



# DOCUMENTATION

## DISPOSABLE MEDICAL MASK Small **IIR** (S)

MASCARILLA MÉDICA QUIRÚRGICA IIR DESECHABLE (S)  
MASQUE CHIRURGICAL ET DE PROTECTION MÉDICALE IIR (S)  
MASCHERINA MEDICA CHIRURGICA IIR (S)

REF. CV-18



MASTER BOX: 1000 pcs



CV-18

DESCRIPTION: **NAAMIO IIR (S)**

MATERIAL: 3 PLY. Inner layer: PP non-woven (28%), Middle layer: meltblown non-woven (34%),  
Outer layer: PP non-woven (38%)

QUANTITY:

G.W (GROSS WEIGHT)

N.W (NET WEIGHT)

CNT SIZE (MEASURE OF THE BOX)

BATCH NUMBER:

PRODUCTION DATE:

VALIDITY:

产品名称: 一次性使用医用口罩 (小号) (非无菌)  
执行标准: EN14683:2019+AC: 2019  
生产厂商: 保定银虹裕赫医疗器械制造有限公司  
生产地址: 保定市徐水区大王店工业园区南隆善村口

MADE IN P.R.C.

BOX: 50 pcs

115mm

50 pcs

MASCARILLA MÉDICA QUIRÚRGICA IIR DESECHABLE (S)

**Small IIR (S)**

DISPOSABLE MEDICAL MASK

B1-A2  
EN 149

**INSTRUCCIONES DE USO**

1. Lavarse las manos con agua y jabón o frotárselas con una solución hidroalcohólica antes de manipular la mascarilla.
2. Identificar la parte superior de la mascarilla.
3. Colocar la mascarilla en la cara y ajustar la pínza nasal en la nariz.
4. Sostener la mascarilla desde el exterior y pasar el armazón de cabeza o anudarlo detrás de la misma, a ambos lados de las orejas, sin cruzarse.
5. Bajar la parte inferior de la mascarilla a la barbilla y verificar que la mascarilla cubre la barbilla.
6. Reforzar la pínza nasal con ambas manos para que quede a la nariz y verificar que está colocada correctamente.
7. Una vez ajustada, no tocar la mascarilla con las manos.

**DISPOSABLE MEDICAL MASK**

**Small IIR (S)**

Size : 14.5\*9.5cm (BFE≥98%) (Pa/cm2<60)

Type IIR according to EN 14683:2019

Material Composition: 3PLY, Inner layer: PP non-woven (28%)  
Middle layer: meltblown non-woven (34%)  
Outer layer: PP non-woven (38%)

Medical Device  
Production License:

50 pcs/box

**USO PREVISTO**

Las mascarillas faciales médicas deben usarse para proteger principalmente contra la propagación o transmisión de gérmenes infecciosos y agentes patógenos. El objetivo principal es proteger al paciente, y una de las características diferenciadoras de la mascarilla IIR es la protección adicional del usuario, que en ciertas situaciones se ve expuesto a salpicaduras de líquidos y microgotas potencialmente contaminantes y partículas viables.

- Protección de fluidos a pacientes y usuarios
- Suave y fácil de respirar
- No fabricado con látex de caucho natural

160mm

115mm

160mm

115mm

100mm

BAG: 10 pcs

**DISPOSABLE MEDICAL MASK**

**Small IIR (S)**

Size : 14.5\*9.5cm (BFE≥98%) (Pa/cm2<60)

Type IIR according to EN 14683:2019

Material Composition: 3PLY, Inner layer: PP non-woven (28%)  
Middle layer: meltblown non-woven (34%)  
Outer layer: PP non-woven (38%)

Medical Device  
Production License:

Distribuido por:  
**CN** C/ Sofia, 3-5 - Pol. Ind. Cabezo Beaza  
30353 Cartagena (Spain)

**10 uds**

**Instrucciones de uso**

1. Lavarse las manos con agua y jabón o frotárselas con una solución hidroalcohólica antes de manipular la mascarilla.
2. Identificar la parte superior de la mascarilla.
3. Colocar la mascarilla en la cara y ajustar la pínza nasal en la nariz.
4. Sostener la mascarilla desde el exterior y pasar el armazón de cabeza o anudarlo detrás de la misma, a ambos lados de las orejas, sin cruzarse.
5. Bajar la parte inferior de la mascarilla a la barbilla y verificar que la mascarilla cubre la barbilla.
6. Reforzar la pínza nasal con ambas manos para ajustarla a la nariz y verificar que está colocada correctamente.
7. Una vez ajustada, no tocar la mascarilla con las manos.

