FICHA TÉCNICA

MASCARILLAS 3 PLIEGUES
de Niños Unisex con Soft Earloop

Certificación: GB/T38880-2020

IDENTIFICACIÓN DEL PRODUCTO

Modelo	Mascarilla 3 pliegues de Niños Unisex con Soft Earloop
Material	Non Woven de fibra de Polipropileno.
Color	Celeste
Tallas	Única.
Presentación	Caja con 50 unidades. 40 cajas por cartón.

ESPECIFICACIONES TÉCNICAS

Función	Elemento de protección personal que cubre boca y nariz. Filtra los principales gérmenes del ambiente. Ayuda a evitar contagios de virus y bacterias. Además protege contra salpicaduras de sangre y saliva. Se cataloga como un elemento de protección respiratoria.		
Libre de látex	Si	**Estéril**	No
Tamaño	14,5 cm x 9,5 cm		
Vigencia	2 años a partir de la fecha de fabricación indicada en el empaque.		
Almacenamiento	En lugar fresco y seco. Temperatura 5 a 30°C.En caso de cumplir con dichas condiciones el producto tiene duración de hasta 3 años		
Uso	Producto descartable para un solo uso. No reutilizar.		

CARACTERÍSTICAS DEL PRODUCTO

Suave	Si	**Resistente**	Si	**Adaptable**	Si
Hipoalargénico	Si	**Respirable**	Si	**Impermeable**	No
BFE	Sobre 90%. Eficiencia de filtración bacterial.				
Capas	3 capas de non woven de Polipropileno.				
Tiradores	Corte elástico plano para máxima suavidad.				
Clip (cierre nasal)	Cobertura interna de Polietileno + acero.				

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Product: Disposable protective mask

Type Designation: 17.5 × 9.5cm (±0.5cm), 14 × 9cm (±1cm)

