MEDICAL FACE MASK

Type IIR

SAFE, CLEAR COMMUNICATION

The **Smile Shield™** has changed the way people connect. Offering **IIR Mask Protection**, yet allowing **clear communication.**

The mask is perfect for areas where **facial expression, lip reading or greater connection** is required.

CARE HOMES | HOSPITALS | DISABLED CARE | EDUCATION

ANTI FOG CLEAR PANEL

HYPO-ALLERGENIC

COMFORTABLE EAR LOOPS

>98% BFE

ADJUSTABLE NOSE STRIP

Box Code: SSMIIR50

50 p/Box (15x7x7cm)

2,000 p/Case (40x40x60cm)

CE | EN 14683:2019+A1:2019 |

BENEFITS

Human connection is built on clear communication. The benefits of **Smile Shield™** include:

- Clear Communication
- Allows Lip Reading
- Visible Facial Expressions
- Deeper Connection

PERFECT FOR

Smile Shield™ has a clear front panel which makes the mouth visible to facilitate clear communication with people who rely on lip reading and facial expressions to support communication. This includes people who are deaf, have a learning disability, autism or dementia.

Smile Shield™ is recommended for:

- Hospitals Use e.g.
  - Audiology
  - Midwifery
  - Elderly Wards
  - Learning Difficulties
- Disabled Homes
- Care Homes
- Children e.g. Education
- Customer Service areas – e.g. Reception
- Areas where clearer communication & protection are required.

BRIEF DESCRIPTION

The **Smile Shield™** has changed the way people connect. Offering **IIR Mask Protection**, yet allowing **clear communication** through a **clear panel**, the **Smile Shield™** is perfect for areas where **facial expression, lip reading or greater connection** is required.

SMILE SHIELD™ PRODUCT INFORMATION

PRODUCT TECHNICAL INFORMATION

Smile Shield™ is fully compliant to EN14683:2019+A1+2019 as an IIR mask.

EN14683:2019+A1:2019	IIR Requirement	Smile Shield™
Bacterial Filtration Efficiency (BFE) (%)	≥ 98%	Pass
Particulate Filtration Efficiency	<49,0	Pass
Fluid Resistance (kPa)	≥ 16,0	Pass
Differential Pressure (Pa/cm2)	≤ 30	Pass

PACKAGING DETAILS

Unit	Code	Quantity Per Unit	Dimensions (L X W X H cm)	Net Weight (kg)	Gross Weight(kg)
Box	SSMIIR50	50	19 x 9.7 x 7	0.190	0.215
Case	SSMIIR2000	2,000 (40 Boxes)	52 x 41 x 33	7.6	8.8

FEATURES

- Fully Compliant to EN14683 IIR
- Anti Fog Clear Panel
- Fluid Resistant
- Hypoallergenic
- Latex Free
- Comfortable Ear Loops
- Adjustable Nose Strip
- Non Sterile

BENEFITS

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CERTIFICATES

01. EC Declaration of Conformity

Manufacturer:	Name: ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD Add: Industrial park,Renhe Town,Tianchang city 239300,Anhui,China
European Representative:	Name: ZOUSTECH S.L. Add: Pso. Castellana,141–Planta 19, 28046–Madrid, Spain
Product Name:	Disposable Medical Face Mask
Object of the declaration:	Model: RDYL-00305, With Earloop
UMDNS Code:	12-447
Classification (MDD, Annex IX):	I , rule 1
Conformity Assessment Route:	Annex Ⅶ

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC modified with the Directive 2007/47/EC

Applicable standards by EU

ENISO13485:2016	EN 14683:2019+AC:2019	ISO14971:2019
ISO10993-1:2018	ENISO10993-5:2009	ISO10993-10:2010
ENISO 15223-1:2016	EN1041:2008/A1:2013	

Place of Issue: TIANCHANG, CHINA

Date of Issue: 2020-05-19

Signature:

Mr.Yihong Zhang

Position: General Manager

GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD agencia española de medicamentos y productos sanitarios

Envíos Telemáticos

3.0.44

Registro de Responsables de Productos Sanitarios

Usuario: RUBÉN VALLE IBASETA

Desconectar

Registro de Responsables de Productos Sanitarios - RPS/976/2020

Datos de la notificación

Datos de registro

Nº Registro	RPS/976/2020	**Fecha Registro**	21/05/2020

Datos del Responsable

Tipo de Responsable (*)	Rep. Autorizado	**Tipo de entidad**	Empresa
CIF(*)	B87637591	**Nombre (*)**	ZOUSTECH S.L
Dirección(*)	Paseo de la castellana 141 Planta 19		
Localidad (*)	Madrid		
Provincia(*)	Madrid	**CP(*)**	28046
Teléfono(*)	694 426 446	**Fax**	
e-mail(*)	legal@zoustech.eu	**Web**	

Datos del Fabricante

Nombre o Razón Social (*)	ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD		
Dirección (*)	Industrial park,Renhe Town		
Localidad (*)	Tianchang city ,Anhui		
País(*)	República Popular China	**CP**	239300
Teléfono (*)	00865502383216	**Fax**	
e-mail (*)	bao.le@162.com	**Web**	

Datos de Productos Comunicados

Estatus(*) Primera Comunicación

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios			
Nombre Comercial	**Tipo de Producto**	**Estado del producto**	**Acción**
MASCARILLA FACIAL DESECHABLE	Clase I	Primera Comunicación	

Comentarios

Enviar Solicitud

Agencia Española de Medicamentos y Productos Sanitarios
Parque Empresarial "Las Mercedes", Edif. 8, C/ Campezo 1 - 28022 MADRID | e-Mail: incidencias_aplicaciones@aemps.es

TEST REPORTS

REPORT NO: 2847

4ward Testing Ltd
5 Hampers Common
Industrial Estate
Petworth
West Sussex
GU28 9NR
United Kingdom

Tel.: +44 (0)1798 342240
+44 (0)1798 344323
Fax: +44 (0)1798 344482

info@4wardtesting.co.uk

www.4wardtesting.co.uk

REPORT

On the testing of

Medical Face Masks to EN14683:2019+AC:2019
Documented in house methods:
M0121, M0122, M0124, M0125

Supplied by:

TAD Medical Ltd
13 Oakfield Road
Clifton
Bristol
BS8 2AJ

Report Prepared by:

Anthony Hanson

Identification

Mask Description: Blue three ply foldable with ear loops and clear plastic mouth area.
Mask size: 17.5 by 9.5cm
Manufacturer: Anhui Rongda Medical Equipment Co Ltd
Batch number: Not specified
4ward Sample No: 2847
Customer reference: email TAD/PS 110221
Date received: 04/03/2021

Test Summary

	M1	M2	M3	M4	M5	Threshold	Result
Bacterial filtration efficiency (BFE), [%] 5.2.2	99.99	99.99	99.99	99.99	99.99	≥ 98	Pass
Breathability 5.2.3 (differential pressure) average of 5 areas/mask [Pa/cm2]	27.26	26.07	29.51	26.53	26.68	< 60	Pass
Splash resistance pressure 5.2.4 [kPa]	30 of 32 masks passed at 16kPa					≥ 29 @16kPa	Pass

Threshold for type IIR mask

Test Details

The Face Masks were tested as received from the customer

Testing of the Medical Face Masks was carried out to the following sections of EN 14683:2019+ AC:2019

Bacterial Filtration Efficiency Section 5.2.2

Test area: 49 cm^2
Exposed face: Inside
Test flow rate: 28.3L/min
Sample size: Full mask expanded (>10x10cm)
Mean plate counts
Positive controls: 3475 cfu
Negative control 0 cfu

Sample pre-conditioning: >4h @ 21± 5°C 85± 5%RH

BFE for each test specimen shown in summary table.

Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk < 5%.

