

Masques Chirurgicaux



ROSSI CARE
GLOBAL SOLUTIONS

EPI

**+
Type IIR**

A PROPOS

01

QU'EST CE QU'UN MASQUE CHIRURGICAL ?

Un masque chirurgical (aussi nommé anti-projections, ou d'hygiène ou à trois plis) est un masque respiratoire à usage unique conçu pour limiter la propagation vers l'environnement très proche des germes (bactéries, virus) depuis la bouche, le nez et les voies respiratoires de la personne qui le porte, en retenant les gouttelettes respiratoires dans un écran filtrant non tissé pouvant comporter une couche imperméable.

02

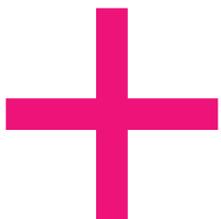
TYPE IIR ?

Il doit filtrer à 98 % ou plus les bactéries. La pression différentielle doit être inférieure à 40 Pa/cm² et la propreté microbienne inférieure à 30 ufc/g. En revanche il a également une résistance aux projections de 16 kPa.

03

COMMENT LE FAISONS-NOUS ?

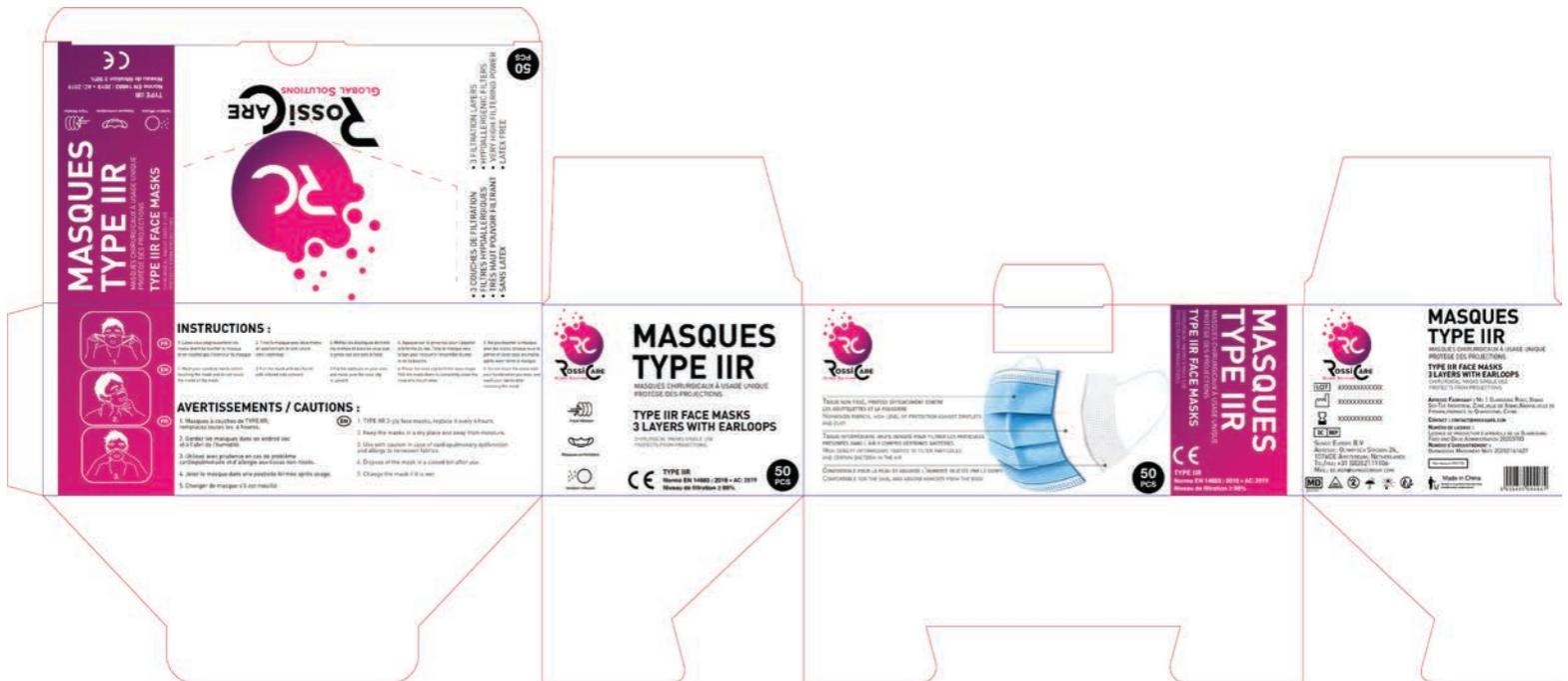
Nous produisons uniquement dans des usines certifiées avec lesquelles nous avons liés des partenariats sur le long terme. Le respect des valeurs humaines et environnementales sont des éléments indispensables dans notre production. Nos masques proviennent de Chine et sont fabriqués dans la province de Guangdong.