**Precauciones:**

- a. Solamente para un único uso. La reutilización del dispositivo puede causar infección cruzada o protección insuficiente.
- b. No lo reutilice después de secar o desinfectar.
- c. Distinga correctamente la parte delantera y trasera antes de usar.
- d. Por favor, preste atención a la fecha de vencimiento del producto antes de su uso.
- e. Deseche adecuadamente las mascarillas usadas de acuerdo con la política local de eliminación de desechos médicos.
- f. El dispositivo no debe usarse durante más de 24 horas.
- g. Manténgalo alejado del fuego.
- h. No usar si es alérgico a telas no tejidas.

**Tipo IIR según EN 14683:2019**

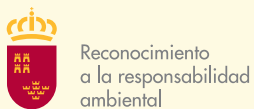
Distribuido por:  
**CN** C/ Sofia, 3-5 - Pol. Ind. Cabezo Beaza  
30353 Cartagena (Spain)

Shanghai Yuhua Medical Device Manufacturing Co., Ltd  
Management Office: Shanghai Yuhua Medical Device Manufacturing Co., Ltd  
Xuhua District, Shanghai City, Hebei Province, China.

CN IIR CNIC Medical Devices S. Duque 26  
Nº 10000000000000000000  
C/ Pinedo Largo 18 - 28005  
Madrid Spain

(For clinical personnel to wear in the process of non-invasive operation)

Colaboramos con



Asociaciones y Entidades a las que pertenecemos



# EC Declaration of Conformity

*Manufacturer:*

Baoding Yinhong Yuhe medical device  
manufacturing Co., Ltd

Nanlongshan village, Dawangdian Industrial  
Park, Xushui District, Baoding City, Hebei  
Province, China

We, the manufacturer, herewith declare that the products

Disposable Medical Mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The Disposable medical mask belongs to Type IIR(S) of EN14683:2019+AC:2019, which is tested and approved by SGS, the test report No. is SL52035260959001Tx-1

The above mentioned declaration of conformity is exclusively under the responsibility of

Baoding Yinhong Yuhe medical device manufacturing Co., Ltd

Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei  
Province, China

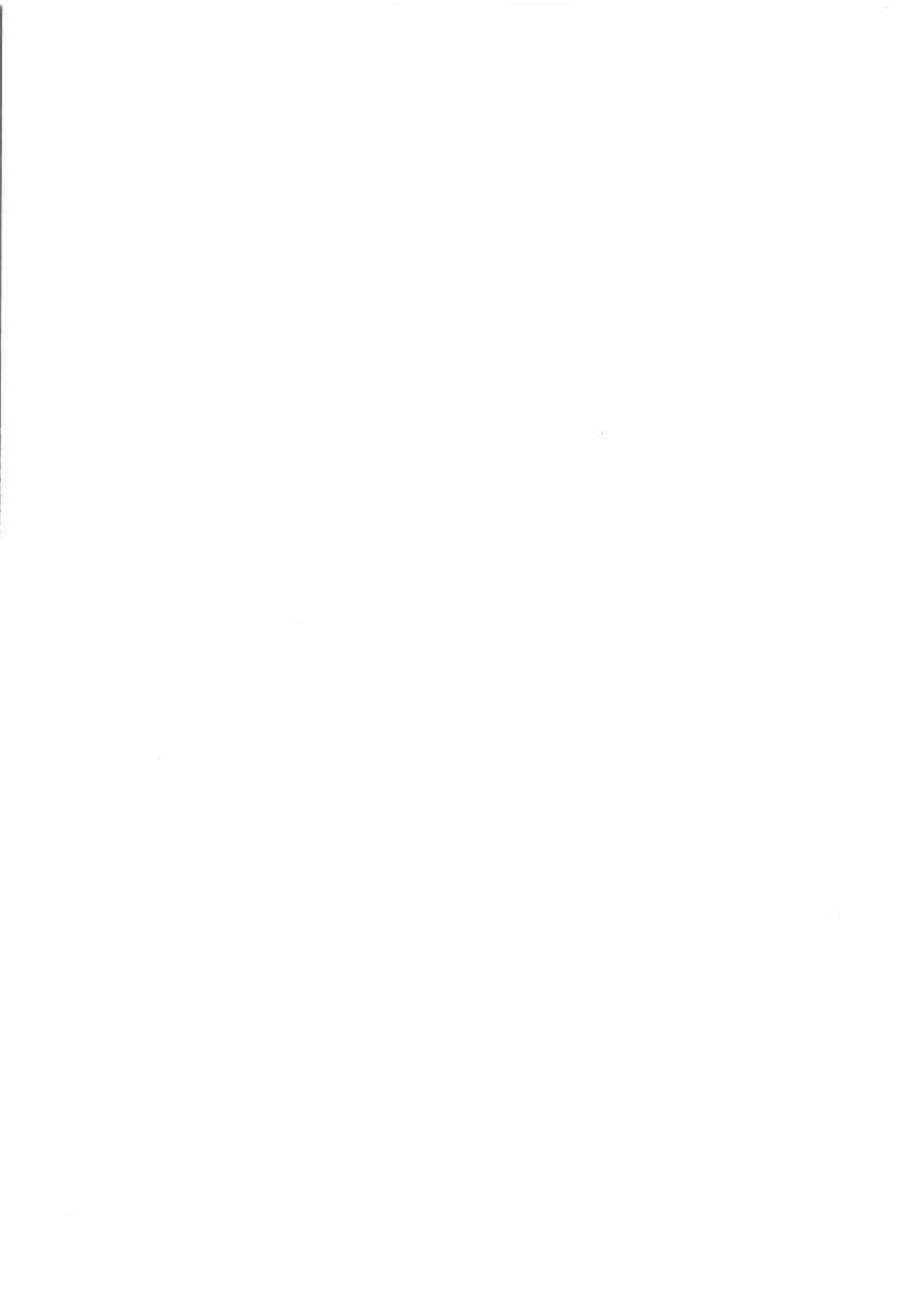
Baoding May 25, 2020.

