/ 1330-43-4/ 12179-04-3	0.01
32	Hexabromocyclododecane(HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	247-148-4 and 221-695-9	25637-99-4 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8)	0.005
33	Lead chromate*	231-846-0	7758-97-6	0.01
34	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)*	235-759-9	12656-85-8	0.01
35	Lead hydrogen arsenate*	232-064-2	7784-40-9	0.01
36	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	215-693-7	1344-37-2	0.01
37	Coal tar pitch, high temperature	266-028-2	65996-93-2	0.01
38	Potassium chromate*	232-140-5	7789-00-6	0.01
39	Potassium dichromate*	231-906-6	7778-50-9	0.01



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TEST REPORT

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Seq.	Test Item(s)	EC. No.	CAS No.	MDL (%)
40	Sodium chromate*	231-889-5	7775-11-3	0.01
41	Sodium dichromate*	234-190-3	7789-12-0/ 10588-01-9	0.01
42	Tetraboron disodium heptaoxide, hydrate*	235-541-3	12267-73-1	0.01
43	Trichloroethylene	201-167-4	79-01-6	0.01
44	Triethyl arsenate*	427-700-2	15606-95-8	0.01
45	Tris(2-chloroethyl)phosphate	204-118-5	115-96-8	0.01
46	Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al ₂ O ₃ , SiO ₂ and ZrO ₂ are present within the following concentration ranges: Al ₂ O ₃ : 35 – 36 % w/w, and SiO ₂ : 47.5 – 50 % w/w, and ZrO ₂ : 15 - 17 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm)***	---	---	0.01
47	2-ethoxyethyl acetate	203-839-2	111-15-9	0.01
48	Strontium chromate*	232-142-6	7789-06-2	0.01
49	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	0.01
50	Hydrazine	206-114-9	7803-57-8 302-01-2	0.01
51	1-methyl-2-pyrrolidone	212-828-1	872-50-4	0.01
52	1,2,3-trichloropropane	202-486-1	96-18-4	0.01
53	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	0.01
54	Lead dipicrate*	229-335-2	6477-64-1	0.01
55	Lead styphnate*	239-290-0	15245-44-0	0.01
56	Lead azide Lead diazide*	236-542-1	13424-46-9	0.01
57	Phenolphthalein	201-004-7	77-09-8	0.01
58	2,2'-dichloro-4,4'-methylenedianiline	202-918-9	101-14-4	0.01
59	N,N-dimethylacetamide	204-826-4	127-19-5	0.01
60	Trilead diarsenate*	222-979-5	3687-31-8	0.01
61	Calcium arsenate*	231-904-5	7778-44-1	0.01
62	Arsenic acid*	231-901-9	7778-39-4	0.01
63	Bis(2-methoxyethyl) ether	203-924-4	111-96-6	0.01
64	1,2-Dichloroethane	203-458-1	107-06-2	0.01
65	4-(1,1,3,3-tetramethylbutyl)phenol	205-426-2	140-66-9	0.01



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TEST REPORT

No. 8621.SH.2102.0020

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Seq.	Test Item(s)	EC. No.	CAS No.	MDL (%)
66	2-Methoxyaniline; o-Anisidine	201-963-1	90-04-0	0.01
67	Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	0.01
68	Formaldehyde, oligomeric reaction products with aniline	500-036-1	25214-70-4	0.01
69	Pentazinc chromate octahydroxide*	256-418-0	49663-84-5	0.01
70	Potassium hydroxyoctaoxodizincatedi-chromate*	234-329-8	11103-86-9	0.01
71	Dichromium tris(chromate)*	246-356-2	24613-89-6	0.01
72	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	203-977-3	112-49-2	0.01
73	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	203-794-9	110-71-4	0.01
74	Diboron trioxide*	215-125-8	1303-86-2	0.01
75	Formamide	200-842-0	75-12-7	0.01
76	Lead(II) bis(methanesulfonate) *	401-750-5	17570-76-2	0.01
77	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione)	219-514-3	2451-62-9	0.01
78	β -TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	423-400-0	59653-74-6	0.01
79	4,4'-bis(dimethylamino) benzophenone (Michler's ketone)	202-027-5	90-94-8	0.01
80	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	202-959-2	101-61-1	0.01
81	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] ****	208-953-6	548-62-9	0.01
82	[4-[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] ****	219-943-6	2580-56-5	0.01
83	α,α -Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] ****	229-851-8	6786-83-0	0.01
84	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] ****	209-218-2	561-41-1	0.01
85	Bis(pentabromophenyl) ether (DecaBDE)	214-604-9	1163-19-5	0.01
86	Pentacosafuorotridecanoic acid	276-745-2	72629-94-8	0.01
87	Tricosafuorododecanoic acids	206-203-2	307-55-1	0.01
88	Henicosafuoroundecanoic acid	218-165-4	2058-94-8	0.01
89	Heptacosafuorotetradecanoic acid	206-803-4	376-06-7	0.01
90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated -covering well-defined substances and UVCB substances, polymers and homologues	---	---	0.01
91	4-Nonylphenol, branched and linear -substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual	---	---	0.01

