PROMASK

Mascarillas FFP2 NR – Talla M

Mascarilla filtrante FFP2 no reutilizable (NR).
Sin válvula. NO-MEDICA.
Filtración mayor al 95% de las partículas.

Documentación técnica

- Ficha técnica
- Certificado CE
- Declaración de conformidad
- Informe técnico
- Test report
- Test tintes colores
- Test libres de grafeno
- Responsabilidad Social Corporativa del fabricante

Mascarilla FFP2 NR - Talla M

Indicadas para niños/as o personas de entre 1,2 y 1,6 m de altura.

Mascarilla filtrante FFP2 no reutilizable (NR). Sin válvula. NO-MEDICA. Filtración mayor al 95% de las partículas.

ESPECIFICACIONES:

- Eficiencia de filtrado: BFE > 95%.
- No estéril.
- No reutilizable (NR).
- Vida útil: 2 años.
- Talla M: niños o personas entre 1,2 o 1,6 m
- Tamaño mascarilla abierta: 186 x 135 mm
- Gomas suaves y elásticas para un ajuste confortable en ambos pabellones auditivos.
- Incorpora banda metálica para ajuste nasal.

5 capas de protección

Transpirable

COLORES Y ESTAMPADOS:

- Blanco
- Azul claro
- Azul oscuro
- Morado
- Fresas
- Rosa
- Negro
- Militar

COMPOSICIÓN:

Estructura	Material	Peso
Capa exterior	100% Polipropileno	100 gr/m^2
3 capas filtrantes	Tejido "Melt Blown"	30 gr/m^2
Capa interior	100% Polipropileno	40 gr/m^2

PACKAGING:

- 1 mascarilla por bolsa individual termosellada.
- Cajas: 50 unidades.
- Cajas máster: 1000 unidades
  Dimensiones caja máster: 80x40x30 cm
  Peso bruto caja máster: 8 kg.

NORMAS Y CERTIFICACIONES:

Este dispositivo es equipo de protección individual según el Reglamento UE / 2016/425.
Evaluación y certificación de los tintes de colores en SGS.

Certificado Europeo CE
Nº de informe: CE-2163-PPE-704
UNE EN-149:2001 + A1:2009

Mascarillas certificadas en Universal, centro autorizado localizado en Turquía. Número de organismo notificado: 2163.

Universal Certification and Surveillance Service Trade Ltd. Co.
Dirección: Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No: 44/84
Yukarı Dudullu, Ümraniye-Istanbul, Turquía
Teléfono: +90 216 455 80 80
Email: info@universalcert.com
Página web: www.universalcert.com

FOTOGRAFÍAS DEL PRODUCTO:

Vista lateral de la mascarilla

Bolsa individual

Caja de 50 unidades

INSTRUCCIONES DE USO:

1. Lavarse las manos durante 40-60 segundos antes de manipularla.
2. Tocar solo las gomas de la mascarilla.
3. Colocar la mascarilla sobre la nariz y boca.
4. Pasar las gomas elásticas por detrás de las orejas.
5. Pellizcar la banda metálica para ajustarla a la nariz.
6. Evitar tocar la parte exterior de la mascarilla. Si ocurre, lavar las manos antes y después.
7. Lavar las manos antes de retirarse la mascarilla.
8. Retirarla tocando solo las gomas elásticas.
9. Para desecharla, introducirla en una bolsa de plástico. Depositarla cerrada en la basura y lavar las manos.

Condiciones de almacenaje: Almacenar en un ambiente seco y fresco, alejado de la luz directa del sol y fuentes de calor.

Mascarilla FFP2 NR – Talla M

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-704

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

CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO. LTD.
No: 88 Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu 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 (Dated 01.10.2020) 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: ChangAnDa **Model:** *CAD-01* **Sizes:** *Standard - Medium*
Filtering half mask
Classification: FFP2 NR
Model have white, light blue, black, grey, purple, green, orange, rose, deep blue and yellow versions

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **03/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

This certificate is re-issued on 12.10.2020 (Rev2) with updated model name and coloured versions and size definitions of the model. The former model name was KN95. TIL test is only applied for standard size, for details refer to the technical evaluation report provided to the manufacturer.

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
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Mascarilla FFP2 NR – Talla M

EU DECLARATION OF CONFORMITY

We, Manufacturer:Changzhou Ruida Medical Technology Co. Ltd

Address:NO.88 Mahang Middle Road,Hutang Town,Wujin District,Changzhou City,Jiangsu Province,China

Declare on our own responsibility,that the:

Product Definition Brand Name : ChangAnDa

Model : CAD-01 Filtering half mask Classification : FFP2 NR

Model have color : white,light blue ,black ,grey,purple,green,orange,rose, Deep blue and yellow . SIZE; small size

Are in compliance with following Regulation/directive:

R 2016/425 Personal Protective Equipment

and are in compliance with following hamonized standard:

FFP2	EN149:2001+A1:2009

Identical products were certified by Notified Body for PPE Module B+C2

Notified Body No:2163

Necip Fazl Bulvan Keyap Sites E2 Blok No : 44 / 84 Yukan Dudullu Umraniye - ISTANBUL-TURKEY

Chang Zhou 2020.10.3

place.date Signature.Function

Changzhou Ruida Medical Technology Co. Ltd

NO.88 Mahang Middle Road,Hutang Town,Wujin District,Changzhou City,Jiangsu Province,China

Mascarilla FFP2 NR – Talla M

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 12.10.2020 / 2163-KKD-704 / R2

Initial Report Date and Number: 03.06.2020 / 2163-KKD-704

This technical evaluation report is updated with the model name update decision and also use of the same fabric as defined in the initial technical with colored versions in the outher most layer of the mask and earloops. The manufacturer also designed a smaller size (M) and named the initial design as standard size. The purpose of the change is to produce respectively smaller sized masks to better fit for those who have smaller face / chin whn compared to general sizes of adults. One more purpose can be considered as to provide better fitting masks for younger people. There is no other design or material change in the colored or M sie versions of the model. The Total Inward Lekage test is not conducted because of unavailability of subjects for the test. The smaller size (M) is tested for particle filtration efficiency and breathing resistance. See relevant test reports.

Manufacturer: CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO. LTD.

Address: No: 88 Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province, China

This report is for the, given above manufacturer, prepared according to the test results conducted by UNIVERSAL CERTIFICATION, dated 26.05.2020 with Serial No 05-2020-T-095 and dated 08.10.2020 with Serial No 10-2020-T-0415 based on EN 149: 2001 + A1: 2009 standard *and test reports on the material safety by means of toxic, carcinogen, irritationg and sensitivity evaluation.*

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

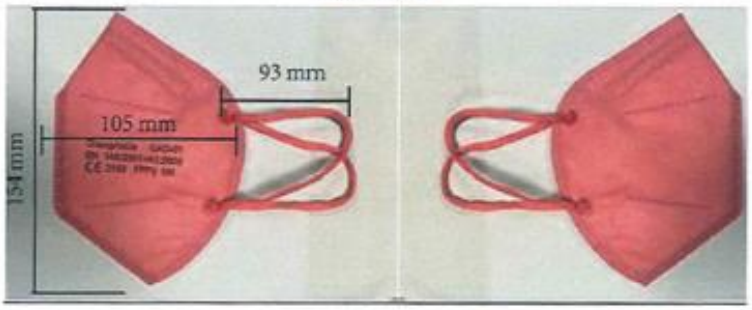
This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask

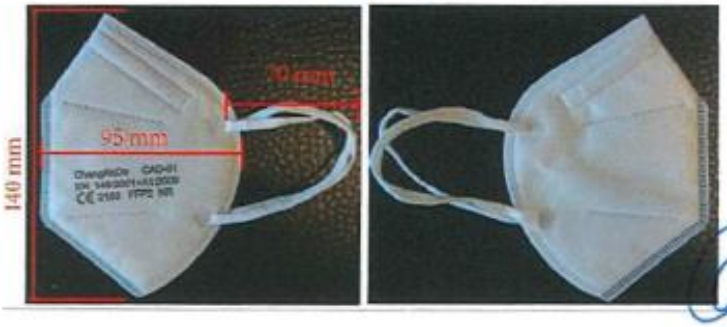
Classification: FFP2 NR

Brand Name: ChangAnDa **Model:** CAD-01 (*Former model name was KN95*), **Sizes:** Standard - Medium

Standard Size



Medium Size



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THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE EU 2016/425 REQUIREMENTS

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 prossible 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 that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

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 condition of all PPE parts in contact with the user

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

1.2.1.3. Maximum permessible user impediment

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3 Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

1.4. Information supplied by the manufacturer

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

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

2.4. PPE subject to ageing
If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.6. PPE for use in potentially explosive atmospheres
PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.8. PPE for intervention in very dangerous situations
The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user
Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety
The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer"s notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS
3.10.2. Protection against cutaneous and ocular contact
PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.
To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.
Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

