

## Declaration of Conformity

for Medical Devices

**European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states**

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

<b>General Product Name:</b>	Face Mask
<b>Specified name:</b>	ANYGUARD Daily Mask (Kids)
<b>Legal Manufacturer:</b>	NTI VINA Co., Ltd. No. 33 Street 7, VSIP II, Hoa Phu Ward, Thu Dau Mot City, Binh Duong Province, Vietnam
<b>Variants:</b>	As per Appendix II (This document) – Product information
<b>Intended Use:</b>	NTI VINA Surgical Mask with accessories is a device made of Non-woven materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.
<b>Risk Classification:</b>	Class I Non-Sterile (Rules 1 & 4 Applied)
<b>EC Certificate Number</b>	
<b>EN ISO 13485:2016 Certificate Number</b>	Q5 067915 0009 Rev.00
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>MDD Conformity Assessment Route:</b>	EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V.

Name Mr. KIM HEUN TAE Position General Director  
Signed [Signature] Date 24-04-2021

Who is the natural and legal person with sole responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



## Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:


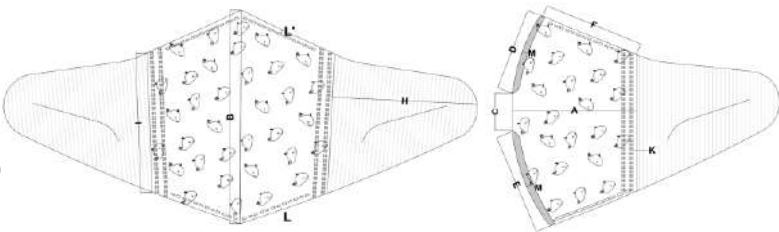
Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 14683: 2019	Medical face masks. Requirements and test methods Barrier level type IIR

## Appendix II – Product Listing/Schedule

Number	Part/Catalogue Number	Description/Name	GMDN Code
01	03132220001DA	ANYGUARD Daily Mask (Kids)	15646

## Version History

Version	Compiled by	Date	Description
1.0	Giap Thi Nga	24-04-2021	First issue

Producto	Mascarilla quirúrgica IIR para uso infantil 2D Dr. Nosk (2 a 4 años)
Referencia	Mascarilla infantil quirúrgica IIR Dr.Nosk 2D Anyguard 2 a 4 años
CN	179404
Imágenes del producto	
Dimensiones	<ul style="list-style-type: none"> <li>- Cuerpo (largo) A : 70mm</li> <li>- Cuerpo (anchura) B : 110mm</li> <li>- Longitud superior F : 60mm</li> <li>- Longitud Inferior G : 55mm</li> <li>- Banda (longitud) H : 70mm</li> <li>- Banda (anchura) I : 65mm</li> <li>- Línea de banda de corte J : 60</li> </ul> 
Características y composición	<ul style="list-style-type: none"> <li>- 4 capas de filtrado: MF (Mask Filter) + MB (Melt Blown) + SB(Spunbond) + SB (Spunbond)</li> <li>- Orejera premium TK50W</li> <li>- Mascarilla antifluidos IIR</li> </ul>
Paquete	<ul style="list-style-type: none"> <li>- Bolsa de polietileno con 3 mascarillas</li> <li>- Caja interior de 12 paquetes de bolsas de polietileno</li> <li>- Caja principal de 10 cajas interiores</li> </ul>
Norma	- EN 14683:2019 + AC:2019
Información de producto	<ul style="list-style-type: none"> <li>- Mascarilla médica facial no estéril</li> <li>- Tipo IIR antifluidos</li> <li>- Melt Blown / Spunbond</li> <li>- BFE : 99.9%</li> <li>- Test de irritación cutánea aprobado</li> </ul>
Almacenamiento	<ul style="list-style-type: none"> <li>- Lugar limpio y seco</li> <li>- Evitar altas temperaturas</li> </ul>
Uso	No utilizar durante más de 4h seguidas. En caso de que se humedezca o deteriore por uso, se recomienda sustituir
Precaución	<ul style="list-style-type: none"> <li>- Si el producto está dañado, no lo use y comuníquese con el vendedor</li> <li>- Dependiendo del entorno de uso, es posible que el producto no funcione a su máximo rendimiento</li> <li>- Desechar después del uso</li> <li>- No utilice el producto para ningún otro propósito</li> </ul>
Fabricante	NTI VINA Co., Ltd
Distribuidor	Filtros Nosk España SL