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Seq.	Test Item(s)	EC. No.	CAS No.	MDL (%)
	isomers or a combination thereof			
92	Diazeno-1,2-dicarboxamide (C,C'-azodi(formamide))	204-650-8	123-77-3	0.01
93	Cyclohexane-1,2-dicarboxylic anhydride (Hexahydrophthalic anhydride - HHPA)	201-604-9	85-42-7	0.01
94	Hexahydromethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	0.01
95	Methoxy acetic acid	210-894-6	625-45-6	0.01
96	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	0.01
97	Diisopentylphthalate (DIPP)	210-088-4	605-50-5	0.01
98	N-pentyl-isopentylphthalate	---	---	0.01
99	1,2-Diethoxyethane	211-076-1	629-14-1	0.01
100	N,N-dimethylformamide; dimethyl formamide	200-679-5	68-12-2	0.01
101	Dibutyltin dichloride (DBT)	211-670-0	683-18-1	0.01
102	Acetic acid, lead salt, basic*	257-175-3	51404-69-4	0.01
103	Basic lead carbonate (trilead bis(carbonate)dihydroxide)*	215-290-6	1319-46-6	0.01
104	Lead oxide sulfate (basic lead sulfate)*	234-853-7	12036-76-9	0.01
105	[Phthalato(2-)]dioxotrilead (dibasic lead phthalate)*	273-688-5	69011-06-9	0.01
106	Dioxobis(stearato)trilead*	235-702-8	12578-12-0	0.01
107	Fatty acids, C16-18, lead salts*	292-966-7	91031-62-8	0.01
108	Lead bis(tetrafluoroborate)*	237-486-0	13814-96-5	0.01
109	Lead cyanamide*	244-073-9	20837-86-9	0.01
110	Lead dinitrate*	233-245-9	10099-74-8	0.01
111	Lead oxide (lead monoxide)*	215-267-0	1317-36-8	0.01
112	Lead tetroxide (orange lead)*	215-235-6	1314-41-6	0.01
113	Lead titanium trioxide*	235-038-9	12060-00-3	0.01
114	Lead Titanium Zirconium Oxide*	235-727-4	12626-81-2	0.01
115	Pentalead tetraoxide sulphate*	235-067-7	12065-90-6	0.01
116	Pyrochlore, antimony lead yellow*	232-382-1	8012-00-8	0.01
117	Silicic acid, barium salt, lead-doped*	272-271-5	68784-75-8	0.01
118	Silicic acid, lead salt*	234-363-3	11120-22-2	0.01
119	Sulfurous acid, lead salt, dibasic*	263-467-1	62229-08-7	0.01
120	Tetraethyllead*	201-075-4	78-00-2	0.01
121	Tetralead trioxide sulphate*	235-380-9	12202-17-4	0.01
122	Trilead dioxide phosphonate*	235-252-2	12141-20-7	0.01



