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

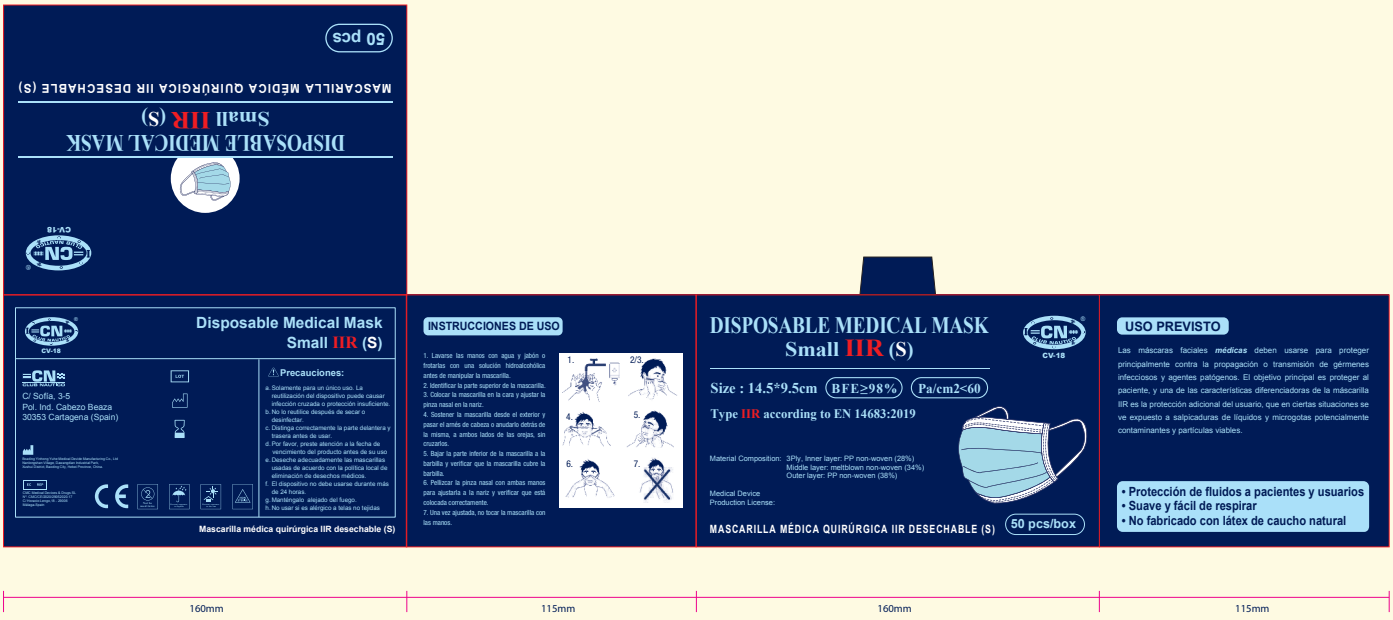
CV-18

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:

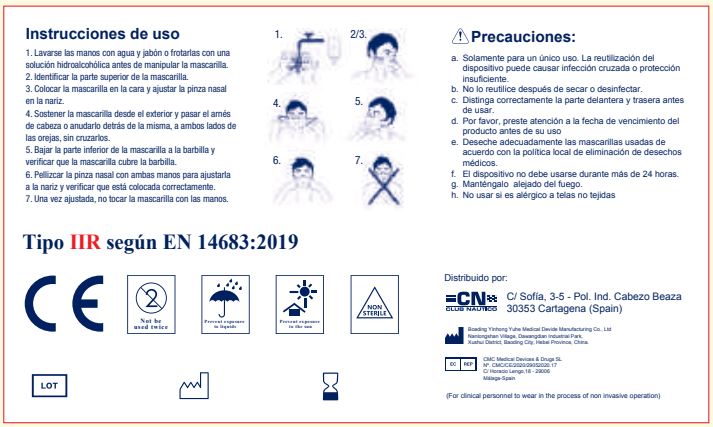
产品名称：一次性使用医用口罩（小号）（非无菌）
执行标准：EN14683:2019+AC：2019
生产厂商：保定银虹裕赫医疗器械制造有限公司
生产地址：保定市徐水区大王店工业园区南隆喜村口

MADE IN P.R.C.