## TEST REPORT: 7191251203-CHM21-01C-RC

Date: 04 JAN 2021

Tel: +65 68851345 Fax: +65 67784301

Client's Ref:

Email: Randy.CHIN@tuvsud.com

**Note:** This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



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### SUBJECT

Bacterial Filtration Efficiency (BFE)

### CLIENT

NTI VINA Co., Ltd  
#33, Street 7, VSIP II, Hoa Phu Ward,  
Thu Dau Mot City, Binh Duong Province,  
Vietnam

Attn : Giap Thi Nga

### SAMPLE SUBMISSION DATE / TEST DATE

21 Dec 2020 / 23 Dec 2020

### DESCRIPTION OF SAMPLE

One sample described as below was received:

Product Name / Brand Name	Manufacturer	Lot No.
2D Elastic Mask (Small) (Whale)	NTI VINA Co., Ltd	20201215-1



Laboratory:  
TÜV SÜD PSB Pte. Ltd.  
No.1 Science Park Drive  
Singapore 118221

Phone : +65-6885 1333  
Fax : +65-6776 8670  
E-mail: enquiries@tuvsud.com  
www.tuvsud.com/en-sg  
Co. Reg : 199002667R

Regional Head Office:  
TÜV SÜD Asia Pacific Pte. Ltd.  
1 Science Park Drive, #02-01  
Singapore 118221  
**TÜV®**

**DESCRIPTION OF SAMPLE** (cont'd)



Figure 1: "2D Elastic Mask (Small) (Whale)" sample as received

**METHOD OF TEST**

BS EN 14683:2019 "Medical face masks – Requirement and test methods" Annex B – Method for *in vitro* determination of bacterial filtration efficiency (BFE)

Area contacting with the bacterial challenge: Inside of the mask

Flowrate:  $28.3 \pm 0.3$  L/min

Mean particle size of the challenge aerosol:  $3 \mu\text{m} \pm 0.3 \mu\text{m}$

Test area: Approximately  $50 \text{ cm}^2$

**TEST REPORT: 7191251203-CHM21-01C-RC**  
04 JAN 2021



**RESULTS**

Sample Description: 2D Elastic Mask (Small) (Whale)

Test sample/ controls	Stage 1, CFU	Stage 2, CFU	Stage 3, CFU	Stage 4, CFU	Stage 5, CFU	Stage 6, CFU	Sum of Total plate count for the 6 sieves, CFU	Average Count for Controls, CFU	BFE (%)
-ve Control	0	0	0	0	0	0	Less than 1		
+ve Control 1	154	379	660	648	432	21	2294	2188	
+ve Control 2	134	323	598	605	411	11	2082		
Sample 1	0	0	0	0	0	0	Less than 1		More than 99.9
Sample 2	0	0	0	0	0	0	Less than 1		More than 99.9
Sample 3	0	0	0	0	1	0	1		More than 99.9
Sample 4	0	0	0	0	0	0	Less than 1		More than 99.9
Sample 5	0	0	0	0	0	0	Less than 1		More than 99.9

# TEST REPORT: 7191251203-CHM21-01C-RC

04 JAN 2021



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## Notes :

CFU : Colony Forming Unit

BFE : Bacterial Filtration Efficiency

## Remarks :

The above test results relate to the samples as received.

A handwritten signature in black ink, appearing to read 'Hwy'.

---

**MS AW HWEE YING**  
HIGHER TECHNICAL EXECUTIVE

A handwritten signature in black ink, appearing to read 'Randy'.