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123	Furan	203-727-3	110-00-9	0.01
124	Propylene oxide; 1,2-epoxypropane; methyloxirane	200-879-2	75-56-9	0.01
125	Diethyl sulphate	200-589-6	64-67-5	0.01
126	Dimethyl sulphate	201-058-1	77-78-1	0.01
127	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	143860-04-2	0.01
128	Dinoseb	201-861-7	88-85-7	0.01
129	4,4'-methylenedi-o-toluidine	212-658-8	838-88-0	0.01
130	4,4'-oxydianiline and its salts	202-977-0	101-80-4	0.01
131	4-Aminoazobenzene	200-453-6	60-09-3	0.01
132	4-methyl-m-phenylenediamine (toluene -2,4 -diamine)	202-453-1	95-80-7	0.01
133	6-methoxy-m-toluidine (p-cresidine)	204-419-1	120-71-8	0.01
134	Biphenyl-4-ylamine	202-177-1	92-67-1	0.01
135	O-aminoazotoluene	202-591-2	97-56-3	0.01
136	O-Toluidine	202-429-0	95-53-4	0.01
137	N-methylacetamide	201-182-6	79-16-3	0.01
138	1-bromopropane(n-propyl bromide)	203-445-0	106-94-5	0.01
139	Cadmium*	231-152-8	7440-43-9	0.01
140	Cadmium oxide*	215-146-2	1306-19-0	0.01
141	Ammonium pentadecafluorooctanoate(APFO)	223-320-4	3825-26-1	0.01
142	Pentadecafluorooctanoic acid(PFOA)	206-397-9	335-67-1	0.01
143	Dipentyl phthalate(DPP)	205-017-9	131-18-0	0.01
144	4-Nonylphenol, branched and linear,ethoxylated	---	---	0.01
145	Cadmium sulphide*	215-147-8	1306-23-6	0.01
146	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	209-358-4	573-58-0	0.03
147	Disodium 4-amino-3'-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	217-710-3	1937-37-7	0.03
148	Dihexyl phthalate	201-559-5	84-75-3	0.01
149	Imidazolidine-2-thione (2-imidazoline-2-thiol)	202-506-9	96-45-7	0.03
150	Lead di(acetate) *	206-104-4	301-04-2	0.01
151	Trixylyl phosphate	246-677-8	25155-23-1	0.01
152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	0.01
153	Sodium perborate; perboric acid, sodium salt *	239-172-9; 234-390-0	---	0.01
154	Sodium peroxometaborate*	231-556-4	7632-04-4	0.01



TÜV Thüringen CHINA

E-mail: shanghai@tuv-thuringen.de Web: <http://www.tuv-thuringen.com.cn>

TUV Thuringen (Shanghai) Co., Ltd.

Room C6, Floor 16th Jiangsu Building, No.526 Laoshan Road, Shanghai 200122, P.R.China



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Seq.	Test Item(s)	EC. No.	CAS No.	MDL (%)
155	Cadmium chloride*	233-296-7	10108-64-2	0.01
156	Cadmium Fluoride	232-222-0	7790-79-6	0.01
157	Cadmium Sulphate	233-331-6	10124-36-4 31119-53-6	0.01
158	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7	0.01
159	2-(2H-benzotriazol-2-yl)-4,6-diterpentylphenol (UV-328)	247-384-8	25963-55-1	0.01
160	2-ethylhexyl-10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate(DOTE)	239-622-4	15571-58-1	0.01
161	Reaction mass of 2-ethylhexyl-10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	-	0.01
162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (EC No. 201-559-5)	271-049-0 272-013-1	68515-51-5 68648-93-1	0.01
163	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]	-	-	0.01
164	1,3-propanesultone	214-317-9	1120-71-4	0.01
165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1	0.01
166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3	0.01
167	Nitrobenzene	202-716-0	98-95-3	0.01
168	Perfluorononane-1-oic-acid and its sodium and ammonium salts	206-801-3	375-95-1 21049-39-8 4149-60-4	0.01
169	Benzo(def)chrysene	200-028-5	50-32-8	0.01
170	4,4-isopropylidenediphenol (Bisphenol A)	201-245-8	80-05-7	0.01
171	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	206-400-3 221-470-5	3108-42-7 335-76-2 3830-45-3	0.01
172	4-heptylphenol, branched and linear (4-HPbl)	-	-	0.01
173	4-tert-penylphenol (PTAP)	201-280-9	80-46-6	0.01
174	Perfluorohexane-1-sulphonic acid and its salts	206-587-1	355-46-4	0.01
175	Dechlorane Plus(TM) and reaction products of 1,3,4-thiadiazolidine-2,5-dithione	/	13560-89-9 135821-74-8 135821-03-3	0.01
176	benz[a]anthracene	200-280-6	56-55-3	0.01
177	cadmium nitrate	233-710-6	10325-94-7	0.01
178	cadmium carbonate	208-168-9	513-78-0	0.01
179	cadmium hydroxide	244-168-5	21041-95-2	0.01
180	chrysene	205-923-4	218-01-9	0.01
181	formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear]	/	/	0.01
182	Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitanhydride)	209-8-0	552-30-7	0.01



