FICHA TÉCNICA
MÁSCARA FFP2 NR
NEGRA, AZUL MARINO Y ROSA

TAMAÑO ADULTO

FÁBRICA
ZHEIJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD

incaFARMA

MASCARILLA FILTRANTE FFP2 NR COLORES - TAMAÑO ADULTO

NOMBRE DEL PRODUCTO: MASCARILLA FILTRANTE FFP2 NR

IMPORTADOR:

INCA PRODUCTS S.L.
C.I.F. B-05115159

FABRICANTE:

ZHEIJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD
Nº680 Century Road, Quzhou City, Zhejiang Province, China

CERTIFICACIONES Y DOCUMENTACIÓN:

Ficha técnica del producto.

Fotos de la mascarilla y blíster de venta.

EU declaración de conformidad del fabricante.

Certificado CE módulo B de CCQS nº CE-PC-200511-364-01-9B
con referencia ON **CE 2834.**

Certificado CE módulo C2 de CCQS nº CE-PC-200511-364-FPC-B
con referencia ON **CE 2834.**

Test report emitido por: **CASST** Nº **WLH0336-2020**
CNAS L0118
Fecha: Mayo 8, 2020
Conforme la normativa: EN 149:2001+A1:2009

Test report colores por: **PTC** (Precise testing & Certification (Guangdong) Co., Ltd)
CNAS L5772
Fecha: Enero 4, 2021
Conforme la normativa: EN 149:2001+A1:2009

Informe de auditoría de capacidad y credibilidad del proveedor emitido por:
SGS Audit- SCCA
Report nº: SCCA220071801

Registrada en la cámara de comercio de China para la Importación y exportación de medicina, productos de salud dispositivos médicos y EPI's con marcado CE en origen.

Adjuntamos documentación

MASCARILLA FILTRANTE FFP2 NR COLORES - TAMAÑO ADULTO

Descripción

FICHA TÉCNICA
PRODUCTO

Mascarilla filtrante FFP2 NR. No estéril.
Tamaño adulto. Con clip en la nariz.
Modelo del fabricante: RB-008
Mascarilla definida por EN 149:2001+A1:2009
Colores: negro, azul marino y rosa.

Dimensiones: 155 (+-0,5cm) *10,5 cm (+-0,5cm)

Propiedades:
Peso base de los tejidos no tejidos (capas interiores): 30 g
Peso básico de los tejidos no tejidos (capas exteriores): 50 g
Peso base de las telas fundidas por soplado (2a capa): 25 g
Peso básico de las telas fundidas por soplado (3a capa): 25 g
Peso básico del algodón de aire caliente (4a capas): 45 g
Media máscara de filtrado de partículas según la definición de EN 149: 2001 + A1: 2009.

Indicaciones:
La máscara puede filtrar las partículas en el aire y bloquear las gotas, la sangre, los fluidos corporales y las secreciones. Es seguro y confiable.
Producto de un solo uso.
NR- No reutilizable

Materiales:
Cuerpo de la mascarilla: PP de tela no tejida (capas interiores y exteriores)
Tejodo Melt blown de polipropileno (2a y 3ª capa) y algodón de aire caliente de poliéster (4ª capa)
Clip de nariz: polietileno + alambre galvanizado
Orejera: Spandex

Esterilización: No estéril

Regulación:
Nombre de la autoridad reguladora: **CCQS** con referencia de ON**: 2834**

Certificado CE módulo B de CCQS nº CE-PC-200511-364-01-9B
con referencia ON **CE 2834.**
Certificado CE módulo C2 de CCQS nº CE-PC-200511-364-FPC-B
con referencia ON **CE 2834.**
(Ver en documentación adjunta)

Fabricación:
Fabricado en China.

Caducidad:
3 años a partir del mes de producción.

Almacenamiento
Mantener el producto en una habitación limpia con una humedad relativa no superior al 80%, sin gases corrosivos, fresco, seco y bien ventilado.

MASCARILLA FILTRANTE FFP2 NR COLORES - TAMAÑO ADULTO

TECHNICAL DATA SHEET

Particle Filtering Half Mask

FFP2 NR

Non-medical

CE 2834

Description

RB-008: FFP2, Non-medical, With nose clip
Black, navy blue, pink

Dimensions

	Length	Width
RB-008	155 mm	105mm

Properties--------5 layers
Basis weight of non-woven fabrics (inner layers): 30g
Basis weight of non-woven fabrics (outer layers): 50g
Basis weight of melt-blown fabrics (2nd layers): 25g
Basis weight of melt-blown fabrics (3rd layers): 25g
Basis weight of hot air cotton (4th layers): 45g
Particle Filtering Half Mask as defined by EN 149:2001+A1:2009.

Indication

The mask can filter the particles in the air, and block the droplets, blood, body fluids and secretions. It is safe and reliable.
Single use product.

Counter indication

None in particular.

Main materials

Mask body: Made of PP non-woven fabrics (inner and outer layers)and polypropylene melt- blown fabrics (2nd & 3rd layers) and Polyester hot air cotton (4th layers)
Nose clip: Polyethylene + Galvanized wire
Ear loop: Spandex

Sterilization

Products are not sterilized.

Not to use latex either on the production line or on the masks.

Manufacturing

Products are manufactured in China.
The factory is Quzhou Rongbo Medical Instrument Co Ltd.

Storage

Store the product in a clean room with a relative humidity of less than 80% at room temperature, no corrosive gases, cool, dry, and well ventilated.
temperature range of storage conditioons: -20℃ to +40℃

Shelf life

3 years after month of production.

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MASCARILLA FILTRANTE FFP2 NR - TAMAÑO ADULTO

DECLARACIÓN DE CONFORMIDAD-CASTELLANO E INGLÉS

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MASCARILLA FILTRANTE FFP2 NR - TAMAÑO ADULTO

DECLARACIÓN DE CONFORMIDAD – ENGLISH VERSION

EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

1. The basic information is as follows:

	Product Name	Model	Classification/Type	CE Expiration Date
	Particle Filtering half mask	RB-008	FFP2 NR	2025-06-08

2. The Manufacturer's name and address is as follows:

Name:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD.
Address:	No.680 century road,quzhou city,zhejiang province china

3. This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

4. Detailed description of the PPE to allow traceability/identification of the PPE.

Model: RB-008 15.5x10.5cm

FFP2 NR

Pink folding half mask without valve

The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149:2001+A1:2009

CCQS Certification Services Limited. (NB 2834) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number:

No.	EU Type Examination (Module B) Certificate Number
1	CE-PC-200511-364-01-9B

Product Category:

☐ This product is Category II.

■ This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

☐ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

not to use latex either on the production line or on the masks

Signature : _____ Date : 2020.12.19 Company stamp and/or legal signature : _____

inca FARMA

EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

1. The basic information is as follows:

	Product Name	Model	Classification/Type	CE Expiration Date
	Particle Filtering half mask	RB-008	FFP2 NR	2025-06-08

2. The Manufacturer's name and address is as follows:

Name:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD.
Address:	No.680 century road,quzhou city,zhejiang province china

3. This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

4. Detailed description of the PPE to allow traceability/identification of the PPE.

Model: RB-008 15.5x10.5cm

FFP2 NR

Navy blue folding half mask without valve




The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149:2001+A1:2009

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No.	EU Type Examination (Module B) Certificate Number
1	CE-PC-200511-364-01-9B

Product Category:

☐ This product is Category II.