Breathability Section 5.2.3

Test area: 4.9± 0.4 cm^2
Test quantity: 5 masks
Test positions: 1 centre, 4 spanning out from the centre
Test flow rate: 8L/min
Sample pre-conditioning: >4h @ 21± 5°C 85± 5%RH

		Mask1	Mask2	Mask3	Mask4	Mask5
Differential pressure [Pa/cm^2]	1	28.86	26.76	27.91	26.38	28.10
	2	24.46	20.26	32.49	23.89	23.51
	3	28.29	28.86	32.49	20.83	27.52
	4	28.86	26.76	25.42	30.58	26.57
	5	25.80	27.71	29.24	30.96	27.71
	Average	27.26	26.07	29.51	26.53	26.68

Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk < 5%.

Splash Resistance Section 5.2.4

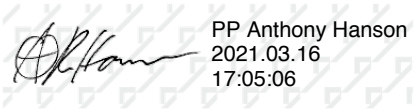
The test was carried out in accordance with ISO 22609:2004
Centre of mask targeted
Conditioned for >4h at 21± 5 °C 85± 5 % RH
Tested at 21± 5 °C 85± 10 % RH
No targeting plate was used
32 masks tested
30 masks Passed
Minimum of 29 Passes required

Pass - The Test passed the requirement AND had a conformance probability, pc>95 % for test conditions (Conditioning and test temperature and RH, synthetic blood surface tension and spray velocity)

Date of testing: 05 - 15/03/2021

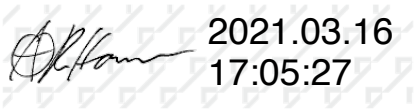
These results relate only to the samples tested

Work carried out and recorded by the following personnel:



Tessa Peters BSc
Laboratory Technician

Work approved by the following personnel:



Anthony Hanson
Quality Assurance Engineer

..... END .....

ANHUI RONGDA MEDEICAL EQUIPMENT CO.,LTD
NO 134 HUWEI ROAD,RENHE TOWN INDUSTRY ZONE,TIANCHANG CITY,ANHUI

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

Sample Description	:	(A)Mask
Composition	:	(A)non woven
Sample Color	:	(A)blue
Lot No.	:	RDY04520200929
Manufacturer	:	Rongda
Supplier	:	Market Union Co.,Ltd
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Oct 10, 2020
Testing Period	:	Oct 14, 2020 - Oct 26, 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 (Authorized Signatory)

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

Test Result

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

Clause 5.2 Performance Requirement

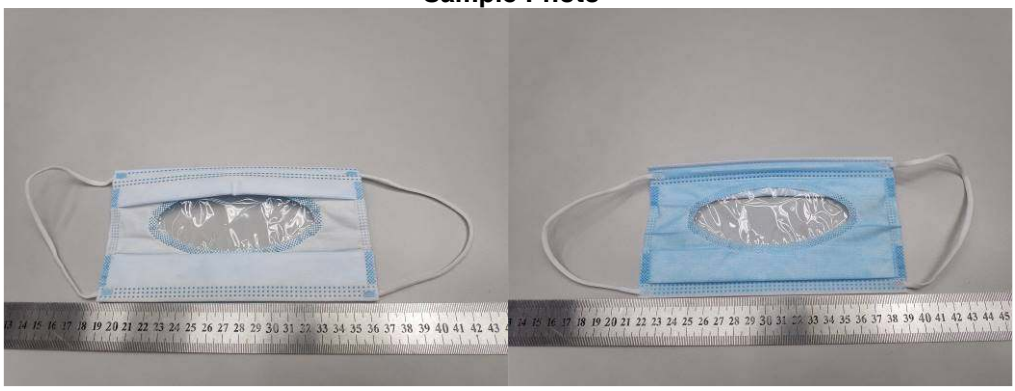
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.55	78	21.97
2#	3.52	78	22.16
3#	3.44	63	18.31
4#	3.63	84	23.14
5#	3.54	81	22.88

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

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

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center
检验检测专用章 Inspection & Testing Services
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

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中国认可
国际互认
检测
TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-03682-03A

Sample Name: SMILE MASK

Study Title: Skin Sensitization Test

Standard: ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD

Industrial Park, Renhe Town, Tianchang City, Anhui, 239300, China

Contents

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The extract of the test article was evaluated for its potential skin sensitization in the Guinea Pig Maximization Test.

The test articles were extracted with 0.9% sodium chloride injection and sesame oil respectively. The test article extract was intradermally injected into guinea pigs and applied topically for induction. Control animals were treated accordingly but with the solvent alone.

The topical challenge with the test article elicited no skin reaction in the test or the control animals. The skin sensitization rates of polar and non-polar group were both determined with 0%.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC17025:2017, IDT) and RB/T214-2017.

Date Received	2021-01-06
Technical Initiation Date	2021-01-11
Technical Completion Date	2021-02-07
Final Report Completion Date	2021-02-07

Edited by Molly Liu — 2021.02.07 Date

Checked by Suri Han — 2021.02.07 Date

Approved by Daisy Zheng — 2021.02.09 Date
Authorized signatory

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization using Guinea Pig Maximization Test.

2.0 Reference

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(ISO 10993-10:2010)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: SMILE MASK

Sterilization state: Unsterilized

Model/Size: N/S

Lot/ Batch#: RDYL20201221Y

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: Non woven Fabric, Melt blown Non Woven, PET

Packing Material: PP

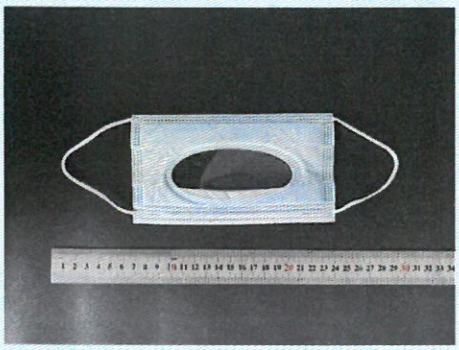
Storage Condition: Room temperature

Others: Sample surface area: 570 cm^2

Manufacturer: ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD

Manufacturer address: Industrial Park, Renhe Town, Tianchang City, Anhui, 239300, China

Sample photograph:



3.2 Control Articles

3.2.1 Polar Negative Control

Name: 0.9% Sodium chloride injection (SC)

Manufacturer: Chenxin Pharmaceutical Co., Ltd.

Size: 250 ml

Physical State: Liquid

Color: Colourless

Lot/ Batch#: 1906112830

Storage Condition: Room Temperature

3.2.2 Non-polar Negative Control

Name: Sesame Oil (SO)

Manufacturer: Ji'an lvyuanxiangliao. Co., Ltd.

Size: 20 kg

Physical State: Liquid

Color: Pale yellow

Lot/ Batch#: 20201116

Storage Condition: Room Temperature

4.0 Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 15 for polar group and 15 for non-polar group (10 for test and 5 for control in each group)

Sex: Male

Health status: Healthy, not previously used in other experimental procedures

Housing: Animals were housed in groups in cages identified by a card indicating the lab number and test code.

Animal identification: Stain with picric acid

The quarantine period: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Genesc Biotechnolongy Co .,Ltd <Permit Code: SCXK (SU) 2020-0001>

Bedding: NA

Feed: Guinea Pig Diet, Beijing Keao Xieli Feed Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Cages: Plastic cage, Suzhou Fengqiao purification equipment Co.,Ltd.

Environment: Temperature 18-29℃, Relative humidity 40%-70%, Lights 12 hours light/dark cycle

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

Veterinarian: Vet takes care of the whole course

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Justification of the test system

6.1 The guinea pig is believed to be the most sensitive animal model for this type of study. The susceptibility of the guinea pig to a known sensitizing agent, dinitrochlorobenzene (DNCB) has been substantiated at SSMT. The skin sensitized positive control test is conducted every six months. The last allergenic rate is 100%. The data was from the report SSMT-R-2020-00198-03 (Date: 2020-09-27) .

6.2 The test article was extracted and administered in vivo through a medium compatible with the test system, which is considered as the best route of administration.