*Place, date*

Xiaoming Xu General Manager.

*Legally binding signature, Function*







中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

Test Report

SL52035260959001TX-1

Date: July 20, 2020

Page 1 of 4

BAODING YINHONG YUHE MEDICAL DEVICE MANUFACTURING CO., LTD.  
NANLONGSHAN VILLAGE, DAWANGDIAN INDUSTRIAL PARK, XUSHUI DISTRICT, BAODING CITY, HEBEI PROVINCE, CHINA.

**THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035260959001TX**  
**DATE: Jul 13, 2020 ISSUED BY SGS (SHANGHAI)**  
**UPDATED SAMPLE INFORMATION**

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

Sample Description : (A) Disposable medical mask (small)

SGS Internal Ref No. : TJHL2006003688MD

Style No. : Batch number:03202023

Sample Color : (A)Blue

ITEM NO. : YH/YY-02

Manufacturer : BAODING YINHONG YUHE MEDICAL DEVICE MANUFACTURING CO., LTD.

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 18, 2020

Testing Period : Jun 18, 2020 - Jul 13, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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Test Report

SL52035260959001TX-1

Date: July 20, 2020

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Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.2 Bacterial filtration efficiency (BFE)**

(EN 14683:2019+AC:2019 Annex B)

Sample: A

Conditioning Parameters : Minimum of 4 hours at 21 5°C and 85 5% R.H.  
 Dimensions of test specimen : ~140 mm x 140 mm  
 Test Area : ~60 cm<sup>2</sup>  
 Test Side : Inside  
 Flow Rate : 28.3 l/min  
 Positive Control Average : 2272 CFU  
 Negative Monitor Count : < 1 CFU

(BFE), %	1#	2#	3#	4#	5#
	99.9	99.9	99.7	99.6	99.8

Remark: Performance Requirement: Type I ≥95%, Type II ≥98%, Type IIR ≥98%

**Clause 5.2.3 Breathability**

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location : 5 random areas for each specimen (face mask)  
 Conditioning Parameters : Minimum of 4 hours at 21 5°C and 85 5% R.H.  
 Test Area : 4.9 cm<sup>2</sup>  
 Flow Rate : 8 l/min

Differential pressure Δ P (Pa/cm <sup>2</sup> )	1#	2#	3#	4#	5#
	45	49	49	46	44

Remark: Performance Requirement: Type I <40 Pa/cm<sup>2</sup>, Type II <40 Pa/cm<sup>2</sup>, Type IIR <60 Pa/cm<sup>2</sup>

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**Clause 5.2.4 Splash Resistance**