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**MR RANDY CHIN KOK FEI**  
PRODUCT MANAGER  
MICROBIOLOGY  
CHEMICAL & MATERIALS



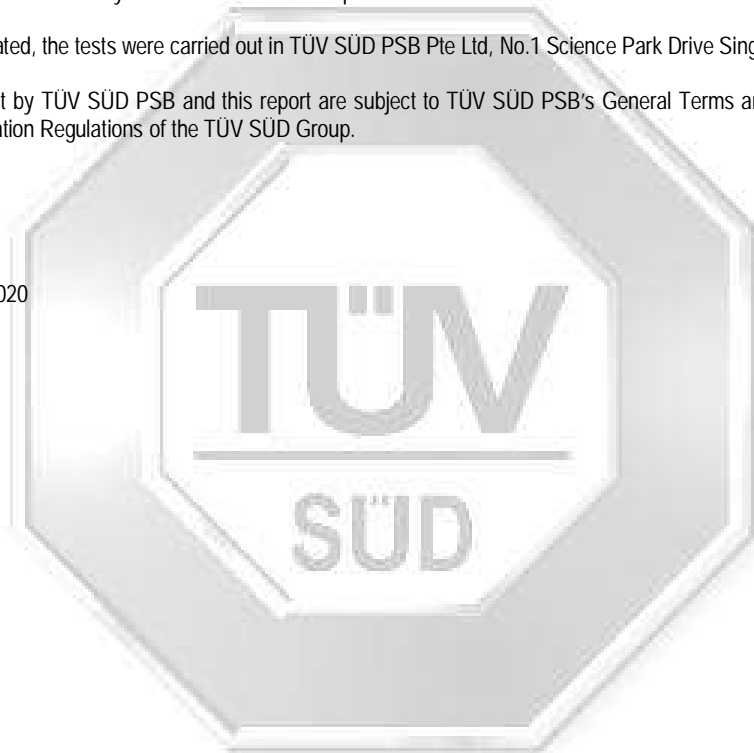
**TEST REPORT: 7191251203-CHM21-01C-RC**  
04 JAN 2021



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Effective 01 September 2020





**Test Report No. 7191251203-EEC21-03C-WBH**  
dated 08 Jan 2021



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**SUBJECT**

Breathability Test (Differential Pressure)

**CLIENT**

NTI VINA Co., Ltd  
#33, Street 7, VSIP II, Hoa Phu Ward,  
Thu Dau Mot City, Binh Duong Province,  
Vietnam

Attn: Giap Thi Nga

**SAMPLE SUBMISSION DATE/ TEST DATE**

21 Dec 2020 / 06 Jan 2021

**DESCRIPTION OF SAMPLES**

One sample described as below was received:

Product Name / Brand Name	Manufacturer	Lot No.
2D Elastic Mask (Small) (Whale)	NTI VINA Co., Ltd	20201215-1



Laboratory:  
TÜV SÜD PSB Pte. Ltd.  
TÜV SÜD @ IBP  
15 International Business Park  
Singapore 609937

Phone : +65-6778 7777  
E-mail: info.sg@tuvsud.com  
<https://www.tuvsud.com/en-sg>  
Co. Reg : 199002667R

**Regional Head Office:**  
**TÜV SÜD Asia Pacific Pte. Ltd.**  
**TÜV SÜD @ IBP**  
15 International Business Park  
Singapore 609937  
**TÜV®**

**DESCRIPTION OF SAMPLE** (cont'd)



Figure 1: "2D Elastic Mask (Small) (Whale)" sample as received

**METHOD OF TEST:**

BS EN 14683:2019 Medical face masks – Requirements and test methods  
-Clause 5.2.3 Breathability / Annex C Method for determination of breathability (differential pressure)

Airflow: 8 L/min  
Tested area: 4.9 cm<sup>2</sup>  
Number of tested specimen: 5  
Number of test area per specimen: 2


**RESULTS**

Sample Description: 2D Elastic Mask (Small) (Whale)

Test Specimen	Average Differential Pressure ( $\Delta P$ ) for tested areas (Pa/cm <sup>2</sup> )	Requirement
1	35	The Differential Pressure of the medical face mask shall conform to the value given for the relevant type in Table 1 of BS EN 14683:2019.  Type I < 40 Pa/cm <sup>2</sup> Type II < 40 Pa/cm <sup>2</sup> Type IIR < 60 Pa/cm <sup>2</sup>
2	30	
3	35	
4	31	
5	34	

**REMARKS**

1. The above test results relate to the samples as received.
2. For the classification of medical face mask type, besides the above Differential Pressure test, other test parameters per Table 1 of BS EN 14683:2019 shall be considered.