7.0 Instruments and reagents

7.1 Instruments

Water bath thermostatic oscillator (SSMT-150)

Electronic balance (SSMT-075)

Electronic balance (SSMT-147)

Clean bench (SSMT-187)

7.2 Reagents

Sodium dodecyl sulfate (SDS)

Freund's Adjuvant, Complete liquid

8.0 Experiment design and dose

8.1 Sample preparation

The test article was extracted as Table 1. Extract was checked and used immediately after extraction without the process of filtering, centrifugation, dilution, etc. The pH of the extract was not adjusted prior to testing. The preparation process was aseptic. The control article was prepared under the same condition.

Table 1 Sample Preparation

Aseptic Sampling			Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Test phase	Actually Sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Take the whole. The surface area of one test sample is 570 cm^2 (Provided by the sponsor). One test sample was used in each test phase.	Intradermal induction phase I	570.0 cm^2	0.9% sodium chloride injection	3 cm^2 : 1 ml	190.0 ml	37 ℃, 72 h	Clear
	Topical induction phase II	570.0 cm^2			190.0 ml	37 ℃, 72 h	Clear
	Challenge phase	570.0 cm^2			190.0 ml	37 ℃, 72 h	Clear
	Intradermal induction phase I	570.0 cm^2	Sesame oil	3 cm^2 : 1 ml	190.0 ml	37 ℃, 72 h	Clear
	Topical induction phase II	570.0 cm^2			190.0 ml	37 ℃, 72 h	Clear
	Challenge phase	570.0 cm^2			190.0 ml	37 ℃, 72 h	Clear

8.2 Test method

8.2.1 Intradermal induction phase I

A pair of 0.1 ml intradermal injections was made for each animal, at the sites (A, B and C) in the clipped

intrascapular region as shown in the following Figure 1.

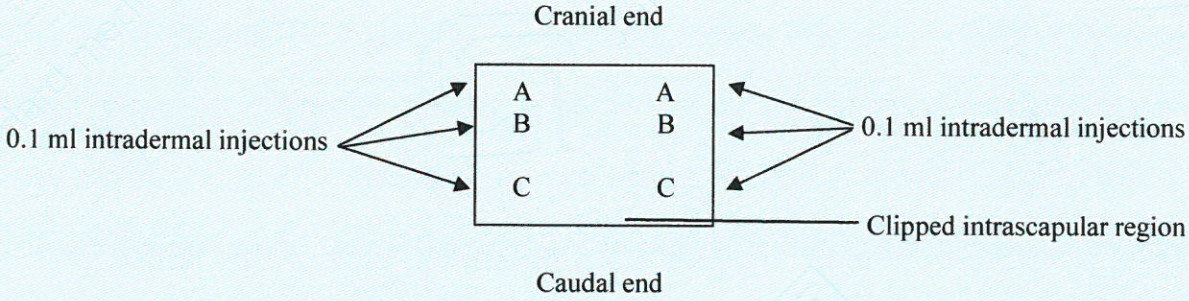


Figure 1 Location of intradermal injection sites

Site A: A 50:50 volume ratio stable emulsion of Freund's complete adjuvant mixed with the solvent.

Site B: The test sample (undiluted extract); inject the control animals with the control articles alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%); inject the control animals with an emulsion of the blank liquid with adjuvant.

8.2.2 Topical induction phase II

At 7 d after completion of the intradermal induction phase, administer the test sample by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze) soaked with 0.5 ml extract, so as to cover the intradermal injection sites. Use the concentration selected in the intradermal induction phase for site B. If the maximum concentration that can be achieved in Intradermal induction phase I did not produce irritation, animals were pretreated with 10% sodium dodecyl sulfate 24 hours before the topical induction application. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48 h.

Treat the control animals similarly, using the blank liquid alone.

8.2.3 Challenge phase

At 15 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer the test sample and a blank by topical application to left and right abdomen of animals respectively, using absorbent gauze (about 8 cm^2) soaked with 0.5ml extracts or solvent control. Secure with an occlusive dressing. Remove the dressings and patches after 24 h.

8.3 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals 24 h and 48 h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 2 for each challenge site and at each time interval.

Table 2 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

9.0 Evaluation criteria

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

10.0 Results of the test

The skin response of guinea pigs and body weight change are shown in Table 3.

Table 3 Guinea pig Sensitization Dermal Reactions

Extraction solvent	Group	Animal Number	Excitation patch removed 24 h	Excitation patch removed 48 h	Positive rate after challenge phase	Weight range before injection (g)	Weight range after experiment (g)	Abnormal appearance except dermal reactions
0.9% sodium chloride injection	Control	J1001	0	0	0%	318.2-342.6	462.8-491.2	None
		J1002	0	0				None
		J1003	0	0				None
		J1004	0	0				None
		J1005	0	0				None
	Test	J2001	0	0	0%	306.4-379.1	453.2-541.9	None
		J2002	0	0				None
		J2003	0	0				None
		J2004	0	0				None
		J2005	0	0				None
		J2006	0	0				None
		J2007	0	0				None
		J2008	0	0				None
		J2009	0	0				None
		J2010	0	0				None
Sesame oil	Control	F1001	0	0	0%	316.8-360.9	471.9-518.2	None
		F1002	0	0				None
		F1003	0	0				None
		F1004	0	0				None
		F1005	0	0				None
	Test	F2001	0	0	0%	308.1-372.4	451.8-541.6	None
		F2002	0	0				None
		F2003	0	0				None
		F2004	0	0				None
		F2005	0	0				None
		F2006	0	0				None

		F2007	0	0				None
		F2008	0	0				None
		F2009	0	0				None
		F2010	0	0				None

Under the condition of this study, the test article did not show significant evidence of causing skin sensitization in the guinea pigs. The skin sensitization rates of polar and non-polar test group were both determined with 0%.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.

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ilac-MRA CNAS
中国认可
国际互认
检测
TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-03682-02A

Sample Name: SMILE MASK

Study Title: Skin Irritation Test

Standard: ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD

Industrial Park, Renhe Town, Tianchang City, Anhui, 239300, China

Contents

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The animal skin irritation test was conducted to assess the potential irritation of the test article or material.

The test sample was extracted with 0.9% sodium chloride injection and sesame oil, respectively. The patches (about 2.5 cm×2.5 cm) which moistened by 0.5 ml extract of test article were directly applied to the rabbit skin for 4 hours. Observation for erythema and edema were conducted at 1 h, 24 h, 48 h and 72 h after removal of the patches.

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. The test result showed that the extract of the test article did not induce skin irritation in rabbit under the test condition.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC 17025:2017, IDT) and RB/T 214-2017.

Date Received	2021-01-06
Technical Initiation Date	2021-01-12
Technical Completion Date	2021-01-15
Final Report Completion Date	2021-02-07

Edited by Molly Liu 2021.02.07
Date

Checked by Suri Han 2021.02.07
Date

Approved by Daisy Zhang 2021.02.09
Authorized signatory
Date

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

New Zealand rabbits were used to evaluate the potential of skin irritation of samples under the condition of this test.

2.0 Reference

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(ISO 10993-10:2010)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: SMILE MASK

Sterilization state: Unsterilized

Model/Size: N/S

Lot/ Batch#: RDYL20201221Y

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: Non woven Fabric, Melt blown Non Woven, PET

Packing Material: PP

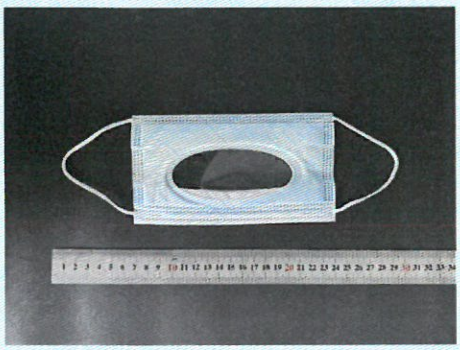
Storage Condition: Room temperature

Others: Sample surface area: 570 cm^2

Manufacturer: ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD

Manufacturer address: Industrial Park, Renhe Town, Tianchang City, Anhui, 239300, China

Sample photograph:



3.2 Control Articles

3.2.1 Polar Negative Control: 0.9% Sodium chloride injection (SC)

Manufacturer: Chenxin Pharmaceutical Co., Ltd.

