

TEST REPORT: 7191237735-CHM20-01-RC

Date: 26 MAY 2020 Tel: +65 68851345 Fax: +65 67732912

Client's Ref: Email: Randy.CHIN@tuv-sud-psb.sg

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SUBJECT

Bacterial Filtration Efficiency (BFE)

CLIENT

GM Nameplate Asia Pte Ltd
53 Joo Koon Circle
Singapore 629103

Attn : Tina Chen

SAMPLE SUBMISSION DATE / TEST DATE

11 May 2020 / 21 May 2020

DESCRIPTION OF SAMPLE

One sample of face mask was submitted by the above company.

Product Name : 3 Ply Mask
Model : PPE-200
Lot Date : 14-APR-20



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 ± 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 cm²



Laboratory:
TÜV SÜD PSB Pte. Ltd.
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Singapore 118221

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Singapore 118221
TÜV®



PSB Singapore

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**RESULTS**

Product Name : 3 Ply Mask

Model : PPE-200

Lot Date : 14-APR-20

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 (%)	Average BFE (%)
-ve Control	0	0	0	0	0	0	0			
+ve Control 1	154	387	627	340	211	217	1936	1996		
+ve Control 2	157	542	498	441	268	149	2055			
Sample 1	0	0	0	0	0	14	14		99.30	99.61
Sample 2	0	0	0	0	0	4	4		99.80	
Sample 3	0	0	0	0	2	2	4		99.80	
Sample 4	0	0	0	0	2	12	14		99.30	
Sample 5	0	0	0	0	0	3	3		99.85	

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PSB Singapore

Notes :

CFU : Colony Forming Unit

BFE : Bacterial Filtration Efficiency

Remarks :

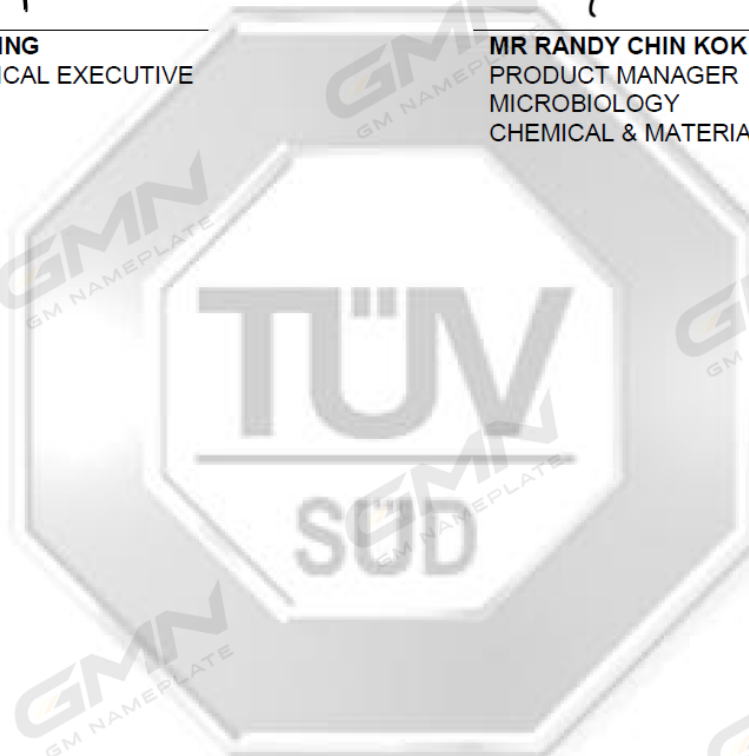
The above test results relate to the samples as received.

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'.

MR RANDY CHIN KOK FEI
PRODUCT MANAGER
MICROBIOLOGY
CHEMICAL & MATERIALS





PSB Singapore

Please note that this Report is issued under the following terms :