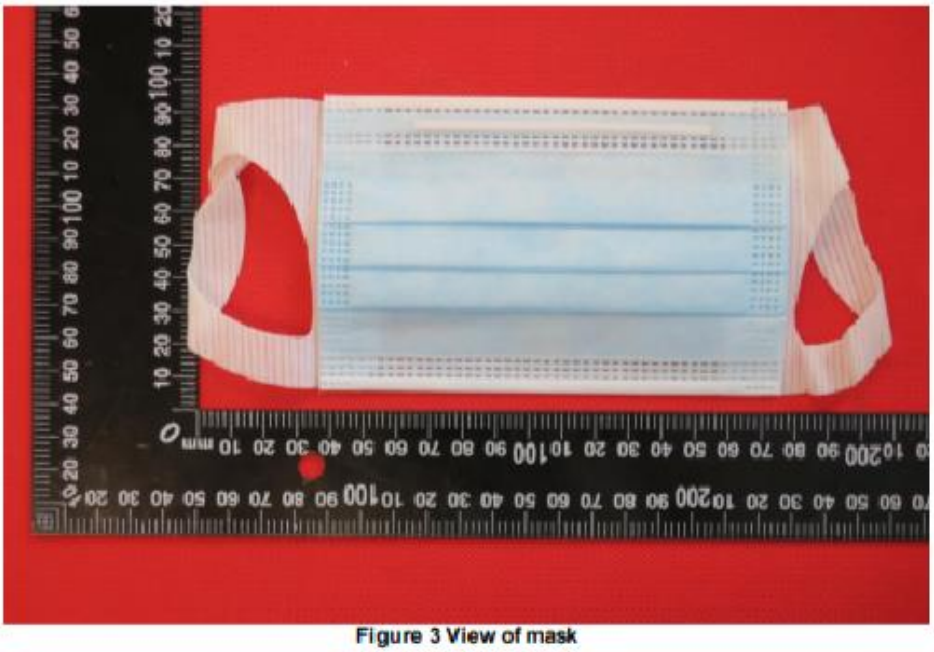

Figure 3 View of mask

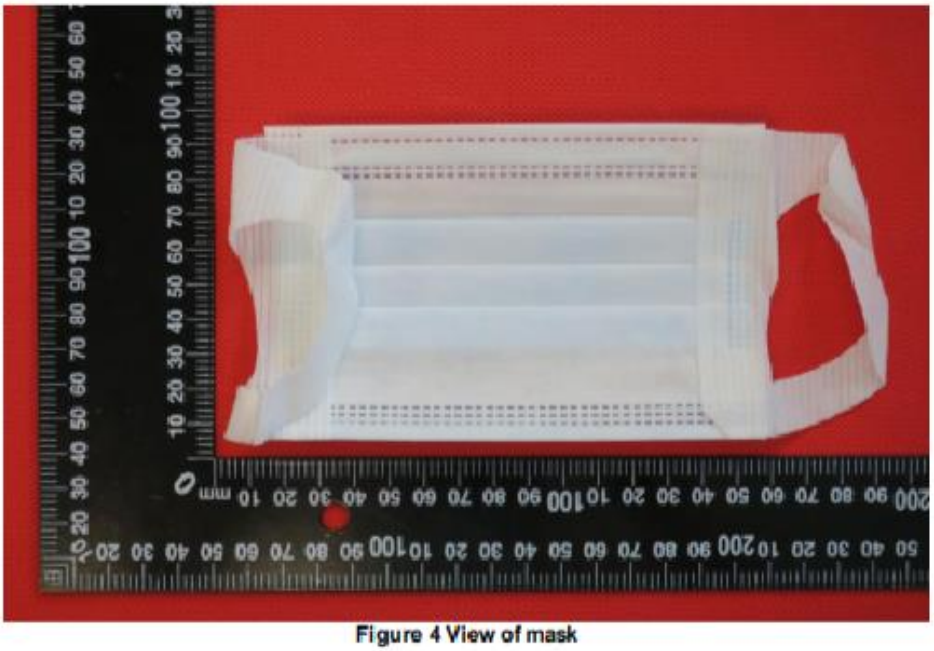

Figure 4 View of mask

ATTACHMENT **Photo Documentation**

TÜVRheinland®

Report No.: 60372575 002

Product: Disposable protective mask

Type Designation: 17.5 × 9.5cm (±0.5cm), 14 × 9cm (±1cm)