■ This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

☐ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

not to use latex either on the production line or on the masks

Signature : _____ Date : 2020.12.19 Company stamp and/or legal signature : _____

inca FARMA

EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

1. The basic information is as follows:

	Product Name	Model	Classification/Type	CE Expiration Date
	Particle Filtering half mask	RB-008	FFP2 NR	2025-06-08

2. The Manufacturer's name and address is as follows:

Name:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD.
Address:	No.680 century road,quzhou city,zhejiang province china

3. This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

4. Detailed description of the PPE to allow traceability/identification of the PPE.

Model: RB-008 15.5x10.5cm

FFP2 NR

Black folding half mask without valve




The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149:2001+A1:2009

CCQS Certification Services Limited. (NB 2834) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number:

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☐ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

not to use latex either on the production line or on the masks

Signature : _____ Date : 2020.12.19 Company stamp and/or legal signature : _____

浙江省衢州荣博医疗器械有限公司

inca FARMA

Declaración de cumplimiento de la UE

Anexo IX Reglamento PPE (UE) 2016/425

La declaración de conformidad de la UE se refiere a los siguientes productos

1. La situación básica es la siguiente:

	Nombre del producto	Modelo	Categoría/Tipo	Fecha de vencimiento CE
	Máscara de filtro de partículas	RB-008	FFP2 NR	2025-06-08

2. El nombre y la dirección del fabricante son los siguientes:

Nombre:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD.
Dirección:	No.680 century road,quzhou city,zhejiang province china

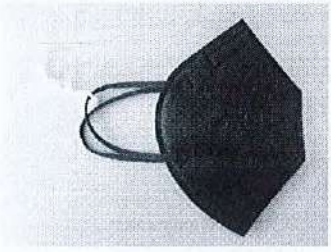
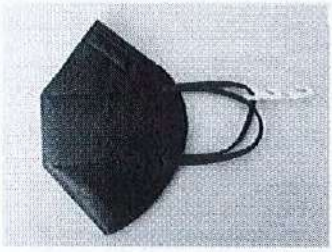
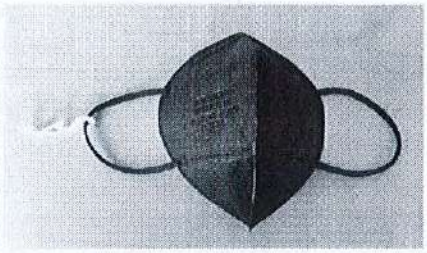
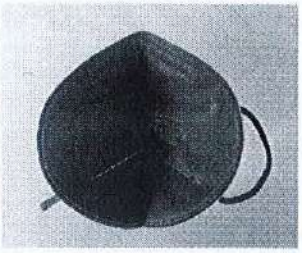
3. Esta declaración de conformidad es emitida exclusivamente por el fabricante.

4. Describa el PPE en detalle para permitir la trazabilidad/identificación del PPE.

Modelo: RB-008 15.5*10.5cm

FFP2 NR

Media máscara azul marino plegable sin válvula

Los términos establecidos en el (4) anterior están en conformidad con el Reglamento Legislativo de Coordinación de la Alianza pertinente (UE) 2016/425.

Se hace referencia a las normas uniformes pertinentes utilizadas, incluidas las fechas estándar, o a otras especificaciones técnicas, incluidas las fechas de las especificaciones, para declarar el cumplimiento:

No	Nombre estándar uniforme
1	EN 149:2001+A1:2009

Servicios de certificación CCQS Co., Ltd. (NB2834) realizó una prueba de tipo de la UE (Unidad B) y emitió un número de certificado de tipo de prueba:

No	Número de certificado de la prueba de tipo de la UE (Módulo B)
1	CE-PC-200511-364-01-9B

Categoría de producto:

☐ Este producto es clase II.

■ Este producto es la tercera categoría, por el módulo C2 control de producción interno y supervisión de la inspección del producto intervalo aleatorio, y en la supervisión de CCQS Certified Services Limited. (nb2834)

☐ Este producto es la tercera categoría, de acuerdo con la garantía de calidad del proceso de producción, en línea con el tipo de módulo D, y bajo la supervisión de CCQS Certified Services Limited. (nb2834)

no usar látex ni en la línea de producción ni en las máscaras

浙江衢州荣博医疗器材有限公司

Firma: _____ Fecha: 2020.12.19 Sello de la empresa y/o firma legal: _____

Declaración de cumplimiento de la UE

Anexo IX Reglamento PPE (UE) 2016/425

La declaración de conformidad de la UE se refiere a los siguientes productos

1. La situación básica es la siguiente:

	Nombre del producto	Modelo	Categoría/Tipo	Fecha de vencimiento CE
	Máscara de filtro de partículas	RB-008	FFP2 NR	2025-06-08

2. El nombre y la dirección del fabricante son los siguientes:

Nombre:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD.
Dirección:	No.680 century road,quzhou city,zhejiang province china

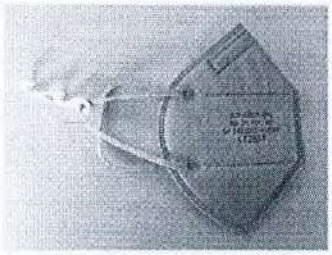
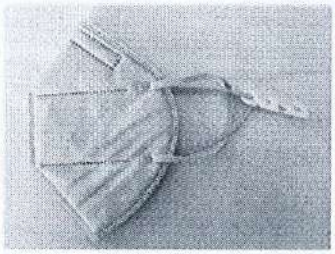
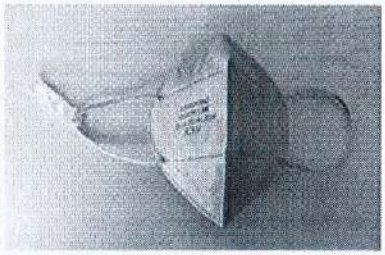
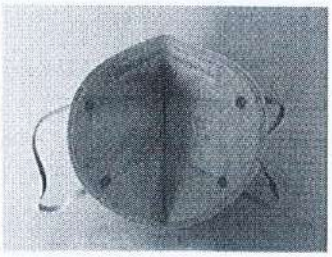
3. Esta declaración de conformidad es emitida exclusivamente por el fabricante.