TÜV Thüringen CHINA

E-mail: shanghai@tuv-thuringen.de Web: <http://www.tuv-thuringen.com.cn>

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Room C6, Floor 16th Jiangsu Building, No.526 Laoshan Road, Shanghai 200122, P.R.China

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183	Benzo[ghi]perylene	205-883-8	191-24-2	0.005
184	Decamethylcyclopentasiloxane (D5)	208-764-9	541-02-6	0.005
185	Dicyclohexyl phthalate (DCHP)	201-545-9	84-61-7	0.01
186	Disodium octaborate	234-541-0	12008-41-2	0.005
187	Dodecamethylcyclohexasiloxane (D6)	208-762-8	540-97-6	0.005
188	Ethylenediamine	203-468-6	107-15-3	0.01
189	Lead	231-100-4	7439-92-1	0.005
190	Octamethylcyclotetrasiloxane (D4)	209-136-7	556-67-2	0.005
191	Terphenyl hydrogenated	262-967-7	61788-32-7	0.005
192	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one	239-139-9	15087-24-8	0.005
193	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	401-720-1	6807-17-6	0.005
194	Benzo[k]fluoranthene	205-916-6	207-08-9	0.005
195	Fluoranthene	205-912-4	206-44-0 93951-69-0	0.005
196	Phenanthrene	201-581-5	85-01-8	0.005
197	Pyrene	204-927-3	129-00-0 1718-52-1	0.005
198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides	---	---	0.01
199	2-methoxyethyl acetate	203-772-9	110-49-6	0.01
200	4-tert-butylphenol	202-679-0	98-54-4	0.01
201	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)	---	---	0.01
202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	0.01
203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	0.01
204	Diisohexyl phthalate	276-090-2	71850-09-4	0.01
205	Perfluorobutane sulfonic acid (PFBS) and its salts	---	---	0.01
206	1-vinylimidazole	214-012-0	1072-63-5	0.01
207	2-methylimidazole	211-765-7	693-98-1	0.01
208	Butyl 4-hydroxybenzoate	202-318-7	94-26-8	0.01
209	Dibutylbis(pentane-2,4-dionato-O,O')tin	245-152-0	22673-19-4	0.01
210	Bis(2-(2-methoxyethoxy)ethyl)ether	205-594-7	143-24-8	0.01
211	Diocetyl tin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	---	---	0.01