Size: 250 ml

Physical State: Liquid

Color: Colourless

Lot/ Batch#: 1906112830

Storage Condition: Room Temperature

3.2.2 Non-polar Negative Control: Sesame Oil (SO)

Manufacturer: Ji'an lvyuanxiangliao. Co., Ltd.

Size: 20 kg

Physical State: Liquid

Color: Pale yellow

Lot/ Batch#: 20201116

Storage Condition: Room Temperature

4.0 Identification of test system

Species: New Zealand white rabbit (single strain)

Number: 6 (3 for polar test group and 3 for non-polar group)

Sex: Female

Weight: Initial body weight not less than 2.0 kg

Health status: Healthy, young adult, nulliparous and not pregnant.

Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date.

Animal identification: Cage card

The quarantine period: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Tongxiang Yinhai Animal Husbandry Professional Cooperative <Permit Code: SCXK (ZHE) 2018-0002>

Bedding: NA

Feed: Rabbit Diet, Beijing Keao Xieli Feed Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality (GB 5749-2006)

Cages: Stainless steel cage, Suzhou Fengqiao purification equipment Co.,Ltd.

Environment: Temperature 16-26℃, Relative humidity 40%-70%, Lights 12 hours light/dark cycle

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy animals were selected

Veterinarian: Vet takes care of the whole course

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics

There were no known contaminants present in the feed, water expected to interfere with the test data.

6.0 Justification of the test system

6.1 The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current

testing standards. Positive control 15% sodium dodecyl sulfate has been substantiated at SSMT with this method. Positive control tests are conducted every six months. The last irritation index of polar test group was 5.6. The last irritation index of non-polar test group was 5.8. The data was from the report SSMT-R-2020-01262-03 (Date: 2020-11-27).

6.2 The test article extract was directly applied to the rabbit skin, which was suggested by the standard.

7.0 Instruments

Water bath thermostatic oscillator (SSMT-150)

Electronic balance (SSMT-075)

Clean bench (SSMT-187)

8.0 Experiment design and dose

8.1 Sample preparation

The test article was extracted as Table 1. Extract was checked and used immediately after extraction without the process of filtering, centrifugation, dilution, etc. The pH of the extract was not adjusted prior to testing. The preparation process was aseptic. The control article was prepared under the same condition.

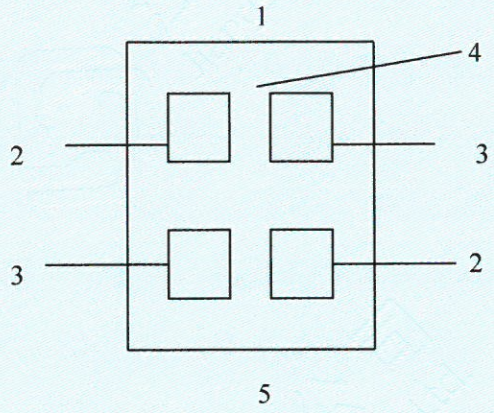
Table 1 Sample Preparation

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually Sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Take the whole. The surface area of one test sample is 570 cm^2 (Provided by the sponsor). One test sample was used in each test group.	570.0 cm^2	0.9% sodium chloride injection	3 cm^2 : 1 ml	190.0 ml	37 ℃, 72 h	Clear
	570.0 cm^2	Sesame oil	3 cm^2 : 1 ml	190.0 ml	37 ℃, 72 h	Clear

8.2 Test method

Use the rabbits with healthy intact skin. Fur is generally clipped on the back of the rabbits 16 h before testing, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10 × 15 cm).

Apply 0.5 ml extract of test article or control to 2.5 cm × 2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side as shown in Figure 1. And then wrap the application site with a bandage (semi-occlusive) for 4 h. At the end of the contact time, remove the dressings.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.3 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 2 for each application site at each time interval. Record the appearance of each application site at 1 h, 24 h, 48 h and 72 h following removal of the patches.

Table 2 Classification System for Skin Reaction

Reaction	Irritation score
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema Formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**

NOTE: Other adverse changes at the skin sites were recorded and are reported.

8.4 Result calculation

Use only 24 h, 48 h and 72 h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades 24 h, 48 h and 72 h are totalled separately for each test sample and blank for each animal. The primary irritation score for an animal is calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test sample add all the primary irritation scores of the individual animals and divide by the number of animals.

Calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

9.0 Evaluation criteria

The primary irritation index is characterized by number (score) and description (response category) given in Table 3.

Table 3 Primary irritation index categories in a rabbit

Mean score	Response category
0-0.4	Negligible
0.5-1.9	Slight
2.0-4.9	Moderate
5-8	Severe

10.0 Results of the test

According to what observed, the reaction of skin on testing side did not exceed that on the control side. See Table 4 .

Table 4 Dermal observations

Extraction solvent	Rabbit No.	Group		Interval			
				1h	24h	48h	72h
0.9% sodium chloride injection	J1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
Sesame oil	F1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	F1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	F1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. Under the conditions of this study, the extract of the test article did not induce skin irritation.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.

CMA
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中国认可
国际互认
检测
TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-03682-01A

Sample Name: SMILE MASK

Study Title: In Vitro Cytotoxicity Test

Standard: ISO 10993-5:2009

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

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Conclusion

The study was to investigate the potential cytotoxicity of the test sample. The extract of the test article was added to L-929 cells and then incubated at 37℃ in 5% CO_2 for 24 hours. After the incubation, observe the cell morphology. The results were detected with MTT method. The results showed that the cytotoxicity ratio of the 100% test article extract was 82.4% and the results of control groups showed the test was valid.

Under the conditions of this study, the extract of the test article did not show potential toxicity to L-929 cells.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (IDT ISO/IEC 17025:2017) and RB/T 214-2017.

Date Received	2021-01-06
Technical Initiation Date	2021-01-11
Technical Completion Date	2021-01-13
Final Report Completion Date	2021-01-20

Edited by Cindy Zhu — 2021.01.20 Date

Checked by Bella Pi — 2021.01.20 Date

Approved by Daisy Zhang — 2021.02.09 Date

Authorized signatory

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Standard

Biological evaluation of medical devices Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5:2009)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: SMILE MASK

Sterilization state: Not sterilized

Model/Size: N/S

Lot/ Batch#: RDYL20201221Y

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: Non woven Fabric, Melt blown Non Woven, PET

Packing Material: PP

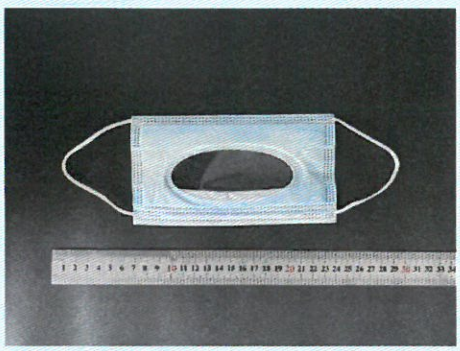
Storage Condition: Room temperature

Others: The surface area of a sample is 570.0 cm^2

Manufacturers: ANHUI RONGDA MEDICAL EQUIPMENT CO., LTD

Manufacturer address: Industrial Park, Renhe Town, Tianchang City, Anhui, 239300, China

Sample photograph:



3.2 Control Articles

3.2.1 Negative Control Article Name: High Density Polyethylene

Manufacturer: Jiangsu haiaosihui biotechnology co., LTD.

Size: 1.6 mm thick, 300*300 mm

Lot/ Batch#: M02F017

Physical State: Solid

Color: White

Storage Conditions: Room temperature

3.2.2 Positive Control Article Name: ZDEC

Manufacturer: Tokyo Into Industrial Co., Ltd.

Size: 25 g

Lot/ Batch#: DUDQG-JF

Physical State: Solid

Color: White

Storage Condition: Room temperature

Concentration: 0.1%

3.2.3 Blank Control Name: MEM medium, with addition 10% FBS

Physical State: Liquid

Color: Pink

Storage Condition: 4 ℃

4.0 Identification of test system

Mouse fibroblast L-929 cells obtained from ATCC CCL1 (NCTC clone 929).