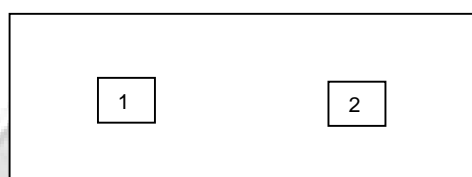
  
William Wei  
Associate Engineer

  
Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

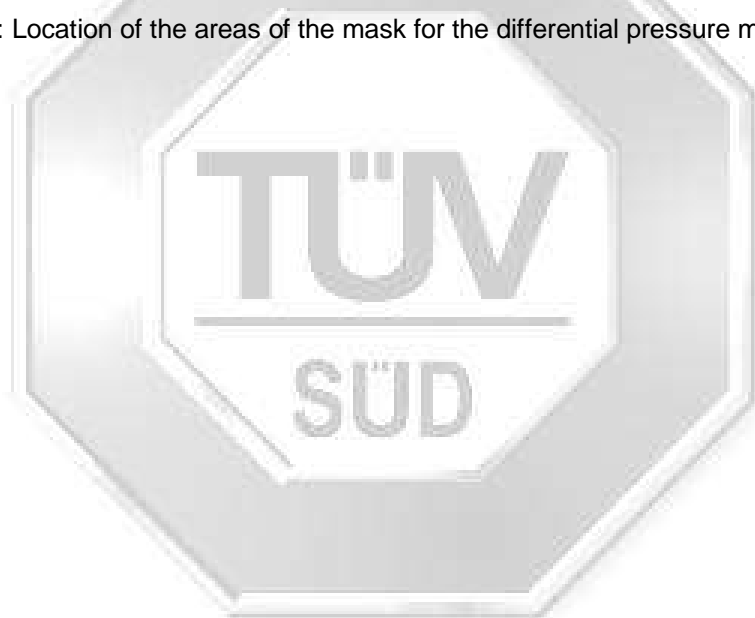
**APPENDIX**

Test areas	Differential Pressure ( $\Delta P$ ) (Pa/cm <sup>2</sup> )				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
1	31	29	33	27	28
2	38	31	36	35	41
Average	35	30	35	31	34

Table: Differential pressure for each tested area of the test specimen



Graph: Location of the areas of the mask for the differential pressure measurements





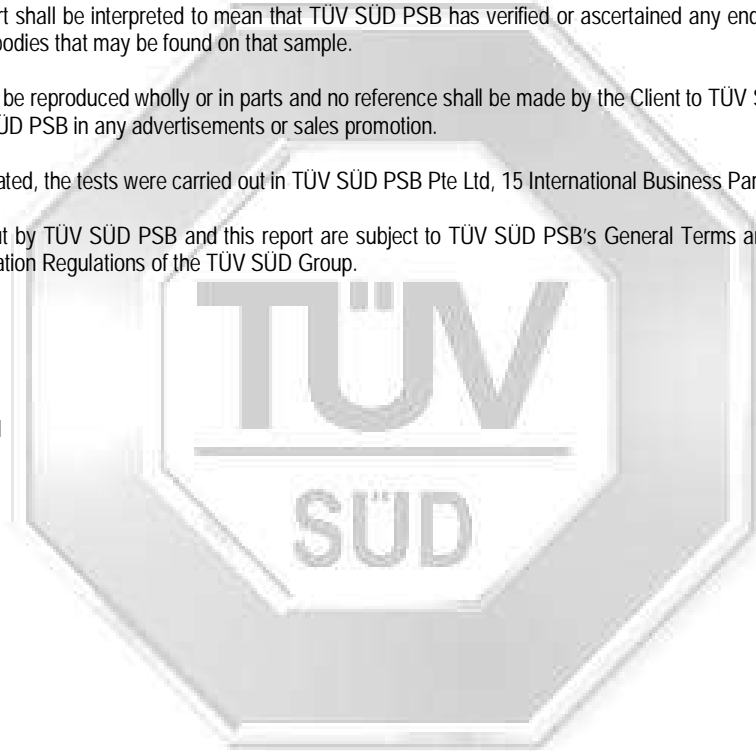
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**dated 08 Jan 2021**