***** To be continued *****



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- Remark 1**
- 1) In accordance with Regulation(EC) No. 1907/2006, any producer or importer of articles shall notify ECHA, in accordance with paragraph 4 of Article 7, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:
 - (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
 - (b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).
 - 2) From 28 October 2008, EU & EEA suppliers of articles which contain substances on the Candidate List in a concentration above 0.1% (w/w) must provide sufficient information, available to them, to their customers and on request to a consumer within 45 days of the receipt of this request. This information must ensure safe use of the article and, as a minimum, include the name of the substance.
- Remark 2**
- 1)* Calculated concentration of cobalt dichloride, cobalt(II) sulphate, cobalt(II) dinitrate, cobalt(II) carbonate and cobalt(II) diacetate is based on the identified heavy metal and anion result. Calculated concentration of diarsenic pentaoxide, diarsenic trioxide, chromium trioxide, sodium dichromate, dehydrate, lead hydrogen arsenate, triethyl arsenate, lead chromate, sodium chromate, strontium chromate, potassium chromate, ammonium dichromate, potassium dichromate, lead chromate molybdate sulfate red, lead sulfochromate yellow and acids generated from chromium trioxide and their oligomers, Lead dipicrate, Lead styphnate, Lead azide Lead diazide, Trilead diarsenate, Calcium arsenate, Arsenic acid, Potassium hydroxyoctaoxodizincatedi-chromate, Dichromium tris(chromate), Pentazinc chromate octahydroxide, Lead(II) bis(methanesulfonate), Diboron trioxide, Acetic acid, lead salt, basic, Basic lead carbonate (trilead bis(carbonate)dihydroxide), Lead oxide sulfate (basic lead sulfate), [Phthalato(2-)]dioxotrilead (dibasic lead phthalate), Dioxobis(stearato)trilead, Fatty acids, C16-18, lead salts, Lead bis(tetrafluoroborate), Lead cyanidate, Lead dinitrate, Lead oxide (lead monoxide), Lead tetroxide (orange lead), Lead titanium trioxide, Lead Titanium Zirconium Oxide, Pentalead tetraoxide sulphate, Pyrochlore, antimony lead yellow, Silicic acid, barium salt, lead-doped, Sulfurous acid, lead salt, dibasic, Tetraethyllead, Tetralead trioxide sulphate, Trilead dioxide phosphonate, Cadmium, Cadmium oxide, Cadmium sulphide and Lead di(acetate), Cadmium chloride are based on the identified heavy metal result, boric acid, disodium tetraborate, anhydrous and tetraboron disodium heptaoxide, hydrate, Sodium perborate; perboric acid, sodium salt, Sodium peroxometaborate are based on the identified result of boron and sodium result. The identities of above metal substances present in the article have to be further confirmed;
 - 2)** Concentration of bis(tributyltin)oxide, TBTO is reported as tributyltin, TBT. The result is a screening test of TBTO and can cover TBTO and other salts under current technologies. Further investigation is needed to have the exact amount of TBTO;
 - 3)*** Calculated concentration of Aluminosilicate, Refractory Ceramic Fibres ;Zirconia Aluminosilicate, Refractory Ceramic Fibres is based on the identified heavy metal result and confirmation by microscope;
 - 4)****The substance does only fulfil the criteria of REACH Art. 57 (a) if it contains Michler's ketone (EC Number: 202-027-5) or Michler's base (EC Number: 202-959-2) in a concentration $\geq 0.1\%$ (weight / weight);
 - 5) N.D. = Not detected, less than MDL.

***** To be continued *****



TÜV Thüringen CHINA

E-mail: shanghai@tuv-thuringen.de Web: <http://www.tuv-thuringen.com.cn>

TUV Thuringen (Shanghai) Co., Ltd.

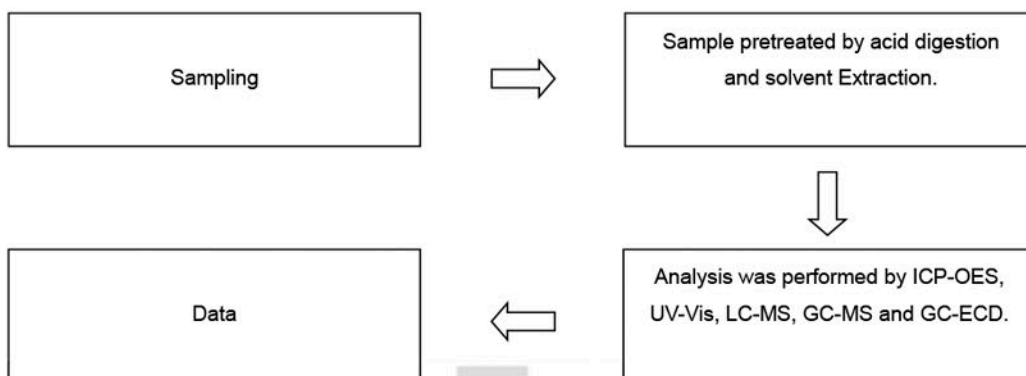
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FLOW CHART



***** To be continued *****



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E-mail: shanghai@tuv-thuringen.de Web: <http://www.tuv-thuringen.com.cn>

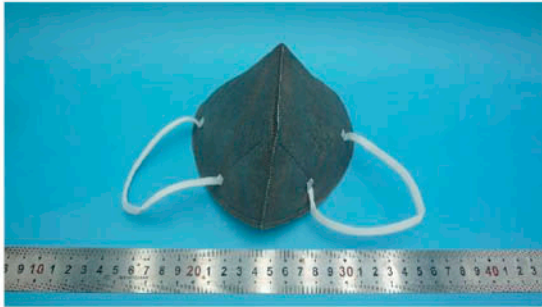
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SAMPLE IMAGE