5.0 Justification of test system

5.1 Historically, mouse fibroblast L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles.

5.2 The test article was extracted and administered in vitro to mouse fibroblast L-929 cells through a solvent compatible with the test system. This was the optimal route of administration available in this test system as recommended in the standard.

6.0 Instruments and Reagents

6.1Instruments

CO_2 Incubator (SSMT-279)

Biological microscope（SSMT-278）

Clean bench (SSMT-028)

Bench type low speed centrifuge (SSMT-048)

Vapour-bathing Constant Temperature Vibrator (SSMT-004)

Electronic Balance (SSMT-015)

Steel Straight Scale (SSMT-072)

Multiskan Spectrum Microplate Spectrophotometer (SSMT-139)

Mini Vibrator (SSMT-311)

6.2 Reagents

FBS

MEM

Trypsin

Penicillin, Streptomycin sulfate

PBS

MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide)

Isopropyl alcohol

7.0 Experiment design and dose

7.1 Sample preparation

Aseptic extracting the test article (test article to volume of vehicle) according to the table below. Sealed and incubated in Vapour-bathing Constant Temperature Vibrator at 37 ℃ and 60 rpm for 24 hours. After the extraction, check the extraction changes, and immediately use for the experiment, the leach was not filtered, centrifuged or diluted. No pH adjustment.

Table 1 Sample preparation

Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Take the whole. The surface area of one sample is 570.0 cm^2(provided by the sponsor). One sample was used in the test.	570.0 cm^2	MEM medium (10% FBS)	3 cm^2 : 1 ml	190.0 ml	37 ℃, 24 h	Clear

The blank control (MEM medium, with addition 10% FBS) and negative/positive controls were prepared in the same condition.

7.2 Test method

Aseptic procedures were used for handling cell cultures.

L-929 cells were cultured in MEM medium (10% FBS, Penicillin 100 U/ml, Streptomycin sulfate 100 μg/ml) at 37℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. And obtain a 1×10^5 cells/ml suspension by centrifuging (200 g, 3 min) and re-dispersing in MEM medium finally.

The suspended cells were dispensed at 100 μl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37℃, >90%humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 μl of extract of test article (100%, 75%, 50%, 25%), control article, negative article (100%) and positive article (100%) respectively. The 96-well plate was incubated at 37℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After 24 h incubation, observe the cell morphology first and then discard the culture medium. A 50 μl aliquot of MTT (1 mg/ml) was added to each well and then incubated at 37℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 μl isopropanol was added to each well to suspend the cell

layer. The microporous plate was vibrated for 10 min and monitored by the optical density at 570 nm on the microplate analyzer.

7.3 Statistical method

Mean±standard deviation ($\bar{x}\pm s$)

Viab. %=100×OD_{570e}/OD_{570b}

Where: OD_{570e}——is the mean value of the measured optical density of test sample/negative control/positive control;

OD_{570b}——is the mean value of the measured optical density of the blanks.

7.4 Observation of the cell morphology

Table 2 Observation of the cell morphology

Grade	Conditions of all cultures
0	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
1	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
3	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed, but more than 50 % growth inhibition observable.
4	Nearly complete or complete destruction of the cell layers.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

Table 3 Results of the cell vitality

Group	$\bar{x}\pm s$	Viability%	The morphology of the extracted cells was observed under the microscope
Blank control	0.750±0.016	100.0	0
Negative control	0.698±0.011	93.1	0

Positive control	0.031±0.033	4.1	4
100% test article extract	0.618±0.019	82.4	0
75% test article extract	0.650±0.021	86.7	0
50% test article extract	0.681±0.014	90.7	0
25% test article extract	0.706±0.014	94.1	0
Quality check	The mean OD_{570} of blanks is ≥ 0.2. The left (row2) and the right (row11) mean of the blanks do not differ by more than 15 %. The test meets the acceptance criteria.		
Conclusion	Under the conditions of this study, the test article did not show potential toxicity to L-929 cells.		

10.0 Deviation statement

There was no deviation from the approved standard operating procedure which were judged to have any impact on the validity of the data.

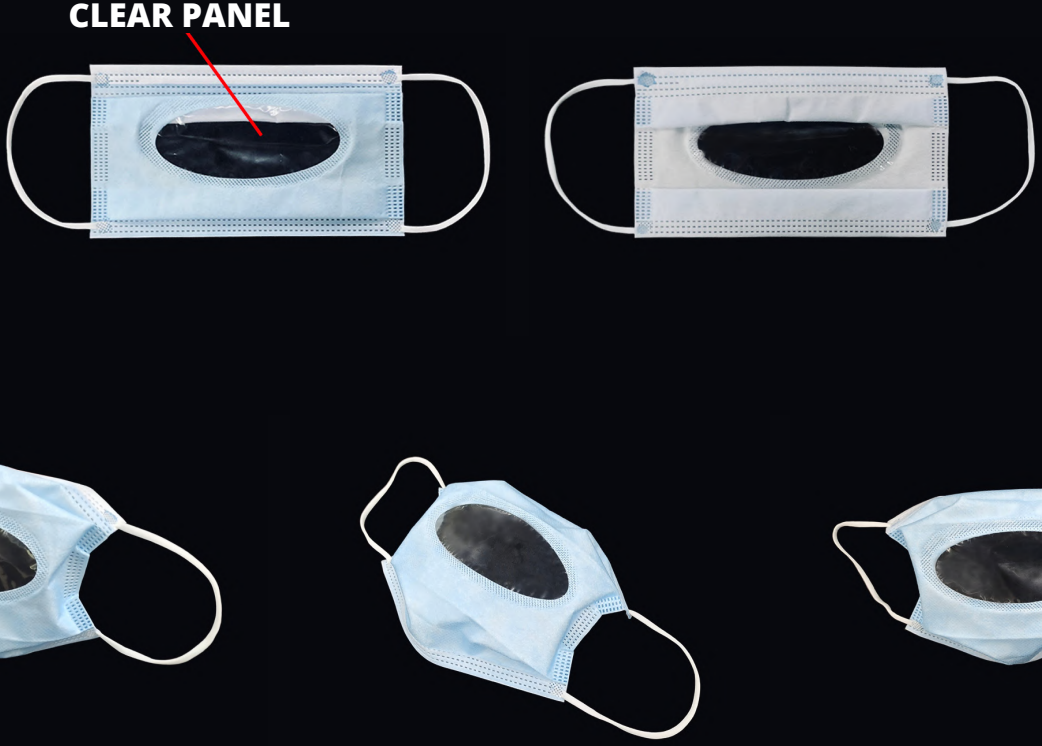
11.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

12.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.

IMAGES


CLEAR PANEL


SMILE
SHIELD
+
MEDICAL FACE MASK
Type IIR
CE
50

SAFE, CLEAR COMMUNICATION

SMILE SHIELD

Type IIR
Non Sterile

DISPOSABLE MEDICAL FACE MASK
Flat Form Ear Loop | 17.5cm*9.5cm | 50pcs/bag

ANHUI RONGDA MEDICAL EQUIPMENT CO LTD.
Industrial Park, Renhe Town, Tianchaing City,
239300, Anhui, China

EC REP ZOUSTECH S.L.
Pso. Castellana, 141-Planta 19, 28046, Madrid
Spain

DISTRIBUTOR Distributed by SMILE SHIELD
13 Oakfield Road, Bristol, BS8 2AJ

Made in China | Product Ref: SSMIIRS0

STORE IN A COOL DRY PLACE

SMILE SHIELD

SAFE, CLEAR COMMUNICATION

CAUTIONS & WARNINGS

1. The mask does not eliminate the risk of contracting any disease or infection.
2. Failure to properly use and maintain this product could result in illness or even death.
3. Product is single-use, do not re-use. Please destroy and dispose according to the regulation after use.
4. Please check manufacturing and expiry date and use within the valid period.
5. Please check the packaging or mask before use. If the packaging or mask is damaged, please do not use and dispose as medical waste.
6. If the mask becomes damaged, soiled, or breathing becomes difficult, leave the contaminated area and replace and refit with a new mask.
7. Please refer to the instructions before use.
8. Please use with caution if you are allergic to non-woven fabric.
9. For adult use only.