4. Describa el PPE en detalle para permitir la trazabilidad/identificación del PPE.

Modelo: RB-008 15.5*10.5cm

FFP2 NR

Media máscara rosa plegable sin válvula

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Se hace referencia a las normas uniformes pertinentes utilizadas, incluidas las fechas estándar, o a otras especificaciones técnicas, incluidas las fechas de las especificaciones, para declarar el cumplimiento:

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☐ Este producto es la tercera categoría, de acuerdo con la garantía de calidad del proceso de producción, en línea con el tipo de módulo D, y bajo la supervisión de CCQS Certified Services Limited. (nb2834)

no usar látex ni en la línea de producción ni en las máscaras

Firma: 陈荣 Fecha: 2020.12.19 Sello de la empresa y/o firma legal:

浙江荣博医疗器材有限公司

Declaración de cumplimiento de la UE

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2. El nombre y la dirección del fabricante son los siguientes:

Nombre:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD.
Dirección:	No.680 century road,quzhou city,zhejiang province china

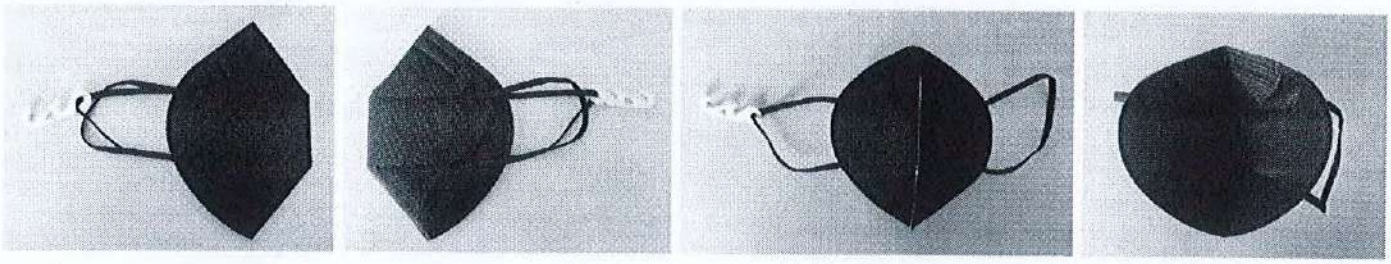
3. Esta declaración de conformidad es emitida exclusivamente por el fabricante.

4. Describa el PPE en detalle para permitir la trazabilidad/identificación del PPE.

Modelo: RB-008 15.5*10.5cm

FFP2 NR

Media máscara negra plegable sin válvula



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☐ Este producto es la tercera categoría, de acuerdo con la garantía de calidad del proceso de producción, en línea con el tipo de módulo D, y bajo la supervisión de CCQS Certified Services Limited. (nb2834)

no usar látex ni en la línea de producción ni en las máscaras

Firma: 朱毅天 Fecha: 2020.12.19 Sello de la empresa y/o firma legal:

MASCARILLA FILTRANTE FFP2 NR COLORES - TAMAÑO ADULTO

MÁSCARA MARCADA CON:

- Nombre de la fábrica/ marca comercial
- Modelo del fabricante
- Tipo de máscara
- NR de no reutilizable
- Normativa que cumple
- CE con el código del organismo notificador

MASCARILLA FILTRANTE FFP2 NR COLORES - TAMAÑO ADULTO

REF.: 00145
EAN:8435142001455

REF.: 00144
EAN:8435142001448

REF.: 00143
EAN:8435142001431

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MASCARILLA FILTRANTE FFP2 NR - TAMAÑO ADULTO

CERTIFICACIONES, TEST REPORTS Y COMPROBACIONES

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MASCARILLA FILTRANTE FFP2 NR - TAMAÑO ADULTO

VERIFICACIÓN DEL ORGANISMO NOTIFICADOR EUROPEO ACORDE REGLAMENTO EPI (EU) 2016/425

LINK PARA VERIFICACIÓN

Notification

Found : 2

Body :

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15 D15 AKK1
Dublin
Country : Ireland

Phone : 00 353 1 588 6920
Fax : -

Email : info@ccqs.ie
Website : www.ccqs.co.uk

Notified Body number : 2834

Legislations

- Regulation (EU) 2016/425 Personal protective equipment	HTML	PDF

MASCARILLA FILTRANTE FFP2 NR - TAMAÑO ADULTO

VERIFICACIÓN DEL LABORATORIO QUE EMITE EL DOCUMENTO CONFORME ESTÁ INCLUIDO EN LA LISTA DE ACREDITADOS POR LA ENTIDAD CHINA DE ACREDITACIÓN. **CNAS L0118**

Verificación de certificados/informes que acompañan a los EPI (06.04.2020) SEGÚN MINISTERIO DE TRABAJO Y ECONOMIA SOCIAL.

LINK DE VERIFICACIÓN

China Academy of Safety Science & Technology

Organization Information:

Registration Number: L0118	
Contact Person: Teng Lixia	TEL: 010-64941342
Post: 100012	Fax: 010-64812561
Web.Site: www.chinasafety.ac.cn	E-mail: gjajzx@sina.com
Address: Building 1A, No.32, Beiyuan Road, Chaoyang District, Beijing, China	
Term of Validity: 2017/10/16 — 2023/11/23	
Accreditation Criteria: ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories* and relevant requirements of CNAS	

Certificate Appendix (Accredited Scope):

Structured Data: Structured Scope Officially Released

Data List of Certificate Appendix (Accredited Scope):

Task Number	Assessment Type	Date of Issue	Release Status of Structured Scope	Appendix (Word)
L00830-2020-01Z	Irregular Surveillance	2020-09-15	Offically released	
L00830-2019-01Z	Reassessment + Expansion + Irregular Surveillance	2020-03-11	Offically released	

Note: For the fields to which this accreditation applies, please refer to the organization's appendix (accredited scope).The accredited scope in Chinese remains the definitive version.

CLOSE WINDOW

MASCARILLA FILTRANTE FFP2 NR - TAMAÑO ADULTO

VERIFICACIÓN DEL LABORATORIO QUE EMITE EL DOCUMENTO CONFORME ESTÁ INCLUIDO EN LA LISTA DE ACREDITADOS POR LA ENTIDAD CHINA DE ACREDITACIÓN. **CNAS L5772**

Verificación de certificados/informes que acompañan a los EPI (06.04.2020) SEGÚN MINISTERIO DE TRABAJO Y ECONOMIA SOCIAL.

LINK DE VERIFICACIÓN

Precise Testing & Certification (Guangdong) Co., Ltd.

Organization Information:

Registration Number: L5772	
Contact Person: Chris Du	TEL: 0769-38808222
Post: 523127	Fax: 0769-38826111
Web.Site: www.ptc-testing.com	E-mail: chris.du@ptc-testing.com
Address: Building 1, No.6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China	
Term of Validity: 2017/09/25 — 2023/09/24	
Accreditation Criteria: ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories* and relevant requirements of CNAS	

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Structured Data: Structured Scope Officially Released

Data List of Certificate Appendix (Accredited Scope):

Task Number	Assessment Type	Date of Issue	Release Status of Structured Scope	Appendix (Word)
L07113-2020-03Z	Irregular Surveillance	2020-11-04	Offically released	
L07113-2020-02Z	Expansion	2020-06-18	Offically released	
L07113-2019-04Z	Irregular Surveillance	2019-12-03	Offically released	
L07113-2019-03Z	Irregular Surveillance	2019-10-14	Offically released	
L07113-2019-01Z	Reassessment + Expansion + Irregular Surveillance	2019-05-29	Offically released	

Note: For the fields to which this accreditation applies, please refer to the organization's appendix (accredited scope).The accredited scope in Chinese remains the definitive version.