UNIVERSAL CERTIFICATION CE 2163 Notified Body

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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 Requirements	
Article 5	**Classification:** Particle Filtering Half Mask Total Inward Leakage: Classification – FFP2
Article 7.4	**Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage.
Article **7.5**	**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports, It is understood withstand handling and wear over the period for which the particle filtering half mask is designed to be used suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. *The model have colored ones manufactured by use of colored spunbound fabrics in the most outer layer of the mask, with the earloops as well. Based on the test results in the test report of SGS (Report numbers CANML2014109401 (Light Blue), CANML2014108401 (Black), CANML2014108601 (Gray), CANML2014108201 (Purple), CANML2014108901 (Green), CANML2014108801 (Orange), CANML2014108301 (Rose), CANML2014108501 (Deep Blue) and CANML2014108701 (Yellow) - prepared by SGS-CSTC Standards Technical Services Co., Ltd Guangzhou Branch SDS (Safety Data Sheet) reports. Based on the results the colored materials (spunbound fabric) used in the most outer layer of the mask is considered to be safe for use on the mask. Annexed sample photos of the colored masks.* *The material properties for both sizes (Standard and Medium are same)*
Article **7.6**	**Cleaning and Disinfection:** Particle filtering half mask is **not** designed to be as re-usable.
Article 7.7	**Practical Performance :** Assessed Elements / Positive / Negative / Requirements in accordance with EN 149:2001 + A1:2009 and Result 1.The face piece fitting: 2 / 0 2.Head harness comfort: 2 / 0 3.Security of fastenings: 2 / 0 4.Speech clearness: 2 / 0 5.Field of vision: 2 / 0 6.Materials compatibility with skin: 10 / 0 Positive results are obtained from the performance tests related to the implementation under real conditions, applied with the compatibility with skin evaluation (7.10). **No imperfections** **Conditioning :** (A.R.) As Received, original
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:** *(Applied only for standard size)* Test Subject / No.of sample / Condition / 1.Walk / Head left /right / Head up /down / Speech / 2. Walk / Average 1 / 31 / A.R / 6,4 / 5 47 / 4,15 / 6,13 / 6,79 / 5,87 2 / 32 / A.R / 6,53 / 4,45 / 6,17 / 7,29 / 7,45 / 6,38 3 / 33 / A.R / 7,36 / 6,92 / 7,1 / 6,19 / 7,12 / 6,94 4 / 34 / A.R / 6,33 / 5,24 / 7,32 / 6,26 / 7,4 / 6,51 5 / 35 / A.R / 6,81 / 6,41 / 7,5 / 6,12 / 8,22 / 7,01 6 / 16 / T.C / 5,63 / 7,45 / 6,75 / 7,21 / 6,2 / 6,65 7 / 17 / T.C / 6,85 / 7,8 / 7,61 / 6,29 / 7,32 / 7,17 8 / 18 / T.C / 7,69 / 7,9 / 8,96 / 8,28 / 8,19 / 8,2 9 / 19 / T.C / 7,58 / 8,19 / 7,37 / 7,6 / 9,2 / 7,99 10 / 20 / T.C / 7,57 / 7,41 / 7,42 / 7,76 / 8,87 / 7,81 Average: 6,88 / 6,86 / 7,04 / 6,91 / 7,68 / 7,05 Min: 5,63 / 4,45 / 4,15 / 6,12 / 6,2 / 5,87 Max: 7,69 / 8,19 / 8,96 / 8,28 / 9,2 / 8,2 **Conditioning :** (A.R.) As Received, original (T.C.) Temperature conditioning Results P (%) Leakage Value It was reported that; All 50 exercise measurement results are smaller or equal to 11%, According to the results maximum measurement is 8,96 %. At least 9 of 10 individual's arithmetic mean is smaller or equal to 8%, According to the results the means for 10 subject varies between 5,87 % to 8,2 %. **According to the reported results, the product meets the limits for FFP1 and FFP2 classification.**

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Article 7.9.2

Penetration of filter material: Sodium Chloride Testing

Standard Size

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	2,65	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. **FFP1, FFP2**
(A.R.)	-	4,03		
(A.R.)	-	5,07		
(S.W.)	-	2,70		
(S.W.)	-	4,06		
(S.W.)	-	5,10		
(M.S. T.C.)	-	2,68		
(M.S. T.C.)	-	4,06		
(M.S. T.C.)	-	5,09		

95 L/min = 1,6 $dm^3.sn^{-1}$

Medium Size

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,55	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. **FFP1, FFP2**
(A.R.)	-	0,83		
(A.R.)	-	0,58		
(S.W.)	-	1,70		
(S.W.)	-	1,28		
(S.W.)	-	0,58		
(M.S. T.C.)	-	1,03		
(M.S. T.C.)	-	1,34		
(M.S. T.C.)	-	1,52		

95 L/min = 1,6 $dm^3.sn^{-1}$

Conditioning : (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Both sizes of the model complies with the FFP2 requirements

Article 7.9.2

Penetration of filter material: : Paraffin Oil Testing

Standard Size

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	3,97	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. **FFP1, FFP2**
(A.R.)	-	3,18		
(A.R.)	-	4,58		
(S.W.)	-	4,01		
(S.W.)	-	3,20		
(S.W.)	-	4,61		
(M.S. T.C.)	-	3,99		
(M.S. T.C.)	-	3,21		
(M.S. T.C.)	-	4,63		

95 L/min = 1,6 $dm^3.sn^{-1}$

Medium Size

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	1,24	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. **FFP1, FFP2**
(A.R.)	-	1,63		
(A.R.)	-	1,49		
(S.W.)	-	1,68		
(S.W.)	-	1,65		
(S.W.)	-	1,47		
(M.S. T.C.)	-	1,71		
(M.S. T.C.)	-	2,98		
(M.S. T.C.)	-	1,76		

Conditioning : (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Both sizes of the model complies with the FFP2 requirements

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.

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Article 7.11

Flammability :

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	2,40	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed** Filtering half masks fulfill requirements of the standard
(A.R.)	-	2,08		
(T.C.)	-	2,19		
(T.C.)	-	2,14		

Conditioning : (A.R.) As Received, original
(T.C.) Temperature Conditioning

Article 7.12

Carbon dioxide content of the inhalation air:

Condition	No. of Sample	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,49	0,57	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed** Filtering half masks fulfil requirements of the standard
(A.R.)	-	0,64			
(A.R.)	-	0,59			

Conditioning : (A.R.) As Received, original

Article 7.13

Head harness: In Practical Performance report, No adverse effects have been reported for holding the mask of the head harness firmly in position, for total inward leakage properties. Tested on samples 10 samples.

Article 7.14

Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision features.

Article 7.16

Breathing Resistance: Inhalation

Standard Size

Condition	Inhalation Resistance (mbar)					
	No. of Sample	Flow Rate 30 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Flow Rate 95 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	42	0,36	FFP1 ≤ 0,6 FFP2 ≤ 0,7 FFP3 ≤ 1,0	1,21	FFP1 ≤ 2,1 FFP2 ≤ 2,4 FFP3 ≤ 3,0	**Passed**
(A.R.)	43	0,38		1,25		
(A.R.)	44	0,37		1,23		
(S.W.)	7	0,38		1,23		
(S.W.)	8	0,40		1,27		
(S.W.)	9	0,39		1,26		
(T.C.)	23	0,37		1,25		
(T.C.)	24	0,38		1,28		
(T.C.)	25	0,38		1,29		

Medium Size

Condition	Inhalation Resistance (mbar)					
	No. of Sample	Flow Rate 30 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Flow Rate 95 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	42	0,58	FFP1 ≤ 0,6 FFP2 ≤ 0,7 FFP3 ≤ 1,0	1,68	FFP1 ≤ 2,1 FFP2 ≤ 2,4 FFP3 ≤ 3,0	**Passed**
(A.R.)	43	0,51		1,43		
(A.R.)	44	0,55		1,50		
(S.W.)	7	0,53		1,67		
(S.W.)	8	0,55		1,69		
(S.W.)	9	0,60		1,73		
(T.C.)	23	0,62		1,76		
(T.C.)	24	0,59		1,68		
(T.C.)	25	0,57		1,49		

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 temparature + mechanical conditioning complies with the limits given in the standard for FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

Passed.

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Article 7.16	**Breathing Resistance:** Exhalation Standard Size

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity /Nonconformity
42	As received	160 l/min	2,18	2,20	2,21	2,20	2,21	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
43			2,23	2,25	2,25	2,27	2,29		Passed
44			2,24	2,26	2,27	2,30	2,31		Passed
7	Simulated wearing treatment		2,20	2,22	2,25	2,28	2,26		Passed
8			2,25	2,30	2,32	2,33	2,30		Passed
9			2,27	2,29	2,30	2,30	2,31		Passed
23	Temperature conditioned		2,21	2,22	2,25	2,27	2,26		Passed
24			2,26	2,28	2,30	2,31	2,30		Passed
25			2,29	2,31	2,32	2,34	2,32		Passed

Medium Size

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity /Nonconformity
42	As received	160 l/min	2,25	2,03	2,06	2,11	2,14	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
43			1,83	2,16	1,98	2,12	2,15		Passed
44			1,92	2,21	1,93	2,08	2,13		Passed
7	Simulated wearing treatment		2,05	2,11	1,98	1,95	2,07		Passed
8			2,03	2,06	1,95	2,04	2,01		Passed
9			2,07	2,09	2,00	2,05	2,03		Passed
23	Temperature conditioned		2,10	2,13	2,11	2,08	2,10		Passed
24			2,06	2,15	2,09	2,13	2,08		Passed
25			2,12	2,10	2,14	2,16	2,11		Passed

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 temparature + mechanical conditioning, *of each size (standard and medium)* 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 7.17.2	**Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*
Article 7.17.3	**Penetration of filter material:** This test is not applied to Particle Filtering Half Mask which is not reusable.
Article 7.18	**Demountable Parts:** There are no demountable parts on the product.
Article 9	**Marking – Packaging:** Manufacturer expected to put necessary information (reference to standard, user instructions etc) markings as defined on the product and its packaging templates. *The tested samples as medium size did not have the correct model name CAD-01 onside, the other expectations of the standard were in conformance.*
Article 10	**Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instruction) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined in the technical file templates.