Type IIR
Non Sterile

0 658556 037720

www.smileshieldmask.com

The product is compliant with **BS EN 14683:2019 Type IIR** Specification and equivalent international standards. This product conforms with the requirements of Directive 93/42/EEC and subsequent amendments including Medical Devices Regulation 2017/745. CE mark of manufacturer is affixed.

INSTRUCTIONS FOR USE

1. Wash your hands before touching the mask.
2. Hold the mask by the ear loops with the coloured side facing outwards and nose strip upwards.
3. Place an ear loop over each ear gently without touching the inside surface of the mask.
4. Adjust the nose clip to match the shape of the nose to prevent unfiltered air from entering.
5. Pull the mask pleats below chin to produce a tight seal.

Intended use: To protect the patient from infective agents and to reduce the risk of spreading infections.

SMILE SHIELD

MEDICAL FACE MASK

Type IIR
Non Sterile

CE
EN14683

ANTI FOG CLEAR PANEL

HYPO-ALLERGENIC

COMFORTABLE EAR LOOPS

>98% BFE

ADJUSTABLE NOSE STRIP

x 50 MASKS

SAFE, CLEAR COMMUNICATION

Client: Lactalis Job Reference: Smile Shield Carton

version 3

ORIGINATION
Origination Date: 26.02.21
Released to Print Date:
Contact Details: Pat Starke
Telephone: 01666 841 415
Email: pat@starkecreative.co.uk

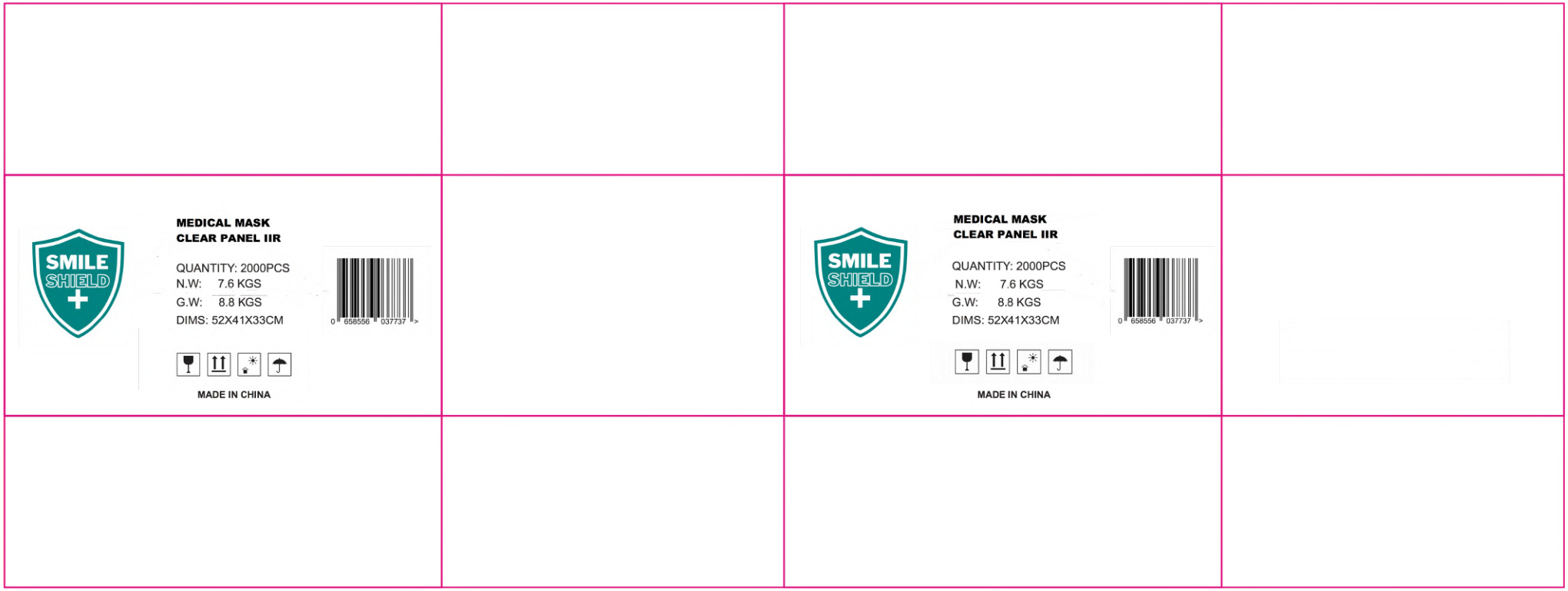
SPECIFICATION
Fonts outlined: No
Artwork size:
Barcode:
Cutter Guide: not supplied

starke branded packaging | artwork | point of sale | gifting | digital brand activation
Starke Creative Limited, Unit 2 The Hay Barn, Pinkney Park, Pinkney, Wiltshire SN16 0NX
T: 01666 841 340 | M: 07887 744036 | pat@starkecreative.co.uk

CUTTER GUIDE HAS BEEN DRAWN FROM A SKETCH YOU MUST CHECK THIS CUTTER GUIDE BEFORE GOING TO PRODUCTION AND WE TAKE NO RESPONSIBILITY FOR ANY ERRORS

52CM 41CM 52CM 41CM

33CM



BENEFITS

Human connection is built on clear communication. The benefits of **Smile Shield™** include:

- Clear Communication
- Allows Lip Reading
- Visible Facial Expressions
- Deeper Connection

PERFECT FOR

Smile Shield™ has a clear front panel which makes the mouth visible to facilitate clear communication with people who rely on lip reading and facial expressions to support communication. This includes people who are deaf, have a learning disability, autism or dementia.

Smile Shield™ is recommended for:

- Hospitals Use e.g.
  - Audiology
  - Midwifery
  - Elderly Wards
  - Learning Difficulties
- Disabled Homes
- Care Homes
- Children e.g. Education
- Customer Service areas – e.g. Reception
- Areas where clearer communication & protection are required.

BRIEF DESCRIPTION

The **Smile Shield™** has changed the way people connect. Offering **IIR Mask Protection**, yet allowing **clear communication** through a **clear panel**, the **Smile Shield™** is perfect for areas where **facial expression, lip reading or greater connection** is required.

SMILE SHIELD™ PRODUCT INFORMATION

PRODUCT TECHNICAL INFORMATION

Smile Shield™ is fully compliant to EN14683:2019+A1+2019 as an IIR mask.

EN14683:2019+A1:2019	IIR Requirement	Smile Shield™
Bacterial Filtration Efficiency (BFE) (%)	≥ 98%	Pass
Particulate Filtration Efficiency	<49,0	Pass
Fluid Resistance (kPa)	≥ 16,0	Pass
Differential Pressure (Pa/cm2)	≤ 30	Pass

PACKAGING DETAILS

Unit	Code	Quantity Per Unit	Dimensions (L X W X H cm)	Net Weight (kg)	Gross Weight(kg)
Box	SSMIIR50	50	19 x 9.7 x 7	0.190	0.215
Case	SSMIIR2000	2,000 (40 Boxes)	52 x 41 x 33	7.6	8.8

FEATURES

- Fully Compliant to EN14683 IIR
- Anti Fog Clear Panel
- Fluid Resistant
- Hypoallergenic
- Latex Free
- Comfortable Ear Loops
- Adjustable Nose Strip
- Non Sterile

BENEFITS

Human connection is built on clear communication. The benefits of **Smile Shield™** include:

- Clear Communication
- Allows Lip Reading
- Visible Facial Expressions
- Deeper Connection

PERFECT FOR

Smile Shield™ has a clear front panel which makes the mouth visible to facilitate clear communication with people who rely on lip reading and facial expressions to support communication. This includes people who are deaf, have a learning disability, autism or dementia.

Smile Shield™ is recommended for:

- Hospitals Use e.g.
  - Audiology
  - Midwifery
  - Elderly Wards
  - Learning Difficulties
- Disabled Homes
- Care Homes
- Children e.g. Education
- Customer Service areas – e.g. Reception
- Areas where clearer communication & protection are required.