CLOSE WINDOW

MASCARILLA FILTRANTE FFP2 NR - TAMAÑO ADULTO

VERIFICACIÓN

CÁMARA DE COMERCIO CHINA PARA IMPORTACIÓN Y EXPORTACIÓN DE MEDICINA Y PRODUCTOS DE SALUD

Lista de nombres de empresas de dispositivos y suministros médicos con certificación / autorización de otros países

LINK DE VERIFICACIÓN

	Yantai Zhonglian Industry Co., Ltd		
505	天津诺泽医疗科技有限公司 Tianjin Nuoze Medical Technology Co.,Ltd	91120112MA06Y54Y58	CE
506	天津市新中医疗器械有限公司 Tianjin Xinzhong Medical Devices Co., Ltd	911201107833192446	CE
507	浙江衢州荣博医疗器材有限公司 Zhejiang Quzhou Rongbo Medical Instrument Co.,Ltd.	913308007625355461	CE
508	重庆康佳森医疗电子科技有限公司 Chongqing Kangjiasen Medical Electronic Technology Co., Ltd.	91500223MA5URYYN50X	CE
509	重庆杏林医疗用品有限责任公司 Chongqing Xinglin Medical Supplies Co., Ltd	91500106MA60QNY173	CE
510	安徽精诚无纺布科技有限公司	91340102674218153G	CE

China academy of safety science and technology (CASST) is accredited for compliance with ISO/IEC 17025.
The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.
CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

EN 149:2001+A1:2009
Filtering half masks to protect against particles

Report no:	**WLH0336-2020**
Product:	**Particle Filtering Half Mask**
Model (s):	**RB-008**
Main components:	**Mask body, without exhalation valve**
Date(s) of tests:	**4th Apr～8th May 2020**

Client

Zhejiang Quzhou Rongbo Medical Instrument. Co., Ltd.

Client order：/
Order(s) received: Apr, 2020

Manufacturer

Zhejiang Quzhou Rongbo Medical Instrument. Co., Ltd.

No.680 Century Road, Quzhou City, Zhejiang Province, China

Contact: Hongyi Lee
E-mail 278518794@qq.com
Phone: 13205890555

Conditions:

This report shall not be reproduced except in full, without the written approval of CASST.

The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the CASST.

Any objection should be submitted within 2 weeks from the date of receipt of the report, and it will not be accepted after the deadline.

Specimens will be disposed of 4 weeks from the date of this report, unless otherwise instructed.

Signed: 张明明/Zhang Mingming, Authorized Signatory

Issued: 2020-05-09

中国安全生产科学研究院/China Academy of Safety Science and Technology
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E-mail: ldfh@chinasafety.ac.cn
Sino-Japanese Cooperative Respiratory Protection Laboratory
Designated Testing Laboratory of the Certification of LA Mark in China

Summary of assessment*

Clause		Assessment
	Model:	**RB-008**
7.4	Packaging	NRq
7.5	Material	Pass
7.6	Cleaning and disinfecting	NAp
7.7	Practical performance	Pass
7.8	Finish of parts	Pass
7.9.1	Total inward leakage	Pass
7.9.2	Penetration of filter material: Sodium chloride	Pass
7.9.2	Penetration of filter material: Paraffin oil	Pass
7.10	Compatibility with skin	Pass
7.11	Flammability	Pass
7.12	Carbon dioxide content of the inhalation air	Pass
7.13	Head harness	Pass
7.14	Field of vision	Pass
7.15	Exhalation valve(s)	NAp
7.16	Breathing resistance	Pass
7.17	Clogging	NRq
7.18	Demountable parts	NAp
9	Marking	NRq
10	Information to be supplied by the manufacturer	NRq

Key

	Shading shows the clauses requested.
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "Result details" section for more information.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

* Assessment relates only to those specimens which were tested and are the subject of this report.

Product characteristics

Property	Characteristic
Model	RB-008
Classification claimed	FFP2 NR
Exhalation valve(s)	-

Submission details

Product	Quantity	Date received	Specimen No.
RB-008 Particle Filtering Half Mask	100	4th April 2020	WLH0336-2020-01 to -100

Photographs of the products tested

Zhejiang Quzhou Rongbo Medical Instrument. Co., Ltd.'s model RB-008 Particle Filtering Half Mask

CASST specimen number WLH0336-2020-09

Procedures

Specimens were selected at random from the submission(s) detailed above.

Testing was performed in accordance with EN 149:2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received.

Result details

7.4 Packaging — NRq

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

7.5 Material — Pass[1]

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note 1: In accordance with the requirement.
Specimens -84,-67,-92 were conditioned in accordance with 8.3.1，None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -96,-97,-98 were conditioned in accordance with 8.3.2，None of the specimens conditioned suffered collapse.

7.6 Cleaning and disinfecting — NAp[2]

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

Note 2: Single shift use only.

7.7 Practical performance — Pass[3]

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note 3: No imperfections.

Specimen and subject details:

Specimen	Subject
-69	SM
-74	ZMM

7.8 Finish of parts — Pass[4]

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note 4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 Total inward leakage (%) **Pass**[5]

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25 % for FFP1, **11 % for FFP2**, 5 % for FFP3;

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22 % for FFP1, **8 % for FFP2**, 2 % for FFP3.

Note 5: All 50 individual exercise results were not greater than 7.3%; All 10 individual wearer arithmetic means were not greater than 5.1%. Detailed data are showed below.

Subject	Specimen	Cond	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
TS	-01	AR	3.0	10.4	6.3	8.4	4.5	6.5
ZMM	-02	AR	6.6	3.6	9.3	4.0	2.3	5.2
YZF	-03	AR	4.7	6.4	5.9	7.8	4.2	5.8
LZM	-04	AR	2.7	7.9	5.9	6.5	4.2	5.5
TJ	-05	AR	3.4	9.0	7.5	5.2	4.1	5.9
WCS	-31	TC	2.2	5.2	6.4	4.4	2.8	4.2
CJW	-32	TC	2.4	5.6	6.9	7.3	3.0	5.1
YB	-33	TC	2.4	10.1	7.0	4.2	3.8	5.5
SM	-34	TC	2.0	8.7	6.0	3.2	4.5	4.9
NXL	-35	TC	1.8	5.6	8.0	4.1	2.9	4.5
Maximum permitted			11					8

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
ZMM	114	157	119	50
WCS	109	136	105	56
YZF	113	151	106	48
TS	97	146	102	51
TJ	105	151	110	52
SM	116	144	109	49
CJW	114	147	101	65
YB	112	150	119	66
NXL	113	147	108	53
LZM	118	157	124	44

7.9.2 Penetration of filter material **Pass**

The penetration of the filter of the particle filtering half mask shall meet the requirements:

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min, %, Max	Paraffin oil test 95 l/min, %, Max
FFP1	20	20
FFP2	**6**	**6**
FFP3	1	1

Sodium chloride test results:（Pass）

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-06	A.R.	0.87	
-07		1.23	
-08		0.77	
-57	S.W.	1.37	
-58		0.92	
-59		0.55	
-36	M.S. + T.C.	0.98	1.34
-37		1.08	1.16
-38		1.13	1.42
Maximum permitted		6	

Paraffin oil test results: （Pass）

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-09	A.R.	0.99	
-10		1.37	
-11		1.64	
-60	S.W.	1.83	
-61		1.69	
-62		2.01	
-39	M.S. + T.C.	1.34	2.67
-40		1.56	3.01
-41		1.84	2.98
Maximum permitted		6	

7.10 Compatibility with skin **Pass**[6]

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note 6: Specimens from -12 to -16 (A.R.) and from -42 to -46 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 Flammability **Pass**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than **5 s** after removal from the flame.