BOX: 50 pcs



BAG: 10 pcs



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

CE

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

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. SL520352609590O1TX 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)

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^2
Test Side	:	Inside
Flow Rate	:	28.3 l/min
Positive Control Average	:	2272 CFU
Negative Monitor Count	:	< 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	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^2
Flow Rate	:	8 l/min

	1#	2#	3#	4#	5#
Differential pressure △ P (Pa/cm^2)	45	49	49	46	44

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

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: ≥16.0kPa
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≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

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

3rd Building, No.889 Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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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**

CE

Issued on: 29/05/2020

Valid until: 28/05/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

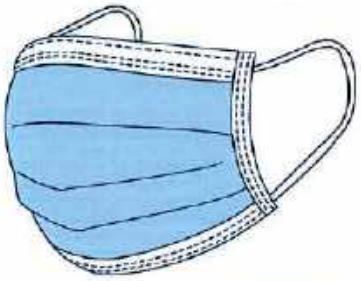
ANNEX I Medical Device Products

Disposable Medical Mask

CE

DISPOSABLE MEDICAL MASK
Small IIR (S)

CN
CV-18



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 Licenses: XXXXXXXXXXX

10 uds

Distribuido por:

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

Instrucciones de uso

1. Lavarse las manos con agua y jabón o frotarlas 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 pinza nasal en la nariz.
4. Sostener la mascarilla desde el exterior y pasar el arnés de cabeza o anudado debajo de la oreja, a ambos lados de las orejas, sin enredos.
5. Bajar la parte inferior de la mascarilla a la barbilla y verificar que la mascarilla cubre la barbilla.
6. Pellizcar la pinza 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 esterilizar 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

CE

LOT XXXXX

XXXXX

XXXXX

Distribuido por:

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

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

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, NOTRE SOCIÉTÉ REVÉRIFIE QUE LA MARCHANDISE EST RÉELLEMENT AUTHENTIQUE EN SE CONFORMANT AUX NORMES LES PLUS EXIGEANTES D'EUROPE.

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:	/
Manufacturered 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

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

TEST REPORT

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

Clause	Test Items/requirement	Test Result Summary
5	**Requirements**	
5.2	**Performance requirements**	
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

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

[a] 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.

[#] - 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.

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

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°Cand 85%±5% R.H.
Dimensions of test specimen:	14cm x 12cm
BFE Test Area:	95 cm^2
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

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

TEST REPORT

Pink mask:

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

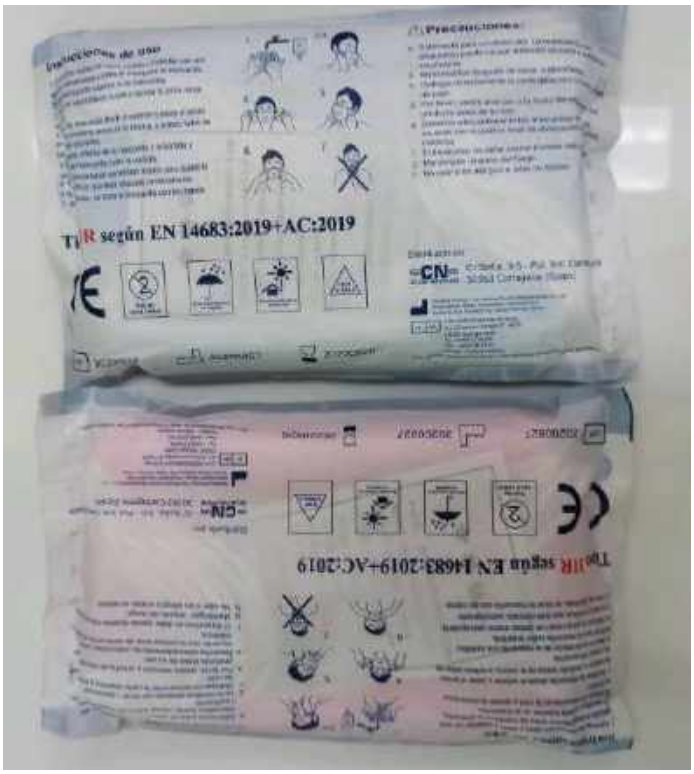
Test Specimen	Percent BFE (%)
1	99.66
2	99.81
3	99.66
4	99.81
5	99.61

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 ******