BRIEF DESCRIPTION

The **Smile Shield™** has changed the way people connect. Offering **IIR Mask Protection**, yet allowing **clear communication** through a **clear panel**, the **Smile Shield™** is perfect for areas where **facial expression, lip reading or greater connection** is required.

CERTIFICATES

01. EC Declaration of Conformity

Manufacturer:	Name: ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD Add: Industrial park,Renhe Town,Tianchang city 239300,Anhui,China
European Representative:	Name: ZOUSTECH S.L. Add: Pso. Castellana,141–Planta 19, 28046–Madrid, Spain
Product Name:	Disposable Medical Face Mask
Object of the declaration:	Model: RDYL-00305, With Earloop
UMDNS Code:	12-447
Classification (MDD, Annex IX):	I , rule 1
Conformity Assessment Route:	Annex Ⅶ

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC modified with the Directive 2007/47/EC

Applicable standards by EU

ENISO13485:2016	EN 14683:2019+AC:2019	ISO14971:2019
ISO10993-1:2018	ENISO10993-5:2009	ISO10993-10:2010
ENISO 15223-1:2016	EN1041:2008/A1:2013	

Place of Issue: TIANCHANG, CHINA

Date of Issue: 2020-05-19

Signature:

Mr.Yihong Zhang

Position: General Manager

GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD agencia española de medicamentos y productos sanitarios

Envíos Telemáticos

3.0.44

Registro de Responsables de Productos Sanitarios

Usuario: RUBÉN VALLE IBASETA

Desconectar

Registro de Responsables de Productos Sanitarios - RPS/976/2020

Datos de la notificación

Datos de registro

Nº Registro	RPS/976/2020	Fecha Registro	21/05/2020

Datos del Responsable

Tipo de Responsable (*)	Rep. Autorizado	Tipo de entidad	Empresa
CIF(*)	B87637591	Nombre (*)	ZOUSTECH S.L
Dirección(*)	Paseo de la castellana 141 Planta 19		
Localidad (*)	Madrid		
Provincia(*)	Madrid	CP(*)	28046
Teléfono(*)	694 426 446	Fax	
e-mail(*)	legal@zoustech.eu	Web	

Datos del Fabricante

Nombre o Razón Social (*)	ANHUI RONGDA MEDICAL EQUIPMENT CO.,LTD		
Dirección (*)	Industrial park,Renhe Town		
Localidad (*)	Tianchang city ,Anhui		
País(*)	República Popular China	CP	239300
Teléfono (*)	00865502383216	Fax	
e-mail (*)	bao.le@162.com	Web	

Datos de Productos Comunicados

Estatus(*) Primera Comunicación

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios			
Nombre Comercial	Tipo de Producto	Estado del producto	Acción
MASCARILLA FACIAL DESECHABLE	Clase I	Primera Comunicación	

Comentarios

Enviar Solicitud

Agencia Española de Medicamentos y Productos Sanitarios
Parque Empresarial "Las Mercedes", Edif. 8, C/ Campezo 1 - 28022 MADRID | e-Mail: incidencias_aplicaciones@aemps.es

TEST REPORTS

REPORT NO: 2847

4ward Testing Ltd
5 Hampers Common
Industrial Estate
Petworth
West Sussex
GU28 9NR
United Kingdom

Tel.: +44 (0)1798 342240
+44 (0)1798 344323
Fax: +44 (0)1798 344482

info@4wardtesting.co.uk

www.4wardtesting.co.uk

REPORT

On the testing of

Medical Face Masks to EN14683:2019+AC:2019
Documented in house methods:
M0121, M0122, M0124, M0125

Supplied by:

TAD Medical Ltd
13 Oakfield Road
Clifton
Bristol
BS8 2AJ

Report Prepared by:

Anthony Hanson

Identification

Mask Description: Blue three ply foldable with ear loops and clear plastic mouth area.
Mask size: 17.5 by 9.5cm
Manufacturer: Anhui Rongda Medical Equipment Co Ltd
Batch number: Not specified
4ward Sample No: 2847
Customer reference: email TAD/PS 110221
Date received: 04/03/2021

Test Summary

	M1	M2	M3	M4	M5	Threshold	Result
Bacterial filtration efficiency (BFE), [%] 5.2.2	99.99	99.99	99.99	99.99	99.99	≥ 98	Pass
Breathability 5.2.3 (differential pressure) average of 5 areas/mask [Pa/cm2]	27.26	26.07	29.51	26.53	26.68	< 60	Pass
Splash resistance pressure 5.2.4 [kPa]	30 of 32 masks passed at 16kPa					≥ 29 @16kPa	Pass

Threshold for type IIR mask

Test Details

The Face Masks were tested as received from the customer

Testing of the Medical Face Masks was carried out to the following sections of EN 14683:2019+ AC:2019

Bacterial Filtration Efficiency Section 5.2.2

Test area: 49 cm^2
Exposed face: Inside
Test flow rate: 28.3L/min
Sample size: Full mask expanded (>10x10cm)
Mean plate counts
Positive controls: 3475 cfu
Negative control 0 cfu

Sample pre-conditioning: >4h @ 21±5°C 85±5%RH

BFE for each test specimen shown in summary table.

Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk < 5%.

Breathability Section 5.2.3

Test area: 4.9± 0.4 cm^2
Test quantity: 5 masks
Test positions: 1 centre, 4 spanning out from the centre
Test flow rate: 8L/min
Sample pre-conditioning: >4h @ 21± 5°C 85± 5%RH

		Mask1	Mask2	Mask3	Mask4	Mask5
Differential pressure [Pa/cm^2]	1	28.86	26.76	27.91	26.38	28.10
	2	24.46	20.26	32.49	23.89	23.51
	3	28.29	28.86	32.49	20.83	27.52
	4	28.86	26.76	25.42	30.58	26.57
	5	25.80	27.71	29.24	30.96	27.71
	Average	27.26	26.07	29.51	26.53	26.68

Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk < 5%.

Splash Resistance Section 5.2.4

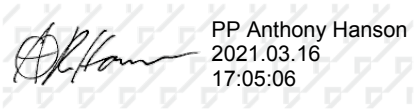
The test was carried out in accordance with ISO 22609:2004
Centre of mask targeted
Conditioned for >4h at 21± 5 °C 85± 5 % RH
Tested at 21± 5 °C 85± 10 % RH
No targeting plate was used
32 masks tested
30 masks Passed
Minimum of 29 Passes required

Pass - The Test passed the requirement AND had a conformance probability, pc> 95 % for test conditions (Conditioning and test temperature and RH, synthetic blood surface tension and spray velocity)

Date of testing: 05 - 15/03/2021

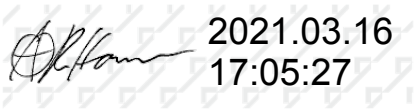
These results relate only to the samples tested

Work carried out and recorded by the following personnel:



Tessa Peters BSc
Laboratory Technician

Work approved by the following personnel:



Anthony Hanson
Quality Assurance Engineer

..... END .....