Specimen	Condition	Results
-17	A.R.	burn for 0.8 s
-18		burn for 0.7 s
-47	T.C.	burn for 0.7 s
-48		burn for 0.5 s

7.12 Carbon dioxide content of the inhalation air **Pass**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Specimen	CO_2 (%)
-19	0.43
-20	0.38
-21	0.41
Maximum permitted	1.0

7.13 Head harness **Pass**[7]

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note 7: Specimens from -22 to -26 (A.R.) and from -49 to -53 (T.C.) were tested. Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

7.14 Field of vision **Pass**[8]

The field of vision is acceptable if determined so in practical performance tests.

Note 8: Specimens from -27 and -28 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 Exhalation valve **NAp**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

7.16 Breathing resistance **Pass**[9]

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min×2.0 l/stroke)
FFP1	0.6	2.1	3.0
FFP2	**0.7**	**2.4**	**3.0**
FFP3	1.0	3.0	3.0

Note 9: FFP2 Filtering face mask. Test results are detailed below.

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)				
		At 30 l/min	At 95 l/min	Breathing machine (25 cycles/min×2.0 l/stroke)				
				A	B	C	D	E
-28	A.R.	0.30	1.17	2.73	2.69	2.68	2.64	2.71
-29		0.32	1.21	2.69	2.65	2.69	2.61	2.72
-30		0.31	1.19	2.64	2.58	2.61	2.62	2.59
-54	T.C.	0.31	1.20	2.58	2.56	2.56	2.52	2.57
-55		0.32	1.22	2.44	2.52	2.51	2.48	2.44
-56		0.31	1.20	2.51	2.46	2.53	2.44	2.52
-63	S.W.	0.30	1.16	2.64	2.58	2.62	2.55	2.61
-64		0.32	1.24	2.69	2.68	2.64	2.61	2.64
-65		0.32	1.25	2.68	2.71	2.64	2.66	2.69
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		0.7	2.4	3.0				

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side.

7.17 Clogging NRq[10]

7.17.2 Breathing resistance

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed,

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar, at 95 l/min continuous flow;

The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Valveless particle filtering half masks:

After clogging the inhalation and exhalation resistances shall not exceed,

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar, at 95 l/min continuous flow.

7.17.3 Penetration of filter material

All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.

Note 10: Single shift use only.

7.18 Demountable parts **NAp**[11]

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note 11: No demountable parts were used.

9 Marking NRq

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:

"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or

"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:

"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or

"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space (see 9.2.4).

Examples FFP3 NR D, FFP2 R D"

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified

10 Information to be supplied by the manufacturer NRq

10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.

10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on:

application/limitations; the meaning of any colour coding; checks prior to use; donning, fitting; use; maintenance (e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.

10.5 Warning shall be given against problems likely to be encountered, for example:

- fit of particle filtering half mask (check prior to use);
- it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
- air quality (contaminants, oxygen deficiency);
- use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift."

End of Test Report.

Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200511-364-FPC-B

Certificate holder:	**Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd.** No.680 Century Road, Quzhou City, Zhejiang Province, China
Manufacturing location:	No.680 Century Road, Quzhou City, Zhejiang Province, China
The scope of the certification for:	**The manufacture of respiratory protective device** See annex for articles covered by this certificate
Validity from:	2020-06-09
Revision date:	2020-09-07
To:	2021-06-08

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation.
The equipment covered by this certificate is listed in the accompanying schedule. This certificate is not complete and has no validity without the accompanying schedule and revision index.
The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE mentioned in the schedule which accompanies this certificate whilst this certificate remains valid.
This certificate and the accompanying schedule remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CE

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

ISO 17065 IVNAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian, Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Schedule of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

Schedule to CCQS FPC Certificate No.: CE-PC-200511-364-FPC-B

Product reference and description		Reference standard
Particle filtering half mask	Model: RB-008	EN 149:2001+A1:2009

Certificate Revision	Revision date	Revision details
A	2020-06-09	Initial issue
B	2020-09-07	Certificate validity extended to one year

This schedule has no validity without the accompanying certificate.
This schedule and the accompanying certificate remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CE

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200511-364-01-9B

Certificate holder:	**Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd.** No.680 Century Road, Quzhou City, Zhejiang Province, China
Product:	**Particle filtering half mask** Detailed product description listed in the Annex
Model(s):	RB-008
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-06-09
Revision date:	2020-09-07
Expiry date:	2021-06-08

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE

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

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

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Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200511-364-01-9B

Applicable standards and specification:
EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Model reference	Product description
RB-008	Folding filtering half mask fitted with ear loops with head harness clip, no valves, internal metal nose clip Mask body color: White Classification: FFP2 NR Test report No.: WLH0336-2020

Certificate Revision	Revision date	Revision details
A	2020-06-09	Initial issue
B	2020-09-07	Certificate validity extended to one year

CCQS Ireland Certification

CE

CCQS Certification Services Limited
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中国认可
国际互认
检测
TESTING
CNAS L5772

Test Report

EN 149:2001+A1:2009 protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

Product:	Particle Filtering half mask
Report No.:	PTC20122101501C-EN01V01
Client:	YIWU COOLS ACCESSORIES CO., LTD
Client Address:	NO.317 Huaxian Road, Niansanli street,Yiwu, Zhejiang, China
Manufacturer:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO., LTD
Manufacturer Address:	No.680 Century Road, Quzhou City, Zhejiang Province, China
Contact:	Apple
Model(s):	RB-008
Classification:	FFP2 NR
Date of Tests:	2020.12.23~2020.12.29

Signed for and on Behalf of PTC

Prepare by: Checked by: Approved by:

PRECISE TESTING & CERTIFICATION (GUANGDONG) CO., LTD.

Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38808222 Fax: 86-769-38826111 http:// www.ptc-testing.com

Test Report

Summary of assessment

Clause	Assessment
7.3 Visual inspection	NOT TESTED
7.4 Packaging	PASS
7.5 Material	PASS
7.6 Cleaning and disinfecting	N/A
7.7 Practical performance	PASS
7.8 Finish of parts	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.10 Compatibility with skin	PASS
7.11 Flammability	PASS
7.12 Carbon dioxide content of the inhalation air	PASS
7.13 Head harness	PASS
7.14 Field of vision	PASS
7.15 Exhalation valve	N/A
7.16 Breathing resistance	PASS
7.17 Clogging	N/A
7.18 Demountable parts	PASS
9 Marking	NOT TESTED

Remark:

PASS: comply with requirement of standard
N/A: not application
NOT TESTED: the clause were not required

Test Result:

Requirement	Test Result	Conclusion
7.3 Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Not tested	**Not tested**
7.4 Packaging Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	In accordance with the requirement.	**Pass**
7.5 Material Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	No mechanical failure after undergoing the conditioning described in 8.3.1, No collapse when conditioned in accordance with 8.3.1 and 8.3.2.	**Pass**
7.6 Cleaning and disinfecting If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	Single shift use only	**N/A**
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions	No imperfections	**Pass**
7.8 Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs.	**Pass**

7.9.1 Total inward leakage

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1, 11 % for FFP2, 5 % for FFP3

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1, 8 % for FFP2, 2 % for FFP3.

FFP2, Test results are shown in Annex A Table 7.9.1-A&B

Pass

7.9.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

FFP2 , Test results are shown in Annex A Table 7.9.2.