(ISO 22609 :2004, Pressure 16.0 kPa)

Sample: A

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			32				
Overall result:			Acceptable				

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR:  $\geq 16.0$  kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300 10mm.
- 3) Condition and Test temperature (21 5)° C, relative humidity (85 10)%
- 4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

**Clause 5.2.5 Microbial Cleanliness**

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.94	66	22.45
2#	2.81	33	11.74
3#	2.98	33	11.07
4#	3.12	36	11.54
5#	3.51	6	1.71

Remark: Performance Requirement: Type I  $\leq 30$  CFU/g, Type II  $\leq 30$  CFU/g, Type IIR  $\leq 30$  CFU/g

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Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*



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# EC REP CERTIFICATE



## CMC MEDICAL DEVICES & DRUGS SL

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

**Baoding Yinhong Yuhe medical device manufacturing Co., Ltd**  
**Nanlongshan village, Dawangdian Industrial Park, Xushui District, Baoding City, Hebei Province, China**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1100/2020**



Issued on: 29/05/2020

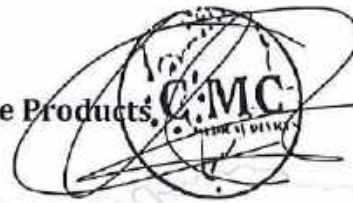
Valid until: 28/05/2021

  
Authorized Signatory  
CMC Medical Devices & Drugs SL

# EC REP CERTIFICATE



ANNEX I Medical Device Products



Disposable Medical Mask

# CE

# DISPOSABLE MEDICAL MASK

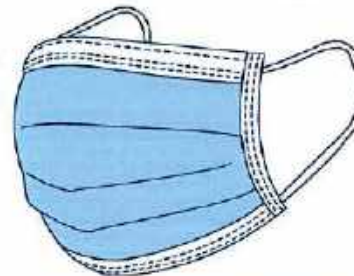
## Small IIR (S)



Size : 14.5\*9.5cm (BFE $\geq$ 98%) (Pa/cm $^2$ <60)

Type IIR according to EN 14683:2019

Material Composition: 3Ply, Inner layer: PP non-woven (28%)  
Middle layer: melblown non-woven (34%)  
Outer layer: PP non-woven (38%)



10 uds

Medical Device: XXXXXXXXXX  
Production License: XXXXXXXXXX

Distribuido por:

**CN** C/ Sofia, 3-5 - Pol. Ind. Cabezo Beaza  
30353 Cartagena (Spain)

### Instrucciones de uso

1. Lávese las manos con agua y jabón o frotelas con una solución hidroalcohólica antes de manipular la mascarilla.
2. Identificar la parte superior de la mascarilla.
3. Colocar la mascarilla en la cara y ajustar la pinta nasal en la nariz.
4. Sujetar la mascarilla desde el exterior y pasar el atrás de cabeza o anudado detrás de la cabeza, a ambos lados de los oídos, sin cruzarlos.
5. Bajar la parte inferior de la mascarilla a la barbilla y verificar que la mascarilla cubra la barbilla.
6. Peligroso la pinta nasal con ambas manos para ajustarla a la nariz y verificar que está colocada correctamente.
7. Una vez quitado, no tocar la mascarilla con las manos.



### Precauciones:

- a. Solamente para un único uso. La reutilización del dispositivo puede causar infección cruzada o protección insuficiente.
- b. No lo reutilice después de estar o disinfestar.
- c. Distinga correctamente la parte delantera y trasera antes de usar.
- d. Por favor, preste atención a la fecha de vencimiento del producto antes de su uso.
- e. Deseche adecuadamente las mascarillas usadas de acuerdo con la política local de eliminación de desechos médicos.
- f. El dispositivo no debe usarse durante más de 24 horas.
- g. Manténgalo alejado del fuego.
- h. No usar si es alérgico a las resinas látex.

### Tipo IIR según EN 14683:2019



Distribuido por:

**CN** C/ Sofia, 3-5 - Pol. Ind. Cabezo Beaza  
30353 Cartagena (Spain)

Shanghai Hongyuan Medical Co., Ltd.  
Hangzhou Village, Daxingpu Industrial Park,  
Xunbi Road, Binhuo District, Suzhou, Jiangsu Province, China

**EN 14683** C/C Material Device & Device S.L.  
M. C/ C/ Sofia, 3-5 - Pol. Ind. Cabezo Beaza  
30353 Cartagena (Spain)

LOT XXXXXX

XXXXXX

XXXXXX

(For disposal personnel to wear in the process of new product production)







# DOCUMENTATION SUPPLÉMENTAIRE

RAPPORT TEST

DE VÉRIFICATION ET CONTRÔLE DE QUALITÉ RÉALISÉE  
PAR NOTRE SOCIÉTÉ DE GUANGZHOU (CHINE) SITUÉ À  
SHENZHEN ACADEMY OF METROLOGY &  
QUALITY INSPECTION.