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Colored samples of the Masks

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** General Manager

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Mascarilla FFP2 NR – Talla M

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Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY

PARTIAL TEST REPORT

Report Date:08.10.2020
Report Number: 10-2020-T0415

CLIENT and SAMPLE INFORMATION

TEST OWNER	CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO. LTD.		
ADDRESS	No: 88 Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province, China		
SAMPLE DESCRIPTION	Folding type protective mask (Coloured - Size M)		
BRAND NAME – MODEL	ChangAnDa – CAD-01		
TESTING STANDARD	EN 149+A1:2009		
CASE NUMBER	CE-PPE-2078		
SAMPLE RECEIVE DATE	02.10.2020	TESTING START DATE	02.10.2020
DISINFECTION INSTRUCTION *If applicable*	Not given, single use only		
NUMBER OF SAMPLES	50	SAMPLE IDs:	1 – 46
AS RECEIVED SAMPLE NO	26-46		
CONDITIONING SAMPLE NO	Simulated wearing treatment	1-2-3-4-5-6-7-8-9 (As Received)	
	Temperature conditioning	10-11-12-13-14-15 (Sample after test of Mechanical Strength)	
		16-17-18-19-20-21-22-23-24-25 (As Received)	
	Mechanical strength	10-11-12-13-14-15 (As Received)	

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

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Sarıgazi V.D. 892 096 8722

Suat KAÇMAZ
Director

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1. *REPORT SUMMARY*

TEST STANDARD	*TEST NAME*	*RESULT*	*EVALUATION*
EN 149:2001 + A1:2009 clause 8.5 EN 13274-1:2001	Total Inward Leakage Testing	**NAs**	-
EN 149:2001 + A1:2009 clause 8.11 EN 13274-7:2019	Penetration of Filter Material	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.6 EN 13274-4:2001	Flammability Testing	**NAs**	-
EN 149:2001 + A1:2009 clause 8.7 EN 13274-6:2001	Carbon Dioxide Content of The Inhalation Air Testing	**NAs**	-
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Breathing Inhalation Resistance-30 l/min	**Pass**	**See results**
	Breathing Inhalation Resistance-95 l/min	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Exhalation Resistance, flow rate 160 l/min	**Pass**	**See results**

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2. *TEST RESULTS and EVALUATION*

7.4 PACKAGING (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Clause 8.2-Visual inspection

REQUIREMENT	RESULTS	COMMENT
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.	Pass	The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use

Lab A

7.5 MATERIAL (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)

Test Method: Clause 8.2-Visual inspection

Clause 8.3.1-Simulated wearing treatment

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head.

For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head.

The air has been saturated at (37 ± 2) °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

The ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of ±1 °C.

a) for 24 h to a dry atmosphere of (70 ± 3) °C;

b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs.

REQUIREMENT	RESULTS	COMMENT
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.	Pass	The materials used were able to withstand handling and wear during the limited laboratory testing carried out.
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass	It was 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.	Pass	None of the specimens conditioned suffered mechanical failure.
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass	None of the specimens had not collapse after conditioning.

Lab B

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7.6 CLEANING AND DISINFECTING (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)

Test Method: Described in Clause 8.4, 8.5 and 8.11

REQUIREMENT	RESULTS	COMMENT
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.	N/A	This article is not applicable for tested protective mask which is single use disposable mask.

7.8 FINISH OF PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs while visual inspection and performance tests.

Lab A

7.9.2 PENETRATION OF FILTER MATERIAL (EN 149:2001 + A1:2009 clause 8.11)

Test Method: Described in Clause 8.11

REQUIREMENT			RESULTS	COMMENT
Classification	Max penetration of test aerosol			
	NaCl test 95 l/min %max	Paraffin oil test 95 l/min %max		
FFP1	20	20	Pass	Detail refer to Annex IIIA and IIIB
FFP2	6	6		
FFP3	1	1		

Annex IIIA-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Sodium Chloride in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
36	As received	0,55	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first, second and third protection class (FFP1, FFP2)
37		0,83		
38		0,58		
1	Simulated wearing treatment	1,70		
2		1,28		
3		0,58		
10	Mechanical strength + Temperature conditioned	1,03		
11		1,34		
12		1,52		

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Annex IIIB-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
39	As received	1,24	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first, second third protection class (FFP1, FFP2)
40		1,63		
41		1,49		
4	Simulated wearing treatment	1,68		
5		1,65		
6		1,47		
13	Mechanical strength + Temperature conditioned	1,71		
14		2,98		
15		1,76		

Lab A + B

7.15 EXHALATION VALVE (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)

Test Method: Clause 8.2, 8.3.4, 8.8, 8.9.1

REQUIREMENT	RESULTS	COMMENT
A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	NAs	The model do not have valve
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	NAs	The model do not have valve
Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	NAs	The model do not have valve
When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	NAs	The model do not have valve

Lab -

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7.16 BREATHING RESISTANCE (EN 149:2001 + A1:2009 clause 8.9)

Test Method: Described in Clause 8.9

REQUIREMENT	RESULTS	COMMENT
See table below	Pass	Classified as FFP3 Detail refer to Annex VIA-VIB

Classification	Max 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

Annex VIA-Test Result:
The test results obtained are given in the tables as follows;

Inhalation Resistance

No. of Sample	Condition	Inhalation Resistance (mbar)				
		Flow rate 30 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42	As received	0,58	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,68	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed Qualifies FFP1, FFP2,FFP3
43		0,51		1,43		
44		0,55		1,50		
7	Simulated wearing treatment	0,53		1,67		
8		0,55		1,69		
9		0,60		1,73		
23	Temperature conditioned	0,62		1,76		
24		0,59		1,68		
25		0,57		1,49		

Exhalation Resistance

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1: 2009	Assessment of Test Result Conformity / Nonconformity
42	As received	160l/min	2,25	2,03	2,06	2,11	2,14	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed Qualifies FFP1,FFP2, FFP3
43			1,83	2,16	1,98	2,12	2,15		
44			1,92	2,21	1,93	2,08	2,13		
7	Simulated wearing treatment		2,05	2,11	1,98	1,95	2,07		
8			2,03	2,06	1,95	2,04	2,01		
9			2,07	2,09	2,00	2,05	2,03		
23	Temperature conditioned		2,10	2,13	2,11	2,08	2,10		
24			2,06	2,15	2,09	2,13	2,08		
25			2,12	2,10	2,14	2,16	2,11		

Lab A

Pass	*Requirement satisfied.*
NCR	*Requirement not satisfied. Refer to the "Result details" section for more information.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

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LABORATORY INFORMATION

Code	Laboratory Name	Competency Explanations
Lab A	UNIVERSAL SERTIFIKASYON VE GOZETIM HIZMETLERI TIC. LTD. STI.	Internal Laboratory Services of Notified Body
Lab B	GCNTR ULUSLARARASI BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI KOCAELI DILOVA SUBESI	Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-1252-T according to EN ISO/IEC 17025:2017.

- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

Sample Photo

- End of Report -

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Mascarilla FFP2 NR – Talla M

SGS

SDS Report No.: CANML2014109701 Date: 19 Aug 2020 Page 1 of 1

CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO.,LTD
NO.88 MAHANG MIDDLE ROAD,HUTANG TOWN,WUJIN DISTRICT,CHANGZHOU CITY,JIANGSU PROVINCE,CHINA

SGS Job No.	:	GZIN2008043399PC
Sample Name	:	non-woven fabric
End Uses	:	Make masks
Composition/Ingredient of sample (as per client submission)	:	See *section 3 Composition/information on ingredients* on the SDS report
Job Receiving Date	:	14 Aug 2020
SDS Preparation Period	:	14 Aug 2020-19 Aug 2020
Service Requested	:	Safety Data Sheet (SDS) for the sample with submitted composition.
Summary	:	As per request, the contents and formats of the SDS are prepared in accordance with European Commission Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) No 2015/830, and is provided per attached.

Remark:
The SDS is prepared based on the information provided by client.

* This sample is likely to be classified as article with substances not intended to be released and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

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

Zmguan

Zm guan
Approved Signatory

Mascarilla FFP2 NR – Talla M libres de grafeno

SGS

TEST REPORT

No. : GZIN2104020576PS
Date : Apr 27, 2021
Page: 1 of 5

scan to see the report
GZIN2104020576PS

CUSTOMER NAME: CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO., LTD.
ADDRESS: NO.88 MAHANG MIDDLE ROAD, HUTANG TOWN, WUJIN DISTRICT, CHANGZHOU CITY, JIANGSU PROVINCE

Sample Name : FFP2 MASK CAD-01

Above information and sample(s) was/were submitted and confirmed by the client. SGS, however, assumes no responsibility to verify the accuracy, adequacy and completeness of the sample information provided by client.