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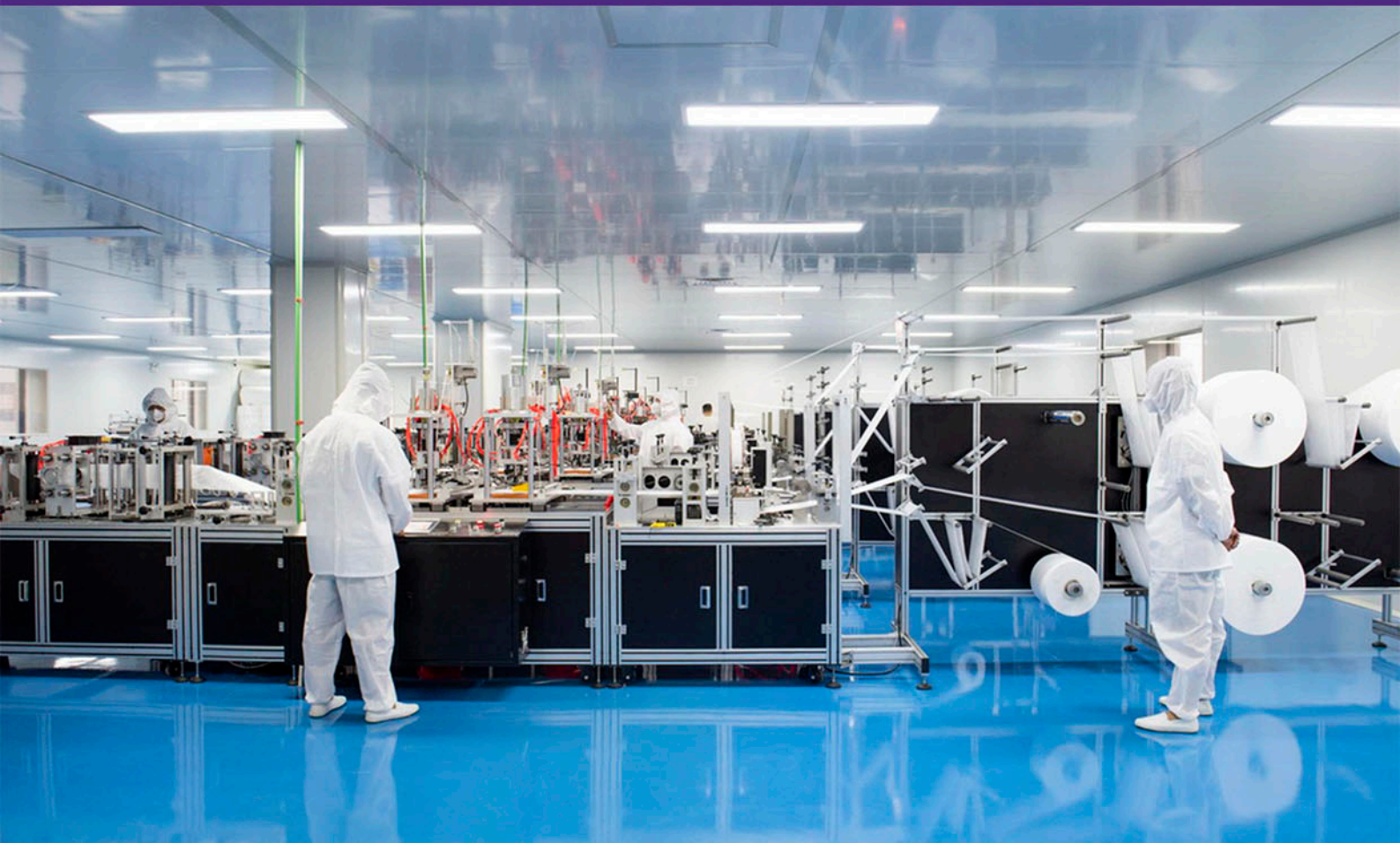


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***** END OF REPORT *****







Control Interlocking



Sala sanitaria



Salidas emergencia



Acceso limpio



Sala presión negativa



Sala primer cambio



Sala segundo cambio

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Vallepharma Andaluz S.L.U.

Calle Marina 228, Barcelona, España

Teléfono: (+34) 931 43 84 33

E-Mail: info@keholltechnology.com

www.keholltechnology.com