Cet organisme de vérification est reconnu internationalement et homologué par la CNAS, organisme accrédité par le gouvernement.

**MÊME SI CE N'EST PAS OBLIGATOIRE,  
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EST RÉELLEMENT AUTHENTIQUE EN SE CONFORMANT  
AUX NORMES LES PLUS EXIGEANTES D'EUROPE.**

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Reconocimiento  
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Asociaciones y Entidades a las que pertenecemos





## TEST REPORT

CIFRA GUANGZHOU OFFICE  
ROOM 2001, NORTH TOWER TIMES NEW WORLD CENTER 2193 GUANGYUAN EAST ROAD

Lot No. / Batch Code:	2020827
Sample Description:	Disposable medical mask small IIR
Quantity Submitted:	100PCS
Manufacturer / Supplier:	/
Manufactured Date:	Aug. 27,2020
Sample Receiving Condition:	In unopened plastic bag under ambient condition
Country of Origin:	China
Sample Receiving Date:	Sep. 09, 2020
Testing Period:	Sep. 09, 2020 –Sep.16, 2020

Test Requested : Please refer to the result summary.

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

Result Summary :

Test Requested	Conclusion
EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods	PASS

Signed for and on behalf of Shenzhen Academy of Metrology & Quality Inspection:

Approver

Checker

Technical Director





## TEST REPORT

### EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

<u>Clause</u>	<u>Test Items/requirement</u>	<u>Test Result Summary</u>
<b>5</b>	<b><u>Requirements</u></b>	
<b>5.2</b>	<b>Performance requirements</b>	
5.2.2	Bacterial filtration efficiency (BFE)	> 98%
5.2.6	Summary of performance requirements	See Table 1

Table 1 Performance requirements for medical face masks

<b>Characteristics</b>	<b>Type I<sup>a</sup></b>	<b>Type II</b>	<b>Type IIR</b>
Bacterial filtration efficiency (BFE), %	≥ 95	≥ 98	≥ 98
Differential pressure, Pa/cm <sup>2</sup>	< 40	< 40	< 60
Splash resistance (kPa) <sup>#</sup>	Not Required	Not Required	≥16.0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

<sup>a</sup> Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

<sup>#</sup> - An acceptable quality limit of 4,0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show “pass” results.



## TEST REPORT

Result 1 Bacterial filtration efficiency (BFE) (EN14683:2019+AC:2019 Appendix B)

Blue mask:  
 Test Side: White Colour (Inside)  
 Pre-Conditioning: 5 hours at 21 °C±5°C and 85%±5% R.H.  
 Dimensions of test specimen: 14cm x 12cm  
 BFE Test Area: 95 cm<sup>2</sup>  
 BFE Flow Rate: 28.3 l/min  
 Test bacteria: Staphylococcus aureus ATCC 6538  
 Positive Control Average: 2065CFU  
 Negative Monitor Count: 0 CFU

Test Specimen	Percent BFE (%)
1	99.95
2	99.47
3	99.85
4	99.81
5	99.56



## TEST REPORT

Pink mask:  
 Test Side: White Colour (Inside)  
 Pre-Conditioning: 5 hours at 21 °C±5°C and 85%±5% R.H.  
 Dimensions of test specimen: 14cm x 12cm  
 BFE Test Area: 95 cm<sup>2</sup>  
 BFE Flow Rate: 28.3 l/min  
 Test bacteria: Staphylococcus aureus ATCC 6538  
 Positive Control Average: 2065CFU  
 Negative Monitor Count: 0 CFU

Test Specimen	Percent BFE (%)
1	99.66
2	99.81
3	99.66
4	99.81
5	99.61





## TEST REPORT

Note:

1. Results reported on the submitted sample on an as received basis.
2. The analysis was performed by a SMQ assessed competent subcontractor laboratory.

Photo Appendix



\*\*\*\*\* End of Report \*\*\*\*\*