****

SGS Ref. No.	:	GZIN2104020519PC
Date of Receipt	:	Apr 19, 2021
Testing Start Date	:	Apr 19, 2021
Testing End Date	:	Apr 27, 2021
Test result(s)	:	For further details, please refer to the following page(s) (Unless otherwise stated the results shown in this test report refer only to the sample(s) tested)

Signed for
SGS-CSTC Standards Technical Services Co., Ltd. GZ Branch Testing Center

Quincey

Quincey lee
Authorized signatory

SGS

TEST REPORT

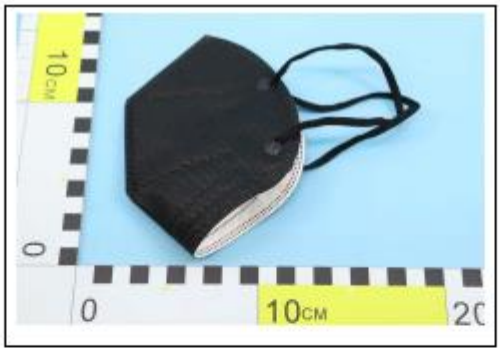
No. : GZIN2104020576PS
Date : Apr 27, 2021
Page: 2 of 5

Summary of Results:

No.	Test Item	Test Method	Result	Conclusion
1	Graphene Identification	SGS in house method	The characteristic structure and elemental composition of graphene were not detected	/

Note: Pass : Meet the requirements;
Fail : Does not meet the requirements;
/ : Not Apply to the judgment.

Original Sample Photo:



SGS

TEST REPORT

No. : GZIN2104020576PS
Date : Apr 27, 2021
Page: 3 of 5

Test Item: Graphene Identification
Sample Description: Facemask
Test Method: SGS in house method
Test Result:

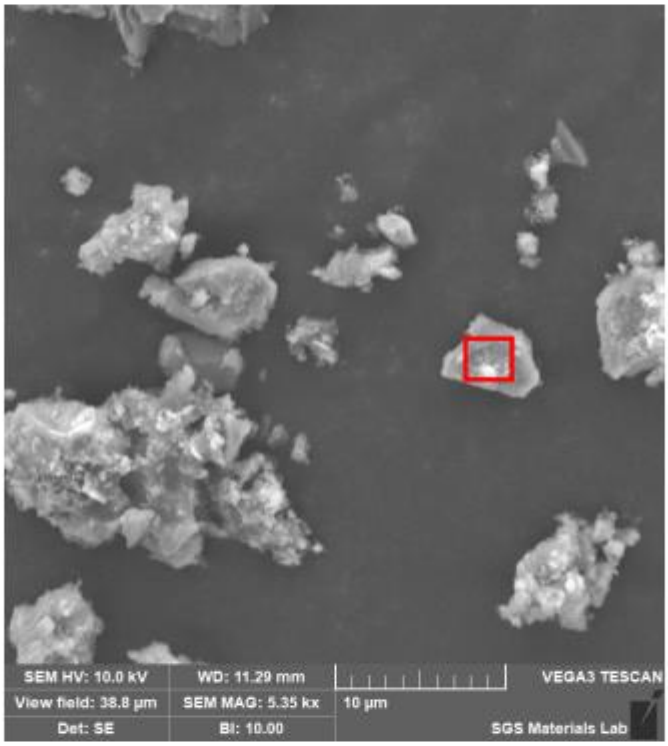


Fig.1 SEM image of the calcination ash of sample (under nitrogen protection)

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TEST REPORT

No. : GZIN2104020576PS
Date : Apr 27, 2021
Page: 4 of 5

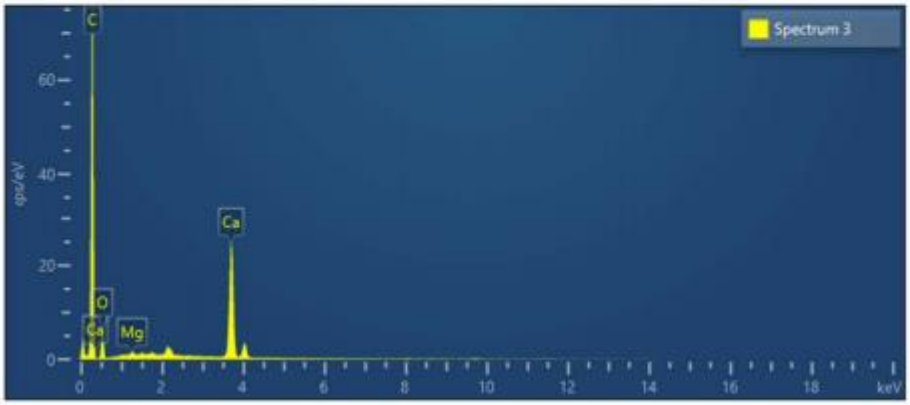

Fig.2 EDS spectra of the red rectangle area shown in fig.1

The elemental composition of the red rectangle area shown in fig.1

Element	Line Type	Weight %	Weight % Sigma	Atomic %
C	K series	65.8	0.28	77.85
O	K series	18.67	0.31	16.58
Ca	K series	15.28	0.12	5.42
Mg	K series	0.25	0.03	0.15
Total		100		100

Conclusion:

As per test specified above, the calcination ash of sample (under nitrogen protection) showed a debris-like morphology, and its elemental composition includes carbon, oxygen and calcium. The characteristic structure and elemental composition of graphene were not found.

SGS

TEST REPORT

No. : GZIN2104020576PS
Date : Apr 27, 2021

Note:

1. According to the related description in ISO/TS 80004-13:2017 and GB/T 30544.13-2018, the graphene layers can be generally referred to the 2D materials consisting of honeycomb-like carbon sheets with a stacking number less than ten.
2. Effected by the particle distribution, processing conditions and stocking conditions, graphene layers might aggregate into graphite flakes with a stacking number more than ten. The poor-reduced and poor-exfoliated reduced oxidized graphene oxide (rGO) might not exhibit the characteristic structure and elemental composition of graphene.

Equipment Information:

Equipment	Model	Equipment No.	Calibration date	Next Calibration date
SEM/EDS	VEGA3 (SEM)/ XMX1010 (EDS)	GZMR-PL-E309	2020-05-27	2021-05-26

Appendix information: The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc., and just for internal reference.

******** End of report********

Changzhou Ruida Medical Treatment Technology Co., Ldt

Certificado de Responsabilidad Social Corporativa.

Esta es una de las pocas fábricas en China que cuenta con el BSCI, “Business Social Compliance Initiative”.

Producer : Changzhou Ruida Medical Treatment Technology Co., Ltd.

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI Trade with purpose

Auditee :	**Changzhou Ruida Medical Treatment Technology Co., Ltd.**
Audit Date From :	**23/07/2020**
Audit Date To :	**23/07/2020**
Expiry Date of the Audit :	**Please refer to the producer profile in the amfori BSCI platform**
Auditing Company :	**Intertek**
Auditor's Name(s) :	**Monica Shi(Lead)**
Auditing Branch (if applicable) :	**Intertek North East China**

amfori BSCI Trade with purpose

This is an extract of the on line Audit Report.The complete report is available in the amfori BSCI Platform.
Access www.bsciplatform.org, for entitled users only.

amfori BSCI Trade with purpose www.bsciplatform.org Page 1/16

Generated on:28/07/2020

PROMASK

Producer : Changzhou Ruida Medical Treatment Technology Co., Ltd.

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

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Rating Definitions

Rating	A combination of ratings per Performance Area where:	Consequence
A **Very Good**	• Minimum 7 Performance Areas rated A • No Performance Areas rated C, D or E These are three examples: A A A A A A A A A A A A A A A A A A A A A A A B B B A A A A A A A B B B B B B	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
B **Good**	• Maximum 3 Performance Areas rated C • No Performance Areas rated D or E These are three examples: A A A A A A B B B B B B B A A A A A B B B B B B B C B B B B B B B B B C C C	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
C **Acceptable**	• Maximum 2 Performance Areas rated D • No Performance Areas rated E These are three examples: A A A A A A A A C C C C A A A A A B B B B C C C D C C C C C C C C C C D D	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
D **Insufficient**	• Maximum 6 Performance Areas rated E These are three examples: A A A A A A A A A D D D A A A B B B C C C D D D E D D D D D D D E E E E E E	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
E **Unacceptable**	• Minimum 7 Performance Areas rated E These are three examples: A A A A A A E E E E E E E A A B B C D E E E E E E E E E E E E E E E E E E E E	amfori BSCI Participants shall closely oversee the auditee's progress as the producer may represent a higher risk than other business partners.
Zero Tolerance	**A Zero Tolerance issue was identified (see amfori BSCI System Manual Part V – Annex 5: amfori BSCI Zero Tolerance Protocol)**	**Immediate actions are required. The amfori BSCI Zero Tolerance Protocol is to be followed.**

PROMASK

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI Trade with purpose

Main Auditee Information

Name of producer :	**Changzhou Ruida Medical Treatment Technology Co., Ltd.**		
DBID number :	**403139**		
Audit ID :	**187652**		
Address :	**No.88, Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province Changzhou**		
Province :	**Jiangsu**	Country :	**China**
Management Representative :	**Ms. Zhou Yuanxiao / HR Manager**		
Contact person:	**Qianqian Zhang**	Sector :	**Non-Food**
Industry Type :	**Others**	Product group :	**Others**
Product Type :	**medical treatment**		