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Effective 01 January 2021



## TEST REPORT: 7191253545-CHM21-02A-RC

Date: 26 FEB 2021

Tel: +65 69736171

Client's Ref:

Email: Randy.CHIN@tuvsud.com

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### SUBJECT

Microbial Cleanliness

### CLIENT

NTI VINA Co., Ltd  
#33, Street 7, VSIP II, Hoa Phu Ward,  
Thu Dau Mot City, Binh Duong Province,  
Vietnam

Attn : Giap Thi Nga

### SAMPLE SUBMISSION DATE / TEST DATE

08 Feb 2021 / 16 Feb 2021

### DESCRIPTION OF SAMPLE

One sample described as below was received:

Product Name / Brand Name	Manufacturer	Lot No.
2D Elastic (Small) (Whale)	NTI VINA Co., Ltd	20210201-1



Laboratory:  
TÜV SÜD PSB Pte. Ltd.  
TÜV SÜD @ IBP  
15 International Business Park  
Singapore 609937

Phone : +65-6778 7777  
E-mail: info.sg@tuvsud.com  
<https://www.tuvsud.com/en-sg>  
Co. Reg : 199002667R

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**DESCRIPTION OF SAMPLE** *(cont'd)*

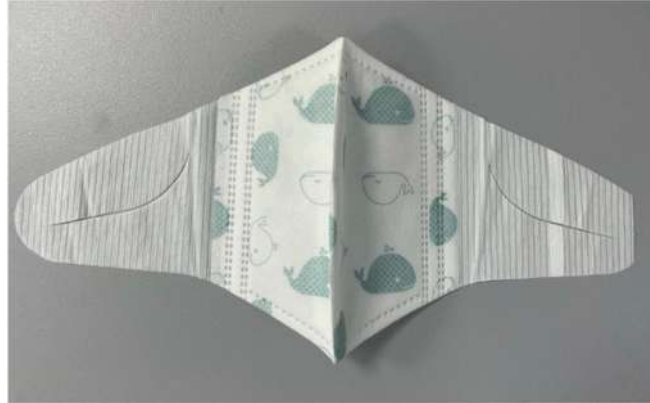
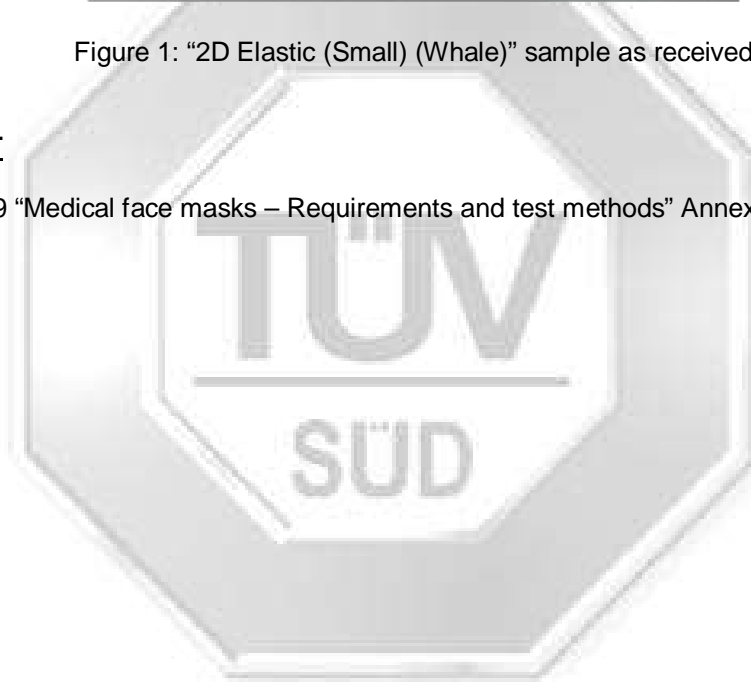