LES MASQUES



LA BOITE



HAUTEUR: 75mm
LONGUEUR: 185mm
LARGEUR: 100mm
POIDS: 180g

CONDITIONNEMENT



Par carton de 2 000 masques
40 boîtes de 50 masques par carton



HAUTEUR: 320mm
LONGUEUR: 520mm
LARGEUR: 390mm
POIDS: 7,5kg

Fiche Technique

Masque

- Masque médical non tissé (70%) et tissu fondu (30%)
- 3 couches de protection
- Taille 17,5cm x 9,5cm
- Fixation par boucles élastiquées
- Efficacité de filtration bactérienne >98 %
- Couleur bleue

Boite

- Sachet de 50 masques
- Taille 18,5cm x 10cm x 7,5cm
- Poids 180 grammes

Carton

- 2 000 masques
- Taille 52cm x 39cm x 32cm
- Poids 7,5kg

Conformité

- CE
- EN 14683:2019 + AC : 2019
- Code douanier 6307909511

NOTICE DANS LES BOITES

NOTICE ET CONSIGNES D'UTILISATION

MASQUE TYPE IIR

EN14683 : 2019 + AC : 2019

AVERTISSEMENT

POUR PROTÉGER VOTRE SANTÉ ET CELLE DES AUTRES, IL EST IMPORTANT DE RESPECTER CES CONSIGNES D'UTILISATION.

- Portez ce masque quand vous êtes en contact avec d'autres personnes et respectez les règles de distanciation sociale.
- Vérifiez toujours que le masque est bien ajusté et couvre votre bouche et votre nez.
- Ce masque ne remplace pas les gestes barrières (lavage régulier des mains, distanciation physique, réduction des contacts avec d'autres personnes). Il ajoute une barrière physique, à utiliser notamment lorsque vous êtes en contact avec d'autres personnes.

COMMENT METTRE ET UTILISER UN MASQUE CHIRURGICAL ?

- 1) Lavez vous soigneusement les mains avant de toucher le masque et ne touchez pas l'intérieur du masque
- 2) Tirez le masque avec deux mains en positionnant le coté coloré vers l'extérieur.
- 3) Mettez les élastiques derrière vos oreilles et assurez-vous que le pince nez soit vers le haut.
- 4) Appuyez sur le pince nez pour l'adapter à la forme du nez. Tirez le masque vers le bas pour recouvrir l'ensemble du nez et de la bouche.
- 5) Ne pas toucher le masque avec les mains lorsque vous le portez et lavez vous les mains après avoir retiré le masque

PRÉCAUTIONS D'USAGE

- 1) Masques à couches de TYPE IIR, remplacez toutes les 4 heures.
- 2) Gardez les masques dans un endroit sec et à l'abri de l'humidité.
- 3) Utilisez avec prudence en cas de problème cardiopulmonaire et d'allergie aux tissus non-tissés.
- 4) Jeter le masque dans une poubelle fermée après usage. Si vous êtes malade, jetez le masque dans un sac fermé et conservez-le 48h avant élimination.
- 5) Changer de masque s'il est mouillé

MISE EN GARDE

- 1) Masque à usage unique pour une durée de 4h maximum. En cas de réutilisation, le masque n'apporte plus de protection.
- 2) Mettre le masque usagé dans une poubelle pourvue à cet effet ou à défaut dans un sac fermé contenant uniquement le masque en question.
- 3) En cas d'incident grave survenu en lien avec le dispositif, ce dernier doit faire l'objet d'une notification au fabricant et à l'autorité compétente de l'Etat membre dans lequel l'utilisateur est établi.
- 4) En cas d'allergies ou effets secondaires tel que acné, toux, rougeurs, prenez rendez-vous avec votre medecin traitant.