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI Trade with purpose

Audit Details

Audit Range :	☒ Full Audit	☐ Follow-up Audit	
Audit Scope :	☒ Main Auditee	☐ Main Auditee & Farms	
Audit Environment :	☒ Industrial	☐ Agricultural	☐ Small Producer
Audit Announcement :	☒ Fully-Announced	☐ Fully-Unannounced	☐ Semi-Announced
Random Unannounced Check (RUC) :	No		
Audit extent (if applicable) :	none		
Audit interferences or contingencies (if applicable) :	none		
Overall rating :	C		
Need of follow-up :	Yes	If YES, by :	23/07/2021

Rating per Performance Area (PA)

PA 1	PA 2	PA 3	PA 4	PA 5	PA 6	PA 7	PA 8	PA 9	PA 10	PA 11	PA 12	PA 13
D	B	A	B	C	D	B	A	A	A	A	C	B

Executive summary of audit report

1. Changzhou Ruida Medical Treatment Technology Co., Ltd. was located at No.88, Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province. In view of factory, 2F of one 3-storey was used as workshop, warehouse and office. The 1F and 3F was used by landlord
Remark: the facility rented all the buildings from the landlord named Changzhou Anda Curtain Co., Ltd. And the lease contract and business license was provided for review.
2. Locked areas encountered during the audit were unlocked timely. At the end of the audit, all the findings were accepted by the management.
3. The local minimum wage standard is set at RMB 2020 per month, equivalent to RMB 11.61 per hour since August 1, 2018.
4. The facility stated operation since February 18, 2020. Payroll records from February 2020 to June 2020 and attendance records from February 18, 2020 to July 22, 2020 were available for review during this audit. 8 samples were randomly selected from June 2020 (current month), May 2020 (random month) and March 2020 (random month).
5. According to the electronic attendance records provided by the facility:
1) the monthly overtime hours of 8 randomly selected employees were 58 hours in June 2020 (current month);
2) the monthly overtime hours of 8 randomly selected employees were 56 hours in May 2020 (random month);
3) the monthly overtime hours of 8 randomly selected employees were 66-72 hours in March 2020 (random month).
6. There are no agencies used by the facility, which makes the agency labour contract not applicable
There are no government waivers in the facility, which makes the government waivers not applicable.
No Collective bargaining agreements were signed by the facility, which makes Collective bargaining agreements not applicable.
No fire license or construction license, which makes not applicable.
6. The business license number is 91320412MA20WE5A7T.
7. The peak month was not obvious.
8. Compliance status:
Performance Area 3: The facility had a clear procedure regarding freedom of association. As the procedure, the facility did respect all employees to associate or join any trade union. Workers can exercise their right to organize in a climate free of violence, pressure, fear, and threats. One union was in the facility. Employee representative exists in the facility. The last Workers' representatives were elected by employees in April 2020. No deviation was observed in this PA.
Performance Area 8: The facility had set up procedure to ensure all applicants' age above legal minimum age. All recruitment staff should be trained for verifying the actual age of applicants. And the facility also established procedure if any active underage worker, terminated underage worker, or historical underage worker is found. But no such case was found in the past. No deviation was observed in this PA.
Performance Area 9: The facility had established a written policy concerning protection of juvenile employees. Through document review, facility tour and employee interview, no juvenile employee was used in the facility. No young worker in the facility. No deviation was observed in this PA.
Performance Area 11: The facility established no-force labor procedure. There was no forced, bonded, indentured, or prison labor in the facility. Through employee interview, all employees work in the facility voluntarily and under their own desire and for their own interest. All employees are free to leave after the work. No forced labor was used in the facility. No deviation was observed in the PA.
9. Leader auditor name: Monica Shi (RA21700421).

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI Trade with purpose

Ratings Summary

Auditee's background information

Auditee's name :	**Changzhou Ruida Medical Treatment Technology Co., Ltd.**	Legal status :	**Co., Ltd.**
Local Name :	常州睿达医疗科技有限公司	Year in which the auditee was founded :	**2020**
Address :	**No.88, Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province**	Contact person (please select) :	**Qianqian Zhang**
Province :	**Jiangsu**	Contact's Email :	**528472253@qq.com**
City :	**Changzhou**	Auditee's official language(s) for written communications :	**Chinese**
Region :	**North East Asia**	Other relevant languages for the auditee :	**None**
Country :	**China**	Website of auditee (if applicable) :	**Not applicable**
GPS coordinates :	**119.992991,31.704964**	Total turnover (in Euros) :	**4009500.00**
Sector :	**Non-Food**	Of which exports % :	**20.00**
Industry :	**Others**	Of which domestic market % :	**80.00**
If other, please specify :	**medical treatment**	Production volume :	**3000000 pieces per month**
Product Group :	**Others**	Production cost calculation :	**Yes**
If other, please specify :	**medical treatment**	Lost time injury calculation cost :	**Yes**
Product Type :	**medical treatment**		

Auditee's employment structure at the time of the audit

Total number of workers : **47** Total number of workers in the production unit to be monitored (if applicable) : **0**

	MALE WORKERS	FEMALE WORKERS
Permanent workers	24	23
Temporary workers	0	0
In management positions	2	3
Apprentices	0	0
On probation	0	0
With disabilities	0	0
Migrants (national citizens)	11	14
Migrants (foreign citizens)	0	0
Workers on the permanent payroll	24	23
Production based workers	0	0
With shifts at night	0	0
Unionised	0	0
Pregnant	-	0
On maternity leave	-	0

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

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amfori BSCI Trade with purpose

Finding Report

Performance Area 1 : Social Management System and Cascade Effect

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: D — Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

The facility had established management procedures, manager (Ms. Zhou Yuanxiao / HR Manager) was appointed to ensure the amfori BSCI values and their level of alignment with amfori BSCI COC, but not all procedures were properly implemented, such as overtime working hours exceeded the legal requirement, etc. Based on satisfactory evidence, the facility partially respected this principle because:
企业建立了社会责任管理体系，指定了经理（周元肖女士/人事经理）以确保遵循amfori BSCI价值和原则要求，但不是所有制度都得以有效实施。如加班超时。基于令人满意的证据，企业部分尊重该原则，原因如下：

1.1 - The facility had set up management procedures to implement the amfori BSCI Code of Conduct, but not all policies were properly implemented, such as overtime working hours exceeded legal requirement, etc. It partially respected Performance area 1.1.
企业建立了确保amfori BSCI COC有效实施的管理制度，但不是所有制度都得以有效实施，比如员工工时超时等。部分尊重绩效区域 1.1。

1.4 - The facility did not evaluate its workforce capacity to meet the expectations of deliver order or contracts. It did not respect Performance area 1.4.
企业没有评估其生产能力是否可以满足其生产订单要求，尚未尊重绩效区域1.4。

Remarks from Auditee:

Performance Area 2 : Workers Involvement and Protection

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: B — Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

According to the grievance record, there was no any complaint in the last one year. And through interview with workers, they were satisfied with facility management, all interviewed workers knew about amfori BSCI Code and their rights and responsibilities. The established written grievance management procedure did not include the content of potential conflicts of interests and how to overcome them. Based on satisfactory evidence, the facility partially respected this principle because:
在过去一年内，无员工进行过申诉。并且，通过员工访谈，员工对企业管理人员感到满意，被访谈工人了解amfori BSCI准则和其权利和责任。建立的申诉机制书面程序未包括潜在的利益冲突以及如何克服这些冲突。基于令人满意的证据，企业部分尊重该原则，原因如下：

2.4 - The facility had provided amfori BSCI training to employees; however, all 8 interviewees did not understand the amfori BSCI requirement. It partially respected Performance area 2.4.
企业有提供amfori BSCI培训给员工，但是随机抽取的8名员工并不理解amfori BSCI行为准则。部分尊重绩效区域2.4。

2.5 - The facility has established grievance procedure in writing, but the procedure was not complete. It did not include information of potential conflicts of interest and no indicators of satisfaction among the users to grievance mechanism. It partially respected Performance area 2.5.
企业已经建立了书面的员工申诉程序，但程序内容没有包含以下信息：潜在利益冲突及如何克服，同时没有建立使用者对投诉机制的满意指标。部分尊重绩效区域2.5。

Remarks from Auditee:

Performance Area 3 : The rights of Freedom of Association and Collective Bargaining

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: A — Deadline date:

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:
None observed
无审核发现点

Remarks from Auditee:

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI Trade with purpose

Performance Area 4 : No Discrimination

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: B — Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

The facility had established anti-discrimination policy to prevent discrimination in hiring, working, training and etc. The facility had a written procedure describing reasons for disciplinary measures, and the disciplinary comply with law. The facility had conducted risk assessments of discrimination throughout the facility. No evidence was found that the facility discriminated in its hiring, salary, benefits etc. on the basis of personal characteristics, gender, race, religion, age, disability, ethnic origin, caste, political opinion and sexual orientation. All interviewed employees stated that they were treated equally. Based on satisfactory evidence, the facility partially respected this principle because:
企业建立了在就业、工作、培训等方面的反歧视政策，也建立了纪律措施程序，纪律措施符合法律要求。企业做了歧视风险评估。没有证据表明企业在个人特征，性别，种族，宗教，年龄，残疾，种族，种姓，政治观点和性取向方面有歧视。所有受访的员工都表示他们受到平等对待。基于令人满意的证据，企业部分尊重本条原则，原因是：

4.2 - The facility did not set up preventative or remedial measures to ensure workers are not disciplined, dismissed or otherwise discriminated against because of their complaints against infringements of their rights. It partially respected Performance area 4.2.
企业没有建立必要的预防或改善措施，以确保工人不因他们对侵权的投诉而被惩戒、解雇或歧视。部分尊重绩效区域4.2.