Figure 1: “2D Elastic (Small) (Whale)” sample as received

**METHOD OF TEST**

BS EN 14683: 2019 “Medical face masks – Requirements and test methods” Annex D – Microbial Cleanliness





**RESULTS**

Sample		Total Aerobic Microbial Count, CFU/mask	Total Yeast and Mould Count, CFU/mask	Total Bioburden, CFU/mask	Mask Weight, g	Total Bioburden, CFU/g of mask	Performance requirements for medical face masks
2D Elastic (Small) (Whale)	1	Less than 3	Less than 3	Less than 6	1.98	Less than 3	≤ 30 cfu/g
	2	Less than 3	Less than 3	Less than 6	1.93	Less than 3	
	3	Less than 3	Less than 3	Less than 6	1.95	Less than 3	
	4	Less than 3	Less than 3	Less than 6	1.95	Less than 3	
	5	Less than 3	Less than 3	Less than 6	1.95	Less than 3	

**Notes :**

CFU : Colony Forming Unit

**Remarks :**

The above test results relate to the samples as received.



**MS GERMAINE KHONG ZHI YU**  
TECHNICAL EXECUTIVE



**MS TI HUI EN**  
MICROBIOLOGIST  
MICROBIOLOGY  
CHEMICAL & MATERIALS

**TEST REPORT: 7191253545-CHM21-02A-RC**  
26 FEB 2021



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Effective 01 January 2021



## TEST REPORT: 7191251203-CHM21-02C-LHS

Date: 05 JAN 2021

Tel: +65 68851322 Fax: +65 67784301

Client's Ref: -

Email: Jia-Yi.SEOW@tuvsud.com

**Note:** This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



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### **SUBJECT**

Synthetic Blood Penetration Test

### **CLIENT**

NTI VINA Co., Ltd  
#33, Street 7, VSIP II, Hoa Phu Ward,  
Thu Dau Mot City, Binh Duong Province,  
Vietnam.

Attn: Giap Thi Nga

### **SAMPLE SUBMISSION DATE / TEST DATE**

21 Dec 2020 / 29 Dec 2020

### **DESCRIPTION OF SAMPLE**

One face mask sample described as below was received:

Product Name / Brand Name	Manufacturer	Lot No.
2D Elastic (Small) (Whale)	NTI VINA Co.,Ltd	20201215-1



Laboratory:  
TÜV SÜD PSB Pte. Ltd.  
No.1 Science Park Drive  
Singapore 118221

Phone : +65-6885 1333  
Fax : +65-6776 8670  
E-mail: enquiries@tuvsud.com  
www.tuvsud.com/en-sg  
Co. Reg : 199002667R