Pass

7.10 Compatibility with skin

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

No irritation or any other adverse effect to health.

Pass

7.11 Flammability

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Test results are shown in Annex A Table 7.11.

Pass

7.12 Carbon dioxide content of the inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Test results are shown in Annex A Table 7.12.

Pass

7.13 Head harness

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be

Head harness can be donned and removed easily, adjustable or self-adjusting and

Pass

sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	have sufficiently robust to hold the particle filtering half mask firmly.	
7.14 Field of vision The field of vision is acceptable if determined so in practical performance tests.	Pass the practical performance tests.	**Pass**
7.15 Exhalation valve A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9. Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	No exhalation valve	**N/A**

7.16 Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

FFP2. Test results are shown in Annex A Table 7.16. **Pass**

7.17 Clogging

7.17.2 Breathing resistance

Valved particle filtering half masks:
After clogging the inhalation resistances shall not exceed:
FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow
The exhalation resistance shall not exceed 3 mbar at 160 L/min

Single shift use only. **N/A**

continuous flow

Valveless particle filtering half masks
After clogging the inhalation and exhalation resistances shall not exceed:
FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

7.18 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand — Comply — **Pass**

9 Marking

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.
9.1.2 Type-identifying marking.
9.1.3 Classification
The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable.
Example: FFP2 R D. — Not tested — **Not tested**
9.1.4 The number and year of publication of this European Standard.
9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.
9.1.6 The sentence ‘see information supplied by the manufacturer’, at least in the official language(s) of the country of destination, or by using

the pictogram as shown in Figure 12b.
9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.
9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask
Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:
9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.
9.2.2 Type-identifying marking.
9.2.3 The number and year of publication of this European Standard.
9.2.4 Classification
The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.
9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space.
9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

Annex A: Summarization of Test Data

Table 7.9.1-A: Inward Leakage Test Data

Test specification：EN 149:2001+A1:2009 Clause 8.5

Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Lv	1	A.R	3.5	3.4	3.0	3.1	3.0	3.2
Li	2	A.R	4.3	4.2	4.2	4.0	4.4	4.2
Zhong	3	A.R	5.9	6.4	6.2	6.5	6.5	6.3
Xu	4	A.R	4.9	4.7	4.5	5.0	5.1	4.8
Ma	5	A.R	5.4	4.1	3.5	4.2	4.3	4.3
Chen	6	T.C	3.5	4.2	3.6	4.0	4.3	3.9
Chen	7	T.C	5.3	5.6	4.9	5.2	4.2	5.0
Zhuo	8	T.C	3.7	3.8	3.6	3.9	4.0	3.8
Chen	9	T.C	3.7	3.8	3.7	4.1	3.1	3.7
Zhang	10	T.C	4.0	4.7	4.4	4.2	3.7	4.2

Table 7.9.1-B: Facial dimension

Subject	Face Length	Face Width	Face Depth	Mouth Width
Lv	113	139	104	53
Li	120	135	112	55
Zhong	108	135	106	56
Xu	120	150	120	70
Ma	130	170	130	80
Chen	110	160	90	40
Chen	115	145	110	50
Zhuo	103	146	100	50
Chen	110	145	95	40
Zhang	144	141	101	54

Table 7.9.2: Penetration of filter material

Test specification：EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.2	Pass
		12	0.2	
		13	0.2	
	Simulated wearing treatment	14	0.2	
		15	0.2	
		16	0.2	
	Mechanical strength + Temperature conditioned	17	0.2	
		18	0.2	
		19	0.2	
Paraffin oil test	As received	20	1.0	
		21	0.6	
		22	0.8	
	Simulated wearing treatment	23	0.7	
		24	0.8	
		25	0.5	
	Mechanical strength + Temperature conditioned	26	1.0	
		27	0.9	
		28	0.7	

Table 7.11: Flammability

Test specification：EN 149:2001+A1:2009 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	No burn	Pass
	30	No burn	
Temperature conditioned	31	No burn	
	32	No burn	

Table 7.12: Carbon dioxide content of the inhalation air

Test specification：EN 149:2001+A1:2009 Clause 8.7

Condition	Sample No.	Result (%)		Assessment
As received	33	0.02	Mean value: 0.02	Pass
	34	0.02		
	35	0.02		

Table 7.16: Breathing resistance (mbar)

Test specification：EN 149:2001+A1:2009 Clause 8.9

As received	**Flow Rate**		**36**					**37**					**38**				
	Inhalation	**30 l/min**	0.16					0.14					0.14				
		95 l/min	0.73					0.73					0.73				
	Exhalation	**160 l/min**	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			1.42	1.42	1.39	1.36	1.37	1.35	1.43	1.38	1.44	1.37	1.40	1.35	1.37	1.31	1.35
Simulated wearing treatment	**Flow Rate**		**39**					**40**					**41**				
	Inhalation	**30 l/min**	0.20					0.20					0.21				
		95 l/min	0.82					0.77					0.79				
	Exhalation	**160 l/min**	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			1.44	1.40	1.42	1.48	1.44	1.41	1.41	1.36	1.44	1.42	1.38	1.36	1.37	1.35	1.37
Temperature conditioned	**Flow Rate**		**42**					**43**					**44**				
	Inhalation	**30 l/min**	0.19					0.17					0.17				
		95 l/min	0.75					0.74					0.73				
	Exhalation	**160 l/min**	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			1.35	1.34	1.36	1.34	1.34	1.31	1.32	1.31	1.31	1.33	1.32	1.31	1.32	1.32	1.32
Assessment	Pass																

A: Facing directly ahead B: Facing vertically upwards C: Facing vertically downwards

D: Lying on the left side E: Lying on the right side

Test	Uncertainty
Total inward leakage	3.8%
Penetration of filter material(NaCl)	3.5%
Penetration of filter material(Paraffin oil)	4.2%
Carbon dioxide content of the inhalation air	4.5%
Breathing resistance(30L/min)	5.2%
Breathing resistance(95L/min)	5.4%
Breathing resistance(160)L/min)	6.0%

Remark: This report supersedes all previous documents bearing the test report number PTC20122101501C-EN01. Report number PTC20122101501C-EN01 was invalid.

Amendments to report

Version	Date of issue	Changes
PTC20122101501C-EN01V01	2021.01.04	Photo(s) of Sample

Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38808222 Fax: 86-769-38826111 http:// www.ptc-testing.com

Test Report

Photo(s) of Sample:

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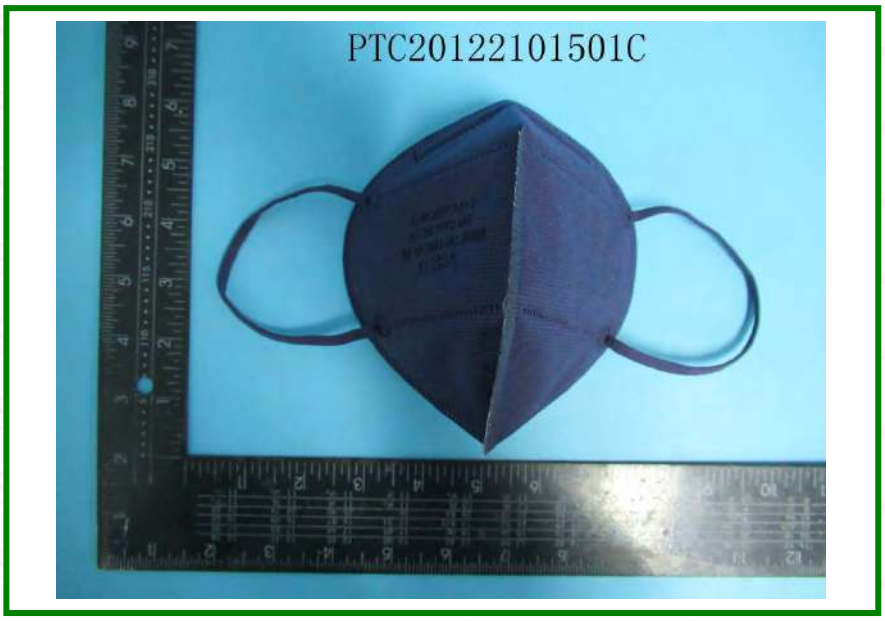

