



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 |



CERTIFICATES



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
Breathability (Pa/cm ²)	< 60,0	Pass
Splash Resistance (kPa)	≥ 29 @ 16k Pa	Pass
Microbial Cleanliness (cfu/g)	≤ 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.

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





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





TEST REPORTS



REPORT NO: 2847



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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/cm ²]	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 cm²
 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: $4.9 \pm 0.4 \text{ cm}^2$
 Test quantity: 5 masks
 Test positions: 1 centre, 4 spanning out from the centre
 Test flow rate: 8L/min
 Sample pre-conditioning: $> 4 \text{ h @ } 21 \pm 5^\circ\text{C } 85 \pm 5\% \text{RH}$

		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 $> 4 \text{ h at } 21 \pm 5^\circ\text{C } 85 \pm 5\% \text{ RH}$

Tested at $21 \pm 5^\circ\text{C } 85 \pm 10\% \text{ RH}$

No targetting 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, $p_c > 95\%$ 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

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without the prior approval of 4ward Testing Ltd in writing.

..... **END**



Test Report

SL52045300037401TX

Date: October 26, 2020

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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)



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Test Result

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

Clause 5.2 Performance Requirement

Clause 5.2.5 Microbial Cleanliness

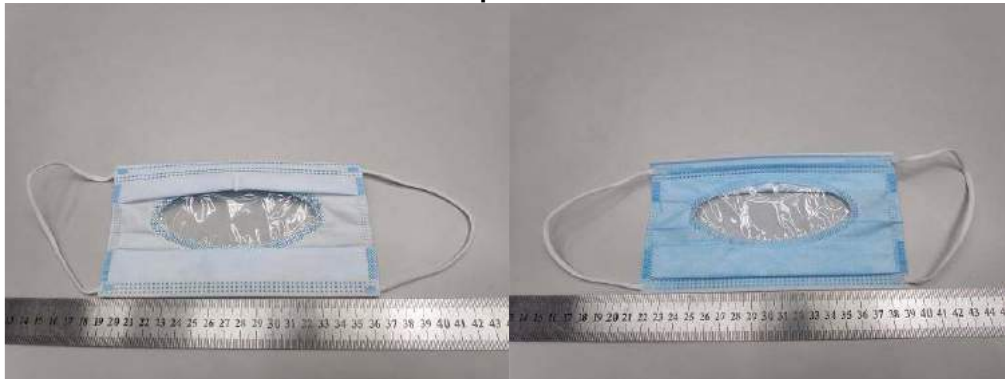
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

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



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