Remarks from Auditee:

Performance Area 5 : Fair Remuneration

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: C — Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

The facility had paid sufficient regular wages above the local minimum wages standard. Wages were paid in time every month with pay slip for employees. Benefits such as annual leave, paternity leave, and child-bearing leave are provided to all employees. No inconsistencies were found during this assessment. The facility kept the latest 5 months payroll records from February 2020 to June 2020 for review. Based on satisfactory evidence, the facility partially respected amfori BSCI principle for the following reasons:
企业支付足额的基本工资高于当地最低工资标准。工资每月及时发放，并提供工资单给员工。给员工提供年假、陪产假、产假等福利假期。审核中没有发现不一致。企业保存了最近5个月的工资(2020年2月到2020年6月)记录。基于令人满意的证据，企业部分尊重amfori BSCI的本条原则，原因如下：

5.4 - It was noted that the facility did not collect the datum and conduct the assessment for the remuneration of decent standard of living as per amfori BSCI requirements. Meanwhile, the interviewed workers and facility management did not know/understand the remuneration of decent standard of living. It did not respect Performance area 5.4.
企业没有按照amfori BSCI要求收集相关数据并对当地体面生活工资标准进行评估。同时，员工和管理层均不理解体面生活工资标准。尚未尊重绩效区域5.4 .

5.5 - Insufficient social insurance participated. Through reviewing the social insurance receipts from June 2020 to July 2020, auditor found that there were 47 employees including 7 retirees, 0 new employee, only 2 employees (5%) had participated in basic endowment insurance and unemployment insurance, maternity insurance, basic medical insurance and employment injury insurance. The facility management stated they had persuaded employees to take part in social insurance, but some employees had participated in rural insurance at based home and they did not want to participate in social insurance. The facility provided commercial injury insurance for 46 employees from April 1, 2020 to March 31, 2021. It did not respect the Performance area 5.5 and did not comply with Social Insurance Law of the People's Republic of China, Article 10 Employees shall participate in the basic endowment insurance, and the basic endowment insurance premiums shall be jointly paid by employers and employees. Article 23 Employees shall participate in the basic medical insurance for employees, and the basic medical insurance premiums shall be jointly paid by employers and employees in accordance with the relevant provisions of the state. Article 33 Employees shall participate in the employment injury insurance, and the employment injury insurance premiums shall be paid by their employers rather than the employees. Article 44 Employees shall participate in unemployment insurance, and the unemployment insurance premiums shall be jointly paid by employers and employees in accordance with the relevant provisions of the state. Article 53 Employees shall participate in maternity insurance, and the maternity insurance premiums shall be paid by employers rather than employees in accordance with the relevant provisions of the state.
社会保险参保不足。通过查看从2020年6月和2020年7月的社保缴费收据，审核员发现企业共47名员工中，其中7名退休员工，0名新员工，其中有2名员工（5%）参加养老保险，失业保险，生育保险，医疗保险和工伤保险。企业管理人员称他们已经积极说服员工缴纳保险，但部分没有缴纳社保的员工已经在老家买了农保，所以他们不愿意交。企业提供商业意外保险给46名员工从2020年4月1日到2021年3月31日。其尚未尊重绩效区域5.5. 且不符合《中华人民共和国社会保险法》第十条，职工应当参加基本养老保险，由用人单位和职工共同缴纳基本养老保险费。第二十三条 职工应当参加职工基本医疗保险，由用人单位和职工按照国家规定共同缴纳基本医疗保险费。第三十二条 职工应当参加工伤保险，由用人单位缴纳工伤保险费，职工不缴纳工伤保险费。第四十四条 职工应当参加失业保险，由用人单位和职工按照国家规定共同缴纳失业保险费。第五十三条 职工应当参加生育保险，由用人单位按照国家规定缴纳生育保险费，职工不缴纳生育保险费。

Remarks from Auditee:

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

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Performance Area 6 : Decent Working Hours	
Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: D	Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

1. The auditor noted that the facility used finger print attendance records system to record employee attendance situation. Some records such as Daily Production records and etc. had been reviewed, those records matched with the attendance records, meanwhile through employee interview, no inconsistency was found. The working hours and wages could be verified in current assessment. 2. Payroll records from February 2020 to June 2020 and attendance records from February 18, 2020 to July 22, 2020 were available for review during this audit. 8 samples were randomly selected from June 2020 (current month), May 2020 (random month) and March 2020 (random month). 3. Through document review and employee interview, normal working hours are 8 hours per day from Monday to Friday and 40 hours per week, which was in compliance with law. Based on satisfactory evidence, the facility partially respected this principle because:
1.审核发现企业使用指纹考勤系统记录员工出勤情况，通过查看生产记录，如生产日报表等，这些记录与考勤记录相吻合，没有发现不一致的日期。企业的工作时间和工资可以验证。 2.企业提供了2020年2月至2020年6月的工资记录和2020年2月18日至2020年7月22日的考勤记录供审核。在2020年6月（当前月），2020年5月（随机月）和2020年3月（随机月）各抽取了8个样本。 3.通过文件审核和员工访谈，正常工作时间为自周一至周五每天8小时每周40小时，符合法律规定。 基于令人满意的证据，企业部分尊重该原则，原因如下:

6.2 - Overtime hours exceeded the legal requirement. Through document review, auditor found that 1) the monthly overtime hours of 8 randomly selected employees were 58 hours in June 2020 (current month); 2) the monthly overtime hours of 8 randomly selected employees were 56 hours in May 2020 (random month); 3) the monthly overtime hours of 8 randomly selected employees were 66-72 hours in March 2020 (random month). It did not respect Performance area 6.2, and did not comply with the PRC Labour Law article 41 The employing unit may extend working hours due to the requirements of its production or business after consultation with the trade union and labourers, but the extended working hour for a day shall generally not exceed one hour; if such extension is called for due to special reasons, the extended hours shall not exceed three hours a day under the condition that the health of labourers is guaranteed. However, the total extension in a month shall not exceed thirty-six hours.
加班时间超过法规要求。通过文件审核，审核员发现:在抽取的1）2020年6月份（当前月）的考勤中，8名随机抽取的员工月加班时间为58小时；2）2020年5月份（随机月）的考勤中，8名随机抽取的员工月加班时间为56小时；3）2020年3月份（随机月）的考勤中，8名随机抽取的员工月加班时间为66-72小时，其尚未尊重绩效区域6.2. 且不符合《中华人民共和国劳动法》第41条，用人单位由于生产经营需要，经与工会和劳动者协商后可以延长工作时间，一般每日不得超过一小时；因特殊原因需要延长工作时间的，在保障劳动者身体健康的条件下延长工作时间每日不得超过三小时，但是每月不得超过三十六小时。

Remarks from Auditee:

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

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Performance Area 7 : Occupational Health and Safety

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: B — Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

Potable water was freely available in all areas. There were at least 2 exits in each work area. Sufficient exit signs, emergency lights and fire alarms were installed. Firefighting equipment, including fire extinguishers and fire hydrants were adequate and functioned. Evacuation maps were posted in all areas. Fire drills were conducted twice a year. The fire drills were conducted in June 2020. There were adequate first aid kits in each production area and all of them were well stocked. There were 2 qualified first aiders in the facility. No dormitory, kitchen and canteen were provided for employees. No transportation was provided for employees. Based on satisfactory evidence, the facility partially respected this principle because:
企业免费向员工提供饮用水。每个工作区域至少有2出口。企业安装了足够的安全出口标志、应急灯和警铃。消防设备，包括灭火器和消防栓是足够的且功能正常。疏散图张贴在所有区域。企业每年进行2次消防演习。消防演习是在2020年6月进行的。在每个生产区域有足够的急救药箱且装有足够的急救药品。企业有2名有资质的急救员。未向员工提供宿舍，餐厅和食堂。企业未给员工提供交通服务。 基于令人满意的证据，企业部分尊重该原则，原因如下:

7.1 - 1. There were some non-compliances on health and safety noted as per legal requirement, please refer to other checkpoint in PA7 for details. It partially respected Performance area 7.1. 2. The facility could not provide the training records / certificate of safety production knowledge and management skill of the principal in charge and persons for the management of work safety for review. It partially respected the Performance area 7.1 and did not comply with Law of the PRC on Work Safety Article 24, The principal in charge and persons for the management of work safety in production and business entities have to have the knowledge about work safety and the competence for the management, which are commensurate with the production and business activities of these entities. The principal in charge and persons for the management of work safety in production and business entities that produce, trade or store hazardous articles, and mines, metal smelting, building construction, and road transport shall only be appointed to the posts after they pass the examinations in their knowledge about work safety and their competence in the management conducted by the competent departments for work safety supervision and administration. No fees shall be charged for taking such examinations. Entities that produce or store hazardous articles, and mines, metal smelting shall have certified safety engineer to work on the management of work safety. 3. No occupational health examination was provided to employees engaged in post with occupational disease hazards. During facility tour, auditor found that there were 3 employees in pressing workshop, 2 employees in welding workshop, 18 employees in cutting workshop contacting noise and dust. However, no periodic occupational health examination reports which required by law for the above employees who engaged in above position were provided for review. It partially respected the Performance area 7.1 and did not comply with the PRC Law of Prevention and Control of Occupational Diseases Article 35, the employer shall conduct regular occupational health examination for those labourers who are engaged in works with occupational hazard(s) as required by production safety supervision and administration department and public health administrative department under the State Council. The occupational health examination shall be conducted before labourers start to take the post, in the course of the work and after leave the post and the employer shall provide the results of the occupational health examinations to labourers in written. The expenses of the occupational health examination shall be borne by employers. The employer shall not arrange labourers to engage in the work with occupational hazard(s) prior to the pre-post occupational health examination, or labourers with any occupational prohibition to engage in the prohibited work from them. Once the occupational health examination indicates that employee is suffering from the occupational damage in relation to his or her occupation, the employer shall transfer such a labourer out of his or her original post, and allocate him or her in a proper way. The employer shall not rescind or terminate the labour contracts signed with those employees without the occupational health examination at time of leaving the post. The occupational health examination shall be undertaken by the Medical and Health Institutions with Practicing Licence of Medical Institution. The Health Administrative Department shall strengthen the standardization management of occupational health examination. The specific administrative measures shall be formulated by the Health Administrative Department of State Council.
1. 在健康安全方面依据法规有发现一些不符合项，详见PA7中其它的点，部分尊重绩效区域7.1。 2. 企业无法提供该企业主要负责人和安全管理人员的安全生产知识和管理能力培训记录/证书供审阅。其部分尊重绩效区域7.1，且不符合《中华人民共和国安全生产法》第24条，生产经营单位的主要负责人和安全生产管理人员必须具备与本单位所从事的生产经营活动相应的安全生产知识和管理能力。危险物品的生产、经营、储存单位以及矿山、金属冶炼、建筑施工、道路运输单位的主要负责人和安全生产管理人员，应当由主管的负有安全生产监督管理职责的部门对其安全生产知识和管理能力考核合格。考核不得收费。危险物品的生产、储存单位以及矿山、金属冶炼单位应当有注册安全工程师从事安全生产管理工作。 3. 企业未为从事职业性危害作业的员工提供的职业健康检查。在现场巡查时，审核员发现3名压片员工，2名焊接员工，18名切片员工接触粉尘和噪声，但是，企业未能提供该些员工的定期职业健康检查报告供审核员审阅。其部分尊重绩效区域7.1，且不符合《中华人民共和国职业病防治法》 第三十五条，对从事接触职业病危害的作业的劳动者，用人单位应当按照国务院安全生产监督管理部门、卫生行政部门的规定组织上岗前、在岗期间和离岗时的职业健康检查，并将检查结果书面告知劳动者。职业健康检查费用由用人单位承担。用人单位不得安排未经上岗前职业健康检查的劳动者从事接触职业病危害的作业；不得安排有职业禁忌的劳动者从事其所禁忌的作业；对在职业健康检查中发现有与所从事的职业相关的健康损害的劳动者，应当调离原工作岗位，并妥善安置；对未进行离岗前职业健康检查的劳动者不得解除或者终止与其订立的劳动合同。职业健康检查应当由取得《医疗机构执业许可证》的医疗卫生机构承担。卫生行政部门应当加强对职业健康检查工作的规范管理，具体管理办法由国务院卫生行政部门制定。

7.2 - Insufficient employment injury participated. Through reviewing the social insurance receipts from June 2020 to July 2020, auditor found that there were 47 employees including 7 retirees, 0 new employee, only 2 employees (5%) had participated in employment injury insurance. The facility provided commercial injury insurance for 46 employees from April 1, 2020 to March 31, 2021. It did not respected Performance area 7.2, and did not comply with requirement of Social Insurance Law of the People's Republic of China, Article 33 Employees shall participate in the employment injury insurance, and the employment injury insurance premiums shall be paid by their employers rather than the employees.
工伤保险参保不足。通过查看从2020年6月和2020年7月的社保缴费收据，审核员发现企业共47名员工中，其中7名退休员工，0名新员工，其中有2名员工（5%）参加工伤保险。企业提供商业意外保险给46名员工从2020年4月1日到2021年3月31日。其尚未尊重绩效区域7.2，且尚未符合《中华人民共和国社会保险法》第三十三条 职工应当参加工伤保险，由用人单位缴纳工伤保险费，职工不缴纳工伤保险费。

7.11 - 1. No fire certificate was provided. During facility tour, auditor found that the facility used 2F of one 3-storey production building. Through document review, the facility could not provide fire certificate for above building. It did not respect Performance area 7.11 and PRC Fire Prevention Law article 11, the Ministry of Public Security of the State Council prescribes, for those densely populated places and special construction works, design documents shall be submitted to public security organs for safety review. Public security fire control institutions shall be responsible for the result. Article 13 the project completed with fire control design in accordance with the requirements of the State Technical Standards on Fire Control for Engineering Construction shall go through acceptance check and filing as stated below: 1. as is stated in Article 11, construction units shall apply to the public security fire control institutions for fire control acceptance check. 2. Other construction works and construction units shall file with public security fire control institutions and public fire control institutions shall conduct random inspection. Construction projects which are supposed to go through fire control acceptance check but do not or considered unqualified shall not be put into use. Other projects considered unqualified after acceptance check in accordance with law shall not be put into use. 2. No construction safety certificate was provided. During facility tour, auditor found that the facility used 2F of one 3-storey production building. Through document review, the facility could not provide construction safety certificate for above building. It did not respected Performance area 7.11 and PRC Construction Law Article 61, a construction project handed over for acceptance checks for completion must conform to the prescribed construction project quality standards, be provided with complete project technical and economic data and signed project warranty, and be provided with other qualified conditions for completion as prescribed by the state. A construction project may only be handed over for use upon passing the acceptance checks for completion; no construction project shall be handed over for use without going through the acceptance checks for

completion or passing the acceptance checks for completion.
1. 无消防验收报告。通过现场走访发现，企业使用1栋3层生产楼的二楼，但是通过文件审核发现企业无法提供上述建筑的消防验收报告。其尚未尊重绩效区域7.11和《中华人民共和国消防法》第十一条 国务院公安部门规定的大型的人员密集场所和其他特殊建设工程，建设单位应当将消防设计文件报送公安机关消防机构审核。公安机关消防机构依法对审核的结果负责。第十三条 按照国家工程建设消防技术标准需要进行消防设计的建设工程竣工，依照下列规定进行消防验收，备案：（一）本法第十一条规定的建设工程，建设单位应当向公安机关消防机构申请消防验收；（二）其他建设工程，建设单位在验收后应当报公安机关消防机构备案，公安机关消防机构应当进行抽查。依法应当进行消防验收的建设工程，未经消防验收或者消防验收不合格的，禁止投入使用；其他建设工程经依法抽查不合格的，应当停止使用；2. 无建筑竣工验收。通过现场走访发现，企业使用1栋3层生产楼的二楼，但是通过文件审核发现企业无法提供上述建筑的竣工验收报告。其尚未尊重绩效区域7.11和《中华人民共和国建筑法》第六十一条，交付竣工验收的建筑工程，必须符合规定的建筑工程质量标准，有完整的工程技术经济资料和经签署的工程保修书，并具备国家规定的其他竣工条件。建筑工程竣工经验收合格后，方可交付使用；未经验收或者验收不合格的，不得交付使用。《中华人民共和国建筑法》第六十一条，交付竣工验收的建筑工程，必须符合规定的建筑工程质量标准，有完整的工程技术经济资料和经签署的工程保修书，并具备国家规定的其他竣工条件。建筑工程竣工经验收合格后，方可交付使用；未经验收或者验收不合格的，不得交付使用。

7.13 - Stacking was stored under lighting sets directly. During facility tour, auditor found that finished production was stored under the lights directly in the finished goods warehouse located at 2F of one 3-storey building. It partially respected Performance area 7.13: and did not comply with the Rules on Administration of Fire Safety in Warehouses, article 39, portable lights shall not be installed in warehouse. No stacking is allowed under lighting sets and the horizontal spacing between the position vertically beneath the lights and the piled goods should be no less than 0.5m.
仓库内照明灯具垂直下方堆放货物。在现场巡查时，审核员发现企业位于1栋3层建筑的2楼用作成品仓库，其成品直接放于照明灯具垂直下方。部分尊重绩效区域7.13，且不符合《仓库防火安全管理规则》第39条，库房内不准设置移动式照明灯具。照明灯具下方不准堆放物品，其垂直下方与储存物品水平间距不得小于零点五米。

7.21 - N/A. No canteen or kitchen was provided.
不适用。企业未提供餐厅和食堂给员工。

7.22 - Through facility tour, auditor found that no privacy door was installed in the toilet. It partially respected Performance area 7.22.
通过现场审核，审核员发现洗手间未设置隐私门。部分尊重绩效区域7.22。