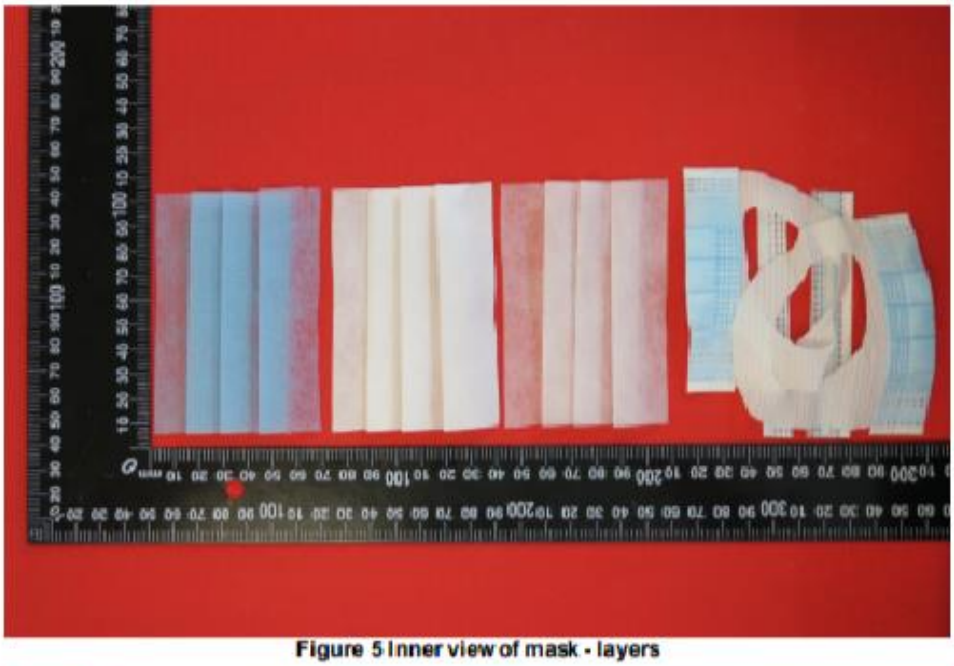

Figure 5 Inner view of mask - layers

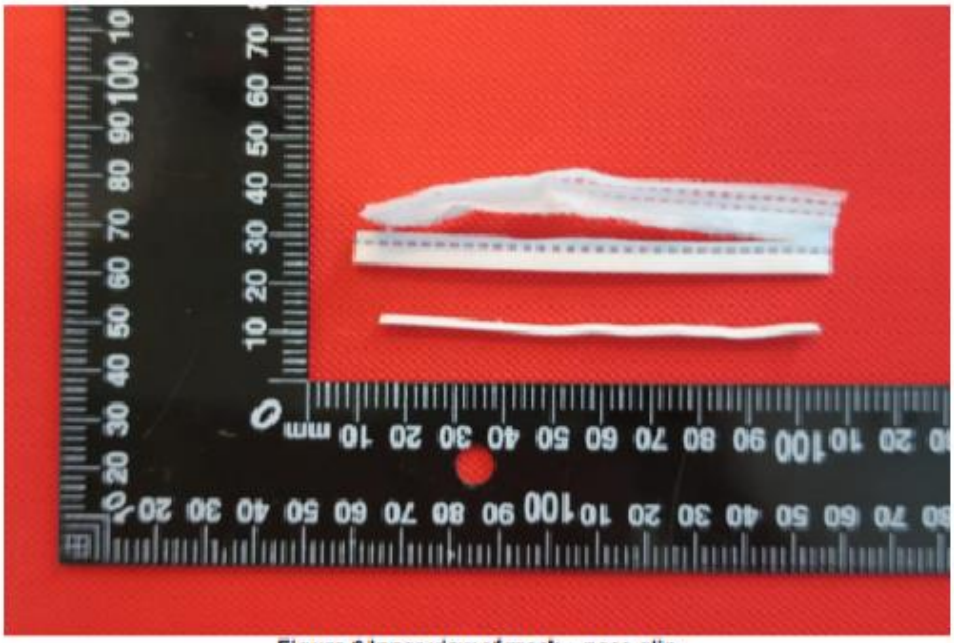

Figure 6 Inner view of mask – nose clip

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ATTACHMENT **Photo Documentation**

TÜVRheinland®

Report No.: 60372575 002

Product: Disposable protective mask

Type Designation: 17.5 × 9.5cm (±0.5cm), 14 × 9cm (±1cm)

Figure 1 View of packaging box for mask
(Final marking of package box refer to Figure 7 to Figure 10 below)

Figure 2 View of packaging for mask in box
(Final marking of label refer to Figure 11 below)

FICHA TÉCNICA

ATTACHMENT **Photo Documentation**

TÜVRheinland®

Report No.: 60372575 002

Product: Disposable protective mask

Type Designation: 17.5 × 9.5cm (±0.5cm), 14 × 9cm (±1cm)

Figure 7 Front/ top view of Package on box for mask

Figure 8 Side view of Package on box for mask

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Produkte
Products

TÜVRheinland®

Prüfbericht-Nr.: *Test Report No.:*	**60372575 002**	**Auftrags-Nr.** *Order No.:*	**168265367**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.:*	N/A	**Auftragsdatum:** *Order date:*	May 18, 2020	
Auftraggeber: *Client:*	**GUANGZHOU SUNRISE SANITARY ARTICLES CO., LTD.** NO.3, BEIYI ROAD, HETING INDUSTRIAL ZONE, BAIYUN DISTRICT, GUANGZHOU, GUANGDONG, 510470, P.R. China			
Prüfgegenstand: *Test item:*	Disposable protective mask			
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	17.5 x 9.5cm (±0.5cm), 14 x 9cm (±1cm)			
Auftrags-Inhalt: *Order content:*	Type test			
Prüfgrundlage: *Test specification:*	EN 14683:2019+AC:2019 except for clause 5.2.6			