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End of Report

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Supplier Creditability & Capacity Audit Report

Report:			
Supplier Name	Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd. 浙江衢州荣博医疗器材有限公司		
Supplier Address	No. 680, Century Road, Quzhou Economic Development Zone, Zhejiang, China		
Client Information	/		
Name of Assessor	Seven Song	Reviewed by	Roger Wang
Audited Date	2020/07/18	Expiry Date	2021/07/17

Assessment Scope:

Section 1: Company Profile
Section 2: Certificate
Section 3: Child Labor Review
Section 4: Sampling
Section 5: Attachment

Comments

Zhejiang quzhou rongbo medical instrument Co., LTD. was established in 1997. It is a professional company registered in the state food and drug administration for the production of sterile medical devices. The company registered capital of 5.28 million yuan, the company mainly production and sales of various specifications of disposable sterile syringes, disposable infusion with needle, one-time blood blood with needles, disposable vacuum blood vessels, one-time use of sterile needles, disposable surgical masks and other products. The company has a wide distribution network of products all over the country, and extends abroad to the Middle East, Pakistan, Syria, Argentina, Singapore and other countries and regions.

Important Notes:

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Section 1: Company Profile

1.1 Basic Information			
Name of Supplier	Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd. 浙江衢州荣博医疗器材有限公司		
Address in License	No. 680, Century Road, Quzhou Economic Development Zone, Zhejiang, China		
Audited Address	No. 680, Century Road, Quzhou Erconomic Development Zone, Zhejiang, China		
Main Product	Sterile Syringe For single use without needle, Disposable Surgical Mask, Disposable Mask		
Industry experience	Disposable Surgical Mask, Disposable Mask : 2020.03 -- Up to now		
License Number	913308007626355461	Corporate Representative	Mr. Xiukui Shen
Registration Date	03. Jun. 2004	Expiry Date	02. Jun. 2034
Registered Capital	RMB 5,280,000	Paid-in Capital	RMB 27,280,000
Area of Office	2,000 square meters	Area of Workshop	7,000 square meters
1.2 Contact Way			
Company Representative	Mr. Xun Wang / General Manager		
Tel. number	86-570-8766298		
E-mail	823006152@qq.com	URL	www.qzrongbo.com
1.3 Nature of Enterprise			
Type of Ownership	[X] Privately Owner [ ] Public Company [ ] Joint Venture [ ] Stated Owned [ ] Others		
Type of Company	[ ] Manufacturer [ ] Foreign trader [X] Both		
Subsidiary Factory	N/A		
Relationship with Subsidiary Factory	[X] No subsidiary factory [ ] Shareholder [ ] Wholly owned [ ] Belong to one group		
Overview			

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Section 2: Certificate

2.1 Management System Certificate				
Certificate	Number	Expiry date	Certifying Body	Scope
ISO13485:2016	Q6 003771 0001 Rev.00	13 Nov. 2018 -- 12.Nov. 2021	TUV SUD	Production and distribution of sterile syringe for single use with/without needle, sterile infusion set for single use with/without needles, sterile precision filter infusion set for single use with/without needle

2.2 Product Certificate				
Certificate	Number	Issued date	Certifying Body	Product and model / type
CE Certificate	G2S 003771 0002 Rev.00	13 Nov., 2018	TUV SUD	Sterile Syringe For single use without needle, Sterile Infusion set for single use without needle, Sterile precision filter infusion set For single use without needle
CE Certificate	CE-PC-20051 1-364-FPC-A	09. Jun. 2020	CCQC Ireland	Particle Filtering Half Mask
CE Certificate	CE-PC-20051 1-364-01-9A	09. Jun. 2020	CCQC Ireland	Particle Filtering Half Mask

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Section 3: Child Labor Review

No.	Audit requirements		Remark
3.11	童工/招聘(招聘文件,员工档案,身份证) Child labor / recruitment (recruitment document, employee file, ID card)	现有雇员是否存在童工 Is there child labor in company?	不存在 No
		是否制定了招聘政策，招聘政策明确要求检查员工年龄，不招聘 16 岁以下员工 Whether there is a recruitment policy, which clearly requires checking the age of employees and not recruiting employees under the age of 16	公司制定了员工手册，明确用工要求，不招聘 16 岁以下员工 The company has developed an employee handbook that specifies employment requirements，and not recruiting employees under the age of 16
3.12	健康与安全(检查记录及现场查看) Health and safety (inspection record and on-site inspection)	新员工入厂是否经过公司级 部门级 岗位级的安全培训并有培训记录？ Have new employees received safety training at company level, department level and post level and have training records?	新员工入厂有三级安全培训，现场查看了培训记录 There is a three-level safety training for new employees, and the training records are checked on site
		特殊工种是否经过培训并取得操作证？ Are special workers trained and certified?	无特殊工种 N/A
		是否定期对员工进行安全培训和消防培训？ Are safety training and fire training provided to employees regularly?	公司每半年进行一次安全和消防培训 The company conducts safety and fire protection training every six months
		是否为员工配备了必要的劳动防护用品 Are necessary labor protection articles provided for employees	工厂为员工提供了必要的劳动防护用品，比如口罩，工作服，防护帽，耳塞等 The factory provides employees with necessary labor protection equipment, such as masks, work clothes, protective caps, earplugs and so on
		车间办公场所是否配备了灭火器材定期点检，车间是否有安全通道和标识？ Whether the workshop and office are equipped with fire-fighting equipment and regular spot inspection, and whether the workshop has safe access and signs?	车间办公场所配备了灭火器材定期点检，车间有安全通道和标识 the workshop and office are equipped with fire-fighting equipment and regular spot inspection, and the workshop has safe access and signs
3.13	工作时间（工资发放记录及打卡记录） Working hours	每周是否有一天休息 Is there a day off every week	每周有一天休息 there is a day off every week
		加班是否有加班工资 Is there overtime pay for overtime work	加班有加班工资 overtime pay for overtime work
3.14	认证 certification	公司是否通过了社会责任相关的审核或体系认证？ Has the company passed the social responsibility related audit or system certification?	公司未通过社会责任相关的审核 The company has not passed the social responsibility related audit

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Section 4: Sampling

款号 Item No.	订单号 PO No.	货品名称 Good Description	订单数量 Order Quantity	现场实际数量 presented Qty for Sampling	抽样数量 Sampling	快递单号 Tracking No.
SUM002	MAS0003	MEDICAL MASK，EN 14683, Type I	85100	0	1box (50pcs in 1 box) (type II)	SF1192473159748

Remark: There is no product of Type I on site, and there is only one box of type II products on site.