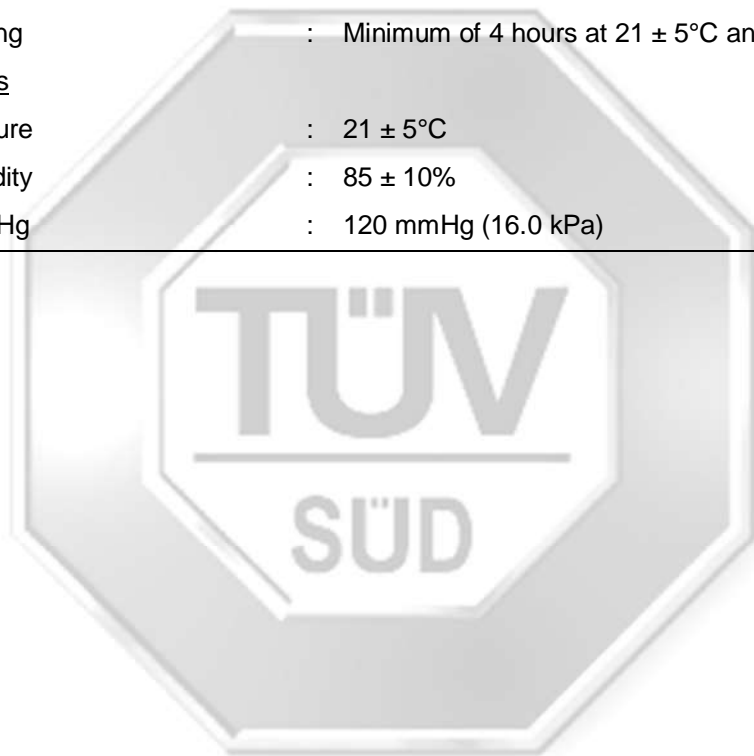
Regional Head Office:  
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1 Science Park Drive, #02-01  
Singapore 118221  
**TÜV**



**METHOD OF TEST**

- 1) BS EN 14683:2019  
"Medical face masks - Requirements and test methods"  
Clause 5.2.4 - Splash resistance
- 2) ISO 22609:2004(E)  
"Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)"

Distance of mask to the tip of cannula	: 30.5 cm
Test volume	: 2 mL
Test side	: Outside
Pre-conditioning	: Minimum of 4 hours at $21 \pm 5^{\circ}\text{C}$ and $85 \pm 5\%$ r.h.
<u>Test conditions</u>	
Test temperature	: $21 \pm 5^{\circ}\text{C}$
Relative humidity	: $85 \pm 10\%$
Pressure, mmHg	: 120 mmHg (16.0 kPa)



**TEST REPORT: 7191251203-CHM21-02C-LHS**

05 JAN 2021



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**RESULTS**

Test article number	Results	BS EN 14683:2019 Table 1 Type IIR Requirement
1	Passed	≥ 16.0 kPa <sup>1</sup>
2	Passed	
3	Passed	
4	Passed	
5	Passed	
6	Passed	
7	Passed	
8	Passed	
9	Passed	
10	Passed	
11	Passed	
12	Passed	
13	Failed	
14	Passed	
15	Passed	
16	Passed	
17	Passed	
18	Passed	
19	Failed	
20	Passed	
21	Passed	
22	Passed	
23	Passed	
24	Passed	
25	Passed	
26	Failed	
27	Passed	
28	Passed	
29	Passed	
30	Passed	
31	Passed	
32	Passed	
No. of passed	29 / 32	

Remark: <sup>(1)</sup> As per ISO 22609:2004, an acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens showed pass results.

Note: Samples were randomly selected and identified for testing.

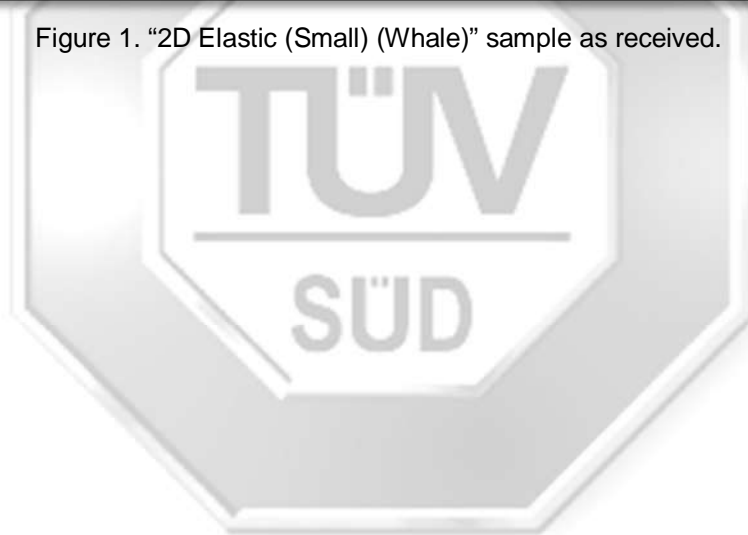
**LIM HUI SIN**  
CHEMIST

**SEOW JIA YI**  
EXECUTIVE CHEMIST  
INDUSTRIAL CHEMICALS  
CHEMICAL & MATERIALS

**APPENDIX**



Figure 1. "2D Elastic (Small) (Whale)" sample as received.