ANHUI RONGDA MEDEICAL EQUIPMENT CO.,LTD
NO 134 HUWEI ROAD,RENHE TOWN INDUSTRY ZONE,TIANCHANG CITY,ANHUI

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

Sample Description	:	(A)Mask
Composition	:	(A)non woven
Sample Color	:	(A)blue
Lot No.	:	RDY04520200929
Manufacturer	:	Rongda
Supplier	:	Market Union Co.,Ltd
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Oct 10, 2020
Testing Period	:	Oct 14, 2020 - Oct 26, 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 (Authorized Signatory)

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

Test Result

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

Clause 5.2 Performance Requirement

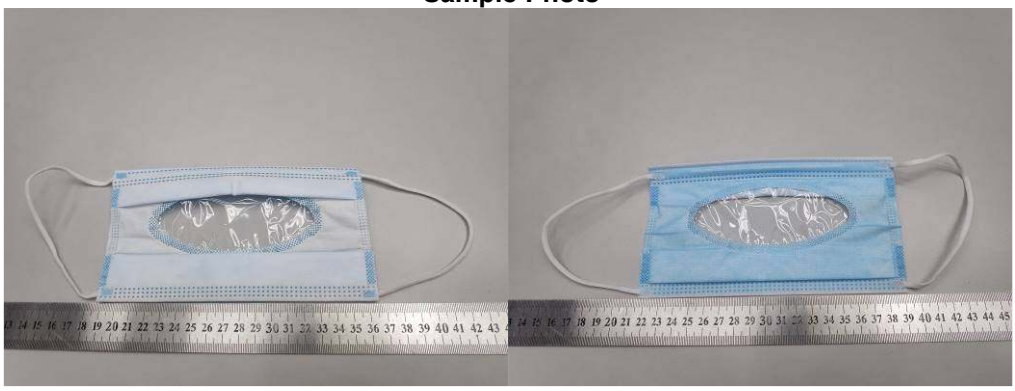
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.55	78	21.97
2#	3.52	78	22.16
3#	3.44	63	18.31
4#	3.63	84	23.14
5#	3.54	81	22.88

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

Sample Photo

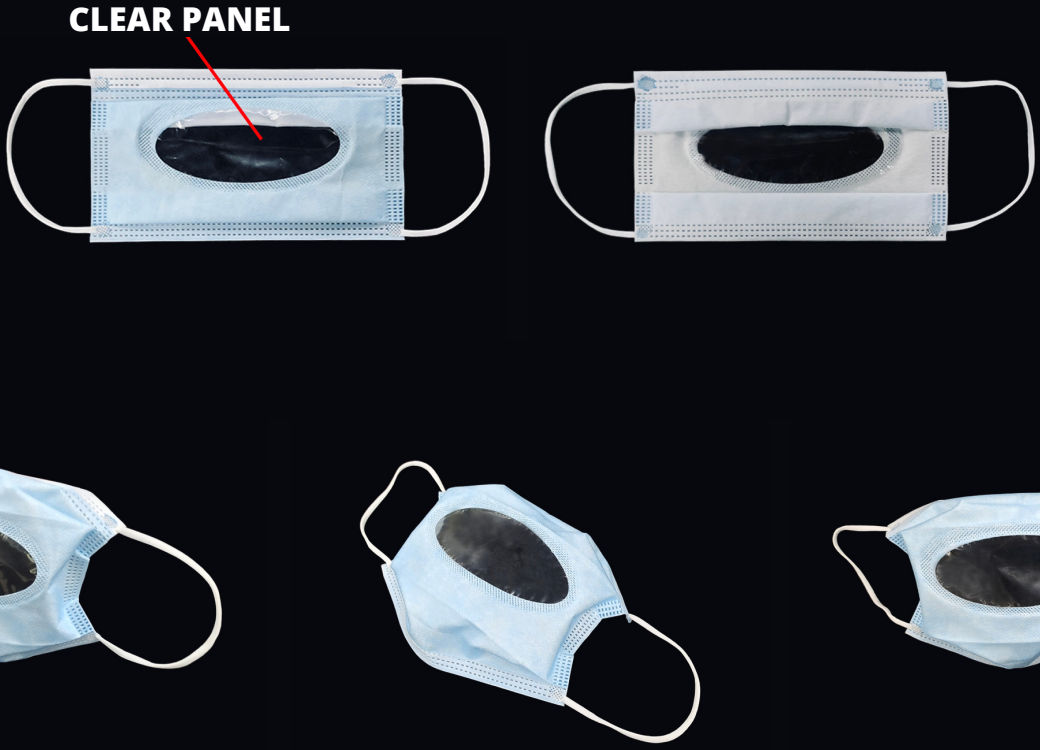


The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center
检验检测专用章 Inspection & Testing Services
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

IMAGES


CLEAR PANEL


SMILE SHIELD
MEDICAL FACE MASK
Type IIR
CE
50

Client: Lactalis Job Reference: Smile Shield Carton

version 3

ORIGINATION
Origination Date: 26.02.21
Released to Print Date:
Contact Details: Pat Starke
Telephone: 01666 841 415
Email: pat@starkecreative.co.uk

SPECIFICATION
Fonts outlined: No
Artwork size:
Barcode:
Cutter Guide: not supplied

starke branded packaging | artwork | point of sale | gifting | digital brand activation
Starke Creative Limited, Unit 2 The Hay Barn, Pinkney Park, Pinkney, Wiltshire SN16 0NX
T: 01666 841 340 | M: 07887 744036 | pat@starkecreative.co.uk

CUTTER GUIDE HAS BEEN DRAWN FROM A SKETCH YOU MUST CHECK THIS CUTTER GUIDE BEFORE GOING TO PRODUCTION AND WE TAKE NO RESPONSIBILITY FOR ANY ERRORS

SAFE, CLEAR COMMUNICATION

SMILE SHIELD

Type IIR
Non Sterile

DISPOSABLE MEDICAL FACE MASK
Flat Form Ear Loop | 17.5cm*9.5cm | 50pcs/bag

ANHUI RONGDA MEDICAL EQUIPMENT CO LTD.
Industrial Park, Renhe Town, Tianchaing City,
239300, Anhui, China

EC REP ZOUSTECH S.L.
Pso. Castellana, 141-Planta 19, 28046, Madrid
Spain

DISTRIBUTOR Distributed by SMILE SHIELD
13 Oakfield Road, Bristol, BS8 2AJ

Made in China | Product Ref: SSMIIRS0

STORE IN A COOL DRY PLACE

SMILE SHIELD

SAFE, CLEAR COMMUNICATION

CAUTIONS & WARNINGS
1. The mask does not eliminate the risk of contracting any disease or infection.
2. Failure to properly use and maintain this product could result in illness or even death.
3. Product is single-use, do not re-use. Please destroy and dispose according to the regulation after use.
4. Please check manufacturing and expiry date and use within the valid period.
5. Please check the packaging or mask before use. If the packaging or mask is damaged, please do not use and dispose as medical waste.
6. If the mask becomes damaged, soiled, or breathing becomes difficult, leave the contaminated area and replace and refit with a new mask.
7. Please refer to the instructions before use.
8. Please use with caution if you are allergic to non-woven fabric.
9. For adult use only.

Type IIR
Non Sterile

0 658556 037720

www.smileshieldmask.com

The product is compliant with **BS EN 14683:2019 Type IIR** Specification and equivalent international standards. This product conforms with the requirements of Directive 93/42/EEC and subsequent amendments including Medical Devices Regulation 2017/745. CE mark of manufacturer is affixed.

INSTRUCTIONS FOR USE
1. Wash your hands before touching the mask.
2. Hold the mask by the ear loops with the coloured side facing outwards and nose strip upwards.
3. Place an ear loop over each ear gently without touching the inside surface of the mask.
4. Adjust the nose clip to match the shape of the nose to prevent unfiltered air from entering.
5. Pull the mask pleats below chin to produce a tight seal.

Intended use: To protect the patient from infective agents and to reduce the risk of spreading infections.

SMILE SHIELD

MEDICAL FACE MASK

Type IIR
Non Sterile

CE
EN14683

ANTI FOG CLEAR PANEL
HYPO-ALLERGENIC
COMFORTABLE EAR LOOPS
>98% BFE
ADJUSTABLE NOSE STRIP

x 50 MASKS

SAFE, CLEAR COMMUNICATION

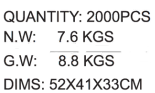
52CM 41CM 52CM 41CM

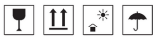
33CM

SMILE SHIELD

MEDICAL MASK
CLEAR PANEL IIR

QUANTITY: 2000PCS
N.W: 7.6 KGS
G.W: 8.8 KGS
DIMS: 52X41X33CM





MADE IN CHINA

SMILE SHIELD

MEDICAL MASK
CLEAR PANEL IIR

QUANTITY: 2000PCS
N.W: 7.6 KGS
G.W: 8.8 KGS
DIMS: 52X41X33CM

MADE IN CHINA