款号 Item No.	订单号 PO No.	货品名称 Good Description	订单数量 Order Quantity	现场实际数量 presented Qty for Sampling	抽样数量 Sampling	快递单号 Tracking No.
SUM003	MAS0003	SURGICAL MASK EN 14683, Type IIR	100000pcs	2120000 pcs	2boxes (50pcs in 1 box)	SF1192473159748

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Section 5: Attachment

5.1 Photos of Document and Certificate

Business License	Account opening permit
	
Certificate for exportation of Medical Products	**Land Certificate**
	

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ISO13485 Certificate	CE Certificate
	
CE Certificate	**CE Certificate**
	

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5.2 Photos of Company and Product Sample	
Company Gate	**Office Building**
	
Workshop	**Workshop**
	
Workshop	**Workshop**
	

SGS-CSTC Standards Technical Services Co., Ltd.
Consumer Testing Services
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Warehouse	Warehouse
	
Product Sample	**Product Sample**
	
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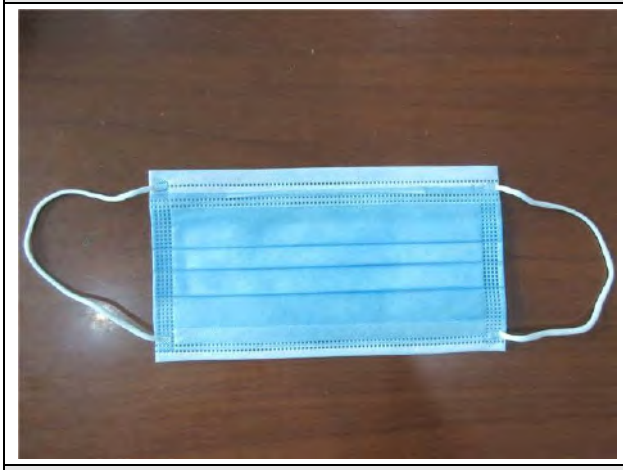
Product Sample	Product Sample
	
Product Sample	**Product Sample**
	
Product Sample	**Product Sample**
	

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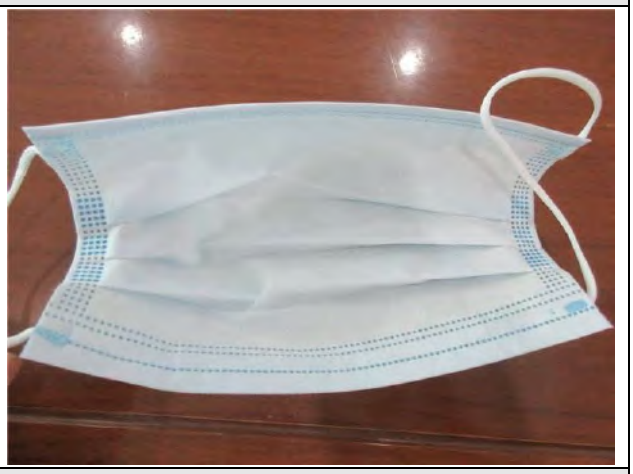
Product Sample	Product Sample
	
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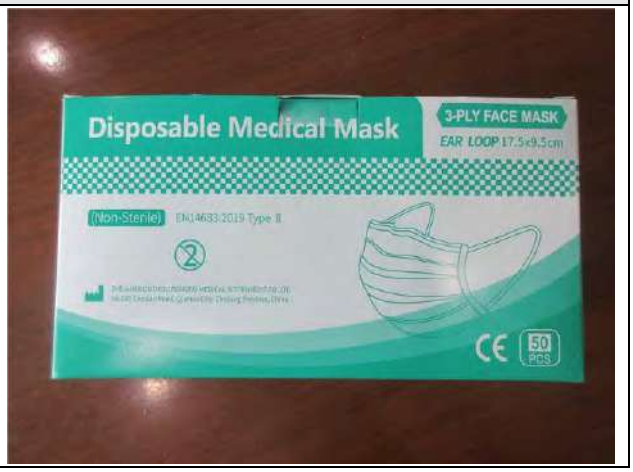
Product Sample	**Product Sample**
	

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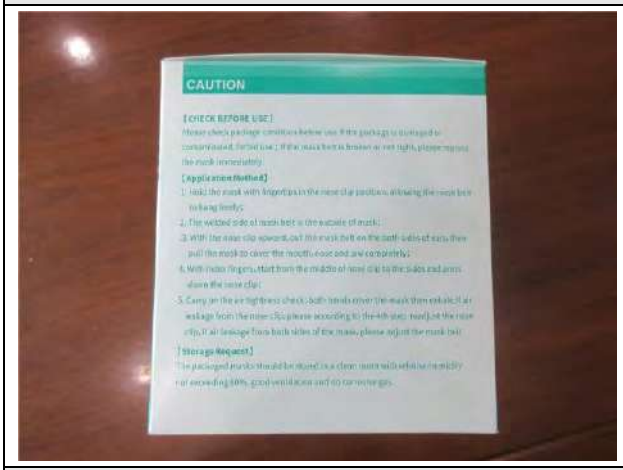
Product Sample	Product Sample
	
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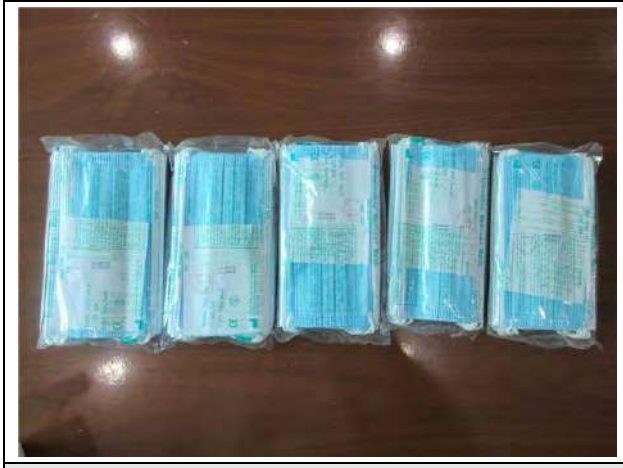	
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	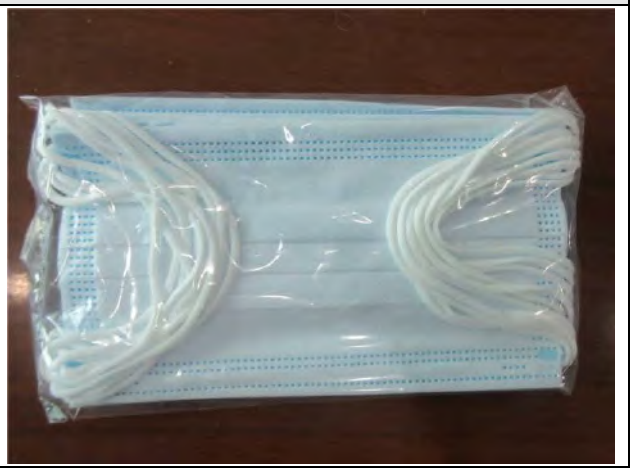

-- End of the Report --

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