# TEST REPORT: 7191251203-CHM21-02C-LHS

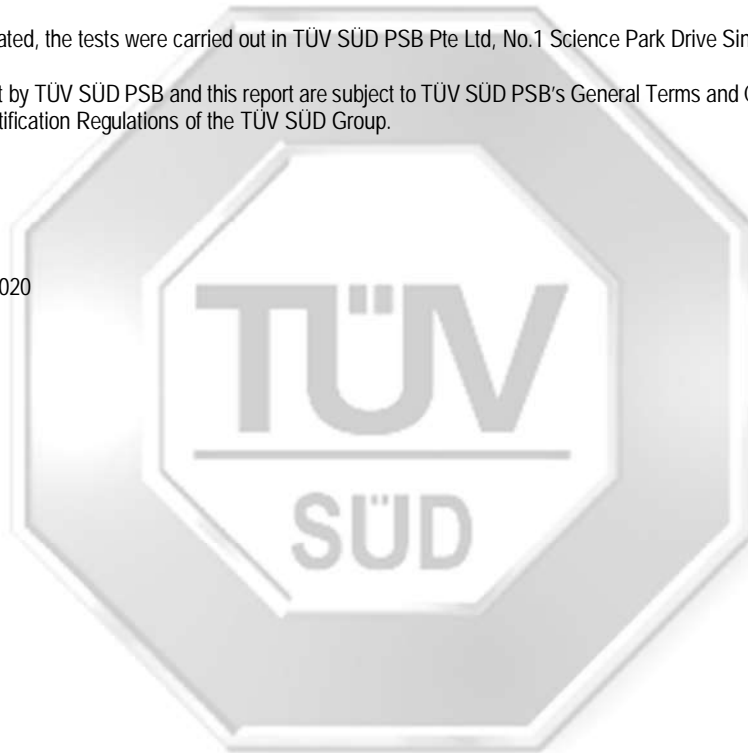
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Effective 01 September 2020





Made in Vietnam

18809233837242

**ANYGUARD**

Dr. **nOSK**

2 D	Sujeción Elástica	2 a 4 años XS	ballena
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SKU

Anyguard Mascarilla quirúrgica IIR para niños (2 a 4 años), Dibujo infantil ballena 3Und

Q'ty

36Und X 10 Expositores (Total 360Und)

18809233837242

Made in Vietnam

Dr. **nOSK**

**ANYGUARD**

2 D	Sujeción Elástica	2 a 4 años XS	ballena
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SKU

Anyguard Mascarilla quirúrgica IIR para niños (2 a 4 años), Dibujo infantil ballena 3Und

Q'ty

36Und X 10 Expositores (Total 360Und)

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Dr. **nosk**



**ANYGUARD**



**MASCARILLA QUIRÚRGICA IIR**

**PRODUCTO  
SANITARIO**

EN14683:2019+AC:2019

Para uso infantil

**BFE 99.9%**

Nuevo elástico  
extrasuave y cómodo



Diseño 2D adaptado al  
rostro infantil



**SKIN IRRITATION TEST**

Superada prueba de irritación  
cutánea por laboratorio

Talla Infantil  
/ 2 a 4 años  
**3 unidades**  
en el interior

\* El producto final podría variar respecto a la imagen.

**ANYGUARD**  
MASCARILLA QUIRÚRGICA IIR Elástica

dr.nosk

FOR KIDS

**ANYGUARD**

MASCARILLA QUIRÚRGICA IIR

EN14683:2019+AC:2019

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**SKIN IRRITATION TEST**  
Superada prueba de irritación  
cutánea por laboratorio

Talla Infantil  
/ 2 a 4 años  
**3 unidades**  
en el interior

**x 12 pack**