CARACTÉRISTIQUES PERFORMANCES

Efficacité de filtration bactérienne (EFB) \geq 98%
 Respirabilité (pression différentielle) $<$ 60Pa/cm²
 Résistance aux projections \geq 16,0 kPa

MANDATAIRE EUROPÉEN

Sungo Europe B.V
 Adresse: Olympisch Stadion 24,
 1076DE Amsterdam, Netherlands
 Mail: ec.rep@sungogroup.com

FABRICANT

Guangdong Winsun Personal Care Products Co Ltd
 No.1 Guangxing Road, Xiqiao
 Sci-Tec Industrial Zone, ville de Xiqiao, Nanhai, ville de
 Foshan, province du Guangdong, Chine.

DISTRIBUTEUR ROSSI CARE

Rossi Corp
 Route de feumusson
 72530 Yvré l'Évêque
 contact@rossicare.com



Made in China

Notice du 24/11/2021 version 1,0

CERTIFICAT DANS LES BOITES

CERTIFICAT DE PRODUIT

Nom du produit: Masque Facial Médical Jetable
Spécification: Non-Stérile/17.5*9.5cm(±5%)
Norme exécutive: EN14683:2019 Type IIR
Contenu: Non-tissé Spunbond 52%, non-tissé fondu 25%,
contour d'oreille élastique 13%, bande de nez 10%
Lot de production.:GD210087EA
Date de Production:2021.03.29
Période de validité:2023.03.28
Conditions de stockage: Stocker dans un environnement
aéré et sec pour éviter l'humidité et la moisissure
Quantité: 50 PCS
Numéro d'enregistrement:
Guangdong Machinery Note 20202141637
Numéro de licence:
Licence de production d'appareils de la Guangdong Food
and Drug Administration 20203703
Numéro de l'inspecteur qualité: QC01
Fabricant:
Guangdong Winsun Personal Care Products Co.,Ltd
Adresse du fabricant:
No.1 Guangxing Road,Xiqiao Sci-Tec Industrial Park,
ville de Xiqiao,Nantai,ville de Foshan,province du
Guangdong, Chine.

**"Ce produit a réussi l'inspection
et est autorisé à quitter l'usine"**

PRODUCT CERTIFICATE 合格证

Product Name(品名): 一次性使用医用口罩
Disposable Medical Face Mask
Specification(规格): 非灭菌型/17.5*9.5cm(±5%)
Non-Sterile/17.5*9.5cm(±5%)
Executive standard(执行标准): EN14683:2019 Type IIR
Content(成分含量):
纺粘无纺布52%, 熔喷布 25%, 耳带 13%, 鼻夹10%
Spunbond nonwoven 52%, meltblown nonwoven 25%, elastic
earloop 13%, nose strip 10%
Production Lot No.(生产批号): GD210087EA
Production Date(生产日期): 2021.03.29
Expiration Date(有效日期): 2023.03.28
Storage conditions(储存条件):
存放于通风干爽环境, 避免受潮发霉
Store in dry and ventilated environment to avoid moisture
and mildew
Quantity(产品片数): 50 PCS
Registration No.(注册证编号): 粤械注准20202141637
Licence No.(许可证编号): 粤食监械生产许20203703号
Inspection No.(质检员工号): QC01
Manufacturer(生产商):
广东昱升个人护理用品股份有限公司
Guangdong Winsun Personal Care Products Co.,Ltd
Manufacturer address(生产商地址):
No.1 Guangxing Road,Xiqiao Sci-Tec Industrial Park,Xiqiao
Town,Nantai district,Foshan City,Guangdong
Province,P.R.China.
广东省佛山市南海区西樵镇西樵科技工业园广兴路1号

本产品经检验质量合格, 准予出厂。
This product is qualified after inspection and is approved
to deliver.

CERTIFICATS

File No: YS-MDR-01-02



EC Declaration of Conformity



Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Guangdong Winsun Personal Care Products Co.,Ltd
Address: NO.1 Guangxing Road,Xiqiao Sci-Tec Industrial Park,Xiqiao Town,Nanhai District,Foshan City,Guangdong Province, P.R.China

European Authorised Representative

Company: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable medical face mask
Model: Non-sterile type PM175, Non-sterile type PM175H01, Non-sterile type PM175H02,
Non-sterile Child type, Non-sterile type 3D14

SRN: -

UDI-DI: -

Classification: I

Rule: According to Rule 1, Annex VIII, EU Medical Device Regulation (2017/745)

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Medical Device Regulation and the following harmonized standards.

- EN ISO 14971: 2012
- EN ISO 15223-1: 2016
- ISO 10993-1: 2018
- EN ISO 10993-5: 2009
- EN ISO 10993-10: 2013
- EN 1041: 2008
- EN 14683 : 2019

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



[Signature]
Authorized Signature (S)

Signature: *[Signature]*

Position: Director

Date: 2020.5.8



Certificate CN20/42094

The management system of

Guangdong Winsun Personal Care Products Co., Ltd.

NO. 1 Guangxing Road, Xiqiao Sci-Tec Industrial Zone, Xiqiao Town, Nanhai District, Foshan City, Guangdong Province, 528211, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

Design and manufacture of single use non-sterile medical face mask

This certificate is valid from 17 June 2020 until 16 June 2023 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2 June 2023

Issue 1. Certified since 17 June 2020

Authorised by

A handwritten signature in black ink, appearing to be the initials "KR" followed by a long horizontal stroke.

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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HC SGS 13485 2016 0118

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GUANGDONG WINSUN PERSONAL CARE PRODUCTS CO., LTD
NO.1 GUANGXING ROAD, XIQIAO SCI-TEC INDUSTRIAL PARK, XIQIAO TOWN, NANHAI DISTRICT,
FOSHAN CITY, GUANGDONG PROVINCE

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

Sample Description : (A) Disposable Medical Face Mask (Claimed Type IIR)
Composition : (A) Spunbond nonwoven, meltblown nonwoven, elastic earloop, nose strip etc
Sample Color : (A) Blue/White
Lot No./Batch No. : Not provided
Proposed Care Instruction : -
Sample Receiving Date : May 28, 2020
Testing Period : May 28, 2020 - Jun 19, 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).
Test Performed : Selected test(s) as requested by applicant

Comment:

| | |
|---|----------|
| EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods | (A) |
| Clause 5.2 Performance Requirement | |
| Clause 5.2.2 Bacterial filtration efficiency (BFE) | M |
| Clause 5.2.3 Breathability | M |
| Clause 5.2.4 Splash Resistance | M |
| Clause 5.2.5 Microbial Cleanliness | M |
| Clause 5.2.6 Biocompatibility | EXCLUDED |

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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

Sara Guo

Sara Guo (Account Executive)

Dongjing Liu Helen Xuan

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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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 : ~172 mm x 152 mm
 Test Area : ~60 cm²
 Test Side : Inside
 Flow Rate : 28.3 l/min
 Positive Control Average : 2914.5 CFU
 Negative Monitor Count : < 1 CFU

| | 1# | 2# | 3# | 4# | 5# |
|----------|------|------|------|------|------|
| (BFE), % | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |

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 cm²
 Flow Rate : 8 l/min

| | 1# | 2# | 3# | 4# | 5# |
|---|----|----|----|----|----|
| Differential pressure ΔP (Pa/cm ²) | 31 | 31 | 32 | 33 | 32 |

Remark: Performance Requirement: Type I <40 Pa/cm², Type II <40 Pa/cm², Type IIR <60 Pa/cm²



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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: $\geq 16.0\text{kPa}$
- 2) Distance of the medical face mask target area surface to the tip of cannula is $300\pm 10\text{mm}$.
- 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: A

| | 1# | 2# | 3# | 4# | 5# |
|-------|----|----|----|----|----|
| CFU/g | 1 | 1 | 1 | <1 | 1 |

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 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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