7.23 - N/A. No transportation was provided for employees.
不适用。企业未给员工提供交通服务。

7.24 - The facility did not conduct evaluation on occupational hazard factors as per legal requirement. Through facility tour, auditor found that pressing workshop, welding workshop and cutting workshop contacting noise and dust. However, the provided evaluation report of occupational hazardous factors did not cover above mentioned items. It did not respect Performance area 7.24 and Provisions on the Supervision and Administration of Workplace Occupational Health Article 20, An employing entity with occupational hazards shall entrust an occupational health technical service agency with corresponding qualification to conduct evaluation on occupational hazard factors at least once every year.
企业没有按要求进行职业危害因素检测。在现场巡查时，审核员发现企业在压片车间，焊接车间和切片接触噪声和粉尘，但是企业提供的上述作业场所的职业危害因素监测报告未包括这些项目。这尚未尊重绩效区域7.24和《工作场所职业卫生监督管理规定》第二十条：存在职业病危害的用人单位，应当委托具有相应资质的职业卫生技术服务机构，每年至少进行一次职业病危害因素检测。

Remarks from Auditee:

Performance Area 8 : No Child Labour

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: A — Deadline date:

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:
None observed
无审核发现点

Remarks from Auditee:

Performance Area 9 : Special protection for young workers

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: A — Deadline date:

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:
None observed
无审核发现点

Remarks from Auditee:

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI Trade with purpose

Performance Area 10 : No Precarious Employment

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: A — Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

1. Through document review and employee interview, the facility signed labor contracts with all permanent employees in the facility within one month to comply with the law. No apprentices and probationary workers were hired in the facility.2. There were 7 retirees which had sign written agreement with the facility. 3. Through document review and employee interview, the labor contracts were in local language (Chinese) and all employees could understand it. The facility signed employment contracts with all employees and all of them received a copy of the signed contract. Based on satisfactory evidence, the facility partially respected this principle because:
1.通过文件审核和员工访谈，企业与员工在入职一个月内签订了劳动合同，企业没有学徒工和实习工。2. 企业有7名退休人员，均签订退休返聘协议。 3.通过文件审核和员工访谈，合同是中文的，所有员工都能看懂，企业与所有员工均签订了劳动合同，且所有员工都收到了签字合同的副本。基于令人满意的证据，企业部分尊重该原则，原因如下：

10.2 - The potential occupational disease hazards, the consequences in the course of work, the measures for prevention of such diseases and the material benefits were not informed to employees contacting occupational hazardous factors (for example noise existed in cutting workshop), also the information was not clearly put down in the contracts. It partially respected Performance area 10.2 and Article 33 of Law of the People's Republic of China on Prevention and Control of Occupational Diseases (extracted): When signing with the workers labor contracts (including contracts of employment), the employer shall truthfully inform the workers of the potential occupational disease hazards the consequences in the course of work, the measures for prevention of such diseases and the material benefits, and it shall have the same clearly put down in the contracts; it may not conceal the facts or deceive the workers.
企业没有将工作过程中可能产生的职业病危害及其后果、职业病防护措施和待遇书面告知涉及职业危害的员工（如切片车间涉及噪声），也没有在劳动合同中载明。部分尊重绩效区域10.2和《中华人民共和国职业病防治法》第33条（节录）用人单位与劳动者订立劳动合同（含聘用合同，下同）时，应当将工作过程中可能产生的职业病危害及其后果、职业病防护措施和待遇等如实告知劳动者，并在劳动合同中写明，不得隐瞒或者欺骗。

Remarks from Auditee:

Performance Area 11 : No Bonded Labour

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: A — Deadline date:

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:
None observed
无审核发现点

Remarks from Auditee:

Performance Area 12 : Protection of the Environment

Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: C — Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

The facility provided the Environmental Impact Assessment (EIA) registration. The facility established procedures in place to ensure integration of local environmental law into the business performance. The facility took ongoing identification of environmental legislation and conducted the self-assessment for environmental impacts. Based on satisfactory evidence, the facility partially respected amfori BSCI principle for the following reasons:
企业提供了建设项目环境影响备案。企业建立了程序来确保在商业模式中结合当地环境法规。企业持续识别环境法规并执行环境影响自我评估。基于令人满意的证据，企业部分尊重amfori BSCI的本条原则，原因如下：

12.1 - The facility did not conduct the identification of environmental factors and major environmental impact in the facility, and the facility did not establish the program on complaint with the outside sensitive receivers in regard to environment by document review, it was not effectively identified the outside sensitive receivers such as the other facilities, residents, schools, etc. in the facility boundary. It did not respect the Performance area 12.1.
企业没有进行环境因素识别和重大环境影响评估，没有建立与外部敏感受体关于环境方面的沟通申诉程序文件，也未对周边敏感受体如学校，居民等进行有效识别。其尚未尊重绩效区域12.1。

12.2 - The facility did not identify new law and update the law summary regularly, such as the PRC Environmental Impact Assessment Law issued in September 2016 was not identified. It partially respected Performance area 12.2.
企业未定期获取新的法律法规并更新法律法规清单，比如2016年9月施行的中华人民共和国环境影响评价法未识别到。部分尊重绩效区域12.2。

Remarks from Auditee:

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

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Performance Area 13 : Ethical Business Behaviour	
Full Audit [Audit Id - 187652] Audit Date: 23/07/2020 PA Score: B	Deadline date:30/06/2021

GOOD PRACTICES:
None observed

AREAS OF IMPROVEMENT:

The facility had established a written policy concerning bribery, corruption and unethical business practices, and identified the situations and activities where acts of corruption, extortion or bribery were most likely to occur in its context.Based on satisfactory evidence, the facility partially respected this principle because:
企业建立了一个关于商业道德方面管控的制度，识别最可能发生贪污、勒索或贿赂行为的情形和活动。基于令人满意的证据，企业部分尊重amfori BSCI的本条原则，原因是：

13.1 - The facility has established the procedure about business ethics, however it did not conduct Ethical Business risk assessment and provide regular ethics and integrity training for employees and managements who working in high risk position. It partially respected Performance area 13.1.
企业已经建立商业道德方面的管控程序，但是未进行商业道德方面的风险评估并且没有给高风险岗位人员定期提供商业诚信培训。部分尊重绩效区域13.1。

13.4 - The facility did not establish effective mechanism or system to collect and use personal information with reasonable care, according to privacy and information security laws and regulatory requirements. It partially respected the Performance area 13.4.
企业没有有效的机制或系统来按照隐私和信息安全法规和监控要求收集、使用个人信息，并进行合理谨慎的处理。其部分尊重绩效区域13.4。

Remarks from Auditee:

Producer : **Changzhou Ruida Medical Treatment Technology Co., Ltd.**

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

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Trade with purpose

Summary

Audit Type	Date	Audit Id	PA1	PA2	PA3	PA4	PA5	PA6	PA7	PA8	PA9	PA10	PA11	PA12	PA13	Overall Rating
Full Audit	23/07/2020	187652	D	B	A	B	C	D	B	A	A	A	A	C	B	C

PROMASK

Producer : Changzhou Ruida Medical Treatment Technology Co., Ltd.

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI Trade with purpose

Producer Photos


External photo(s) of the production unit(s)
facility gate.JPG


External photo(s) of the production unit(s)
facility name and facility address.JPG


External photo(s) of the production unit(s)
facility name-1.JPG


External photo(s) of the production unit(s)
production building.JPG


Photo first aid facilities
first aid kit1.JPG


Photo of fire safety equipment
emergency light testing.JPG


Photo of fire safety equipment
emergency light.JPG


Photo of fire safety equipment
evacuation indication sign.JPG

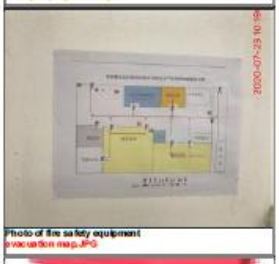
Photo of fire safety equipment
evacuation map.JPG


Photo of fire safety equipment
exit sign.JPG


Photo of fire safety equipment
fire alarm testing.JPG


Photo of fire safety equipment
fire extinguisher.JPG


Photo of fire safety equipment
fire hydrant testing.JPG


Photo of fire safety equipment
fire hydrant.JPG


Photo of non-conformity
stacking was stored under lighting sets directly.JPG

PROMASK

Producer : Changzhou Ruida Medical Treatment Technology Co., Ltd.

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI
Trade with purpose


Photo of non-conformity
toilet without privacy door.JPG


Photo of the code of conduct on display
coc posted.JPG


Photo of the inside of the main production hall
aisle.JPG


Photo of the inside of the main production hall
assembly point.JPG


Photo of the inside of the main production hall
attendance record.JPG


Photo of the inside of the main production hall
cutting workshop.JPG


Photo of the inside of the main production hall
drinking water.JPG


Photo of the inside of the main production hall
electronic box.JPG


Photo of the inside of the main production hall
finished goods warehouse.JPG


Photo of the inside of the main production hall
inspection record-1.JPG


Photo of the inside of the main production hall
inspection record.JPG


Photo of the inside of the main production hall
inspection workshop.JPG

Photo of the inside of the main production hall
no smoking sign-1.JPG


Photo of the inside of the main production hall
no smoking sign.JPG


Photo of the inside of the main production hall
packing workshop.JPG

Producer : Changzhou Ruida Medical Treatment Technology Co., Ltd.

DBID : 403139 and Audit Id : 187652 Audit Date : 23/07/2020

Audit Type : Full Audit

amfori BSCI
Trade with purpose


Photo of the inside of the main production hall
personal locker.JPG


Photo of the inside of the main production hall
raw material warehouse.JPG


Photo of the inside of the main production hall
suggestion box.JPG


Photo of the inside of the main production hall
welding workshop and pressing workshop.JPG


Photo of the personal protection equipments (if applicable)
ppe was provided.JPG