Wareneingangsdatum: *Date of receipt:*	May 18, 2020
Prüfmuster-Nr.: *Test sample No.:*	202004A
Prüfzeitraum: *Testing period:*	May 20, 2020
Ort der Prüfung: *Place of testing:*	See page 3
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland (Shenzhen) Co., Ltd.
Prüfergebnis*: *Test result*:*	Pass

See Attachment: Photo documentation for details.

geprüft von / *tested by:*

Javen Ke

May. 20, 2020 Javen Ke/Assistant Project Engineer

Datum *Date*	Name / Stellung *Name / Position*	Unterschrift *Signature*

kontrolliert von / *reviewed by:*

Angela Ch

May. 21, 2020 Angela Chen / Department Manager

Datum *Date*	Name / Stellung *Name / Position*	Unterschrift *Signature*

Sonstiges / *Other:*
- This report is only valid in conjunction with previous report No. 60372575 001.
- The change is add one model 14 x 9cm (±1cm) which is same as previous model 17.5 x 9.5cm (±0.5cm) except for dimension. No more test deem necessary after review.
- This test report consists of EN 14683 test report including this cover page (6 pages) and attachment: Photo documentation (6 pages).

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m test specification(s)		*F(ail) = failed a.m test specification(s)*	*N/A = not applicable*	*N/T = not tested*

V04

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Report No. 60372575 002

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	**60372575 002**
Date of issue ..... :	**See cover page**
Total number of pages ..... :	**See cover page**
Testing Laboratory ..... :	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address ..... :	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name ..... :	**GUANGZHOU SUNRISE SANITARY ARTICLES CO., LTD.**
Address ..... :	NO.3, BEIYI ROAD, HETING INDUSTRIAL ZONE, BAIYUN DISTRICT, GUANGZHOU, GUANGDONG, 510470, P.R. China
Test specification:	
Standard ..... :	EN 14683.2019+AC.2019
Test procedure ..... :	Type test
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019_A
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-03
Test item description ..... :	Disposable protective mask
Trade Mark ..... :	Not shown
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	17.5 × 9.5cm (±0.5cm), 14 × 9cm (±1cm)
Classification ..... :	Type II

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Report No. 60372575 002

List of Attachments (including a total number of pages in each attachment):
Attachment – Photo Documentation (6 pages)

Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shenzhen) Co., Ltd.** 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China

Copy of marking plate
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks. **See attachment.**

Testing
Date of receipt of test item(s).....: See cover page
Dates of tests performed.....: See cover page
Possible test case verdicts:
- test case does not apply to the test object ..... : N/A
- test object does meet the requirement ..... : P (Pass)
- test object was not evaluated for the requirement ... : N/E (collateral standards only)
- test object does not meet the requirement ..... : F (Fail)
General remarks:
"(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report. **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**
Name and address of factory (ies) .....: Same as the applicant
General product information:
- Refer to previous report No. 60372575 001 for more details. **- This report is only valid in conjunction with previous report No. 60372575 001.** **- The change is add one model 14 × 9cm (±1cm) which is same as previous model 17.5 × 9.5cm (±0.5cm) except for dimension.** **- Clause 5.1.1 & 5.1.2 have been checked accordingly, no more test deem necessary after review.**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
5	**Requirements**		**P**
5.1	**General**		**P**
5.1.1	**Materials and construction**		**P**
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	3 ply designed with two layers of nonwovens and one layer of melt-blown cloth.	**P**
	The medical face mask shall not disintegrate, split or tear during intended use.		**P**
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		**P**
5.1.2	**Design**		**P**
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		**P**
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	With nose clip	**P**
6	**Marking, labelling and packaging**		**P**
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See attachment.	**P**
	The following information shall be supplied:		**P**
	a) number of this European Standard;		**P**
	b) type of mask (as indicated in Table 1).		**P**
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		**P**

End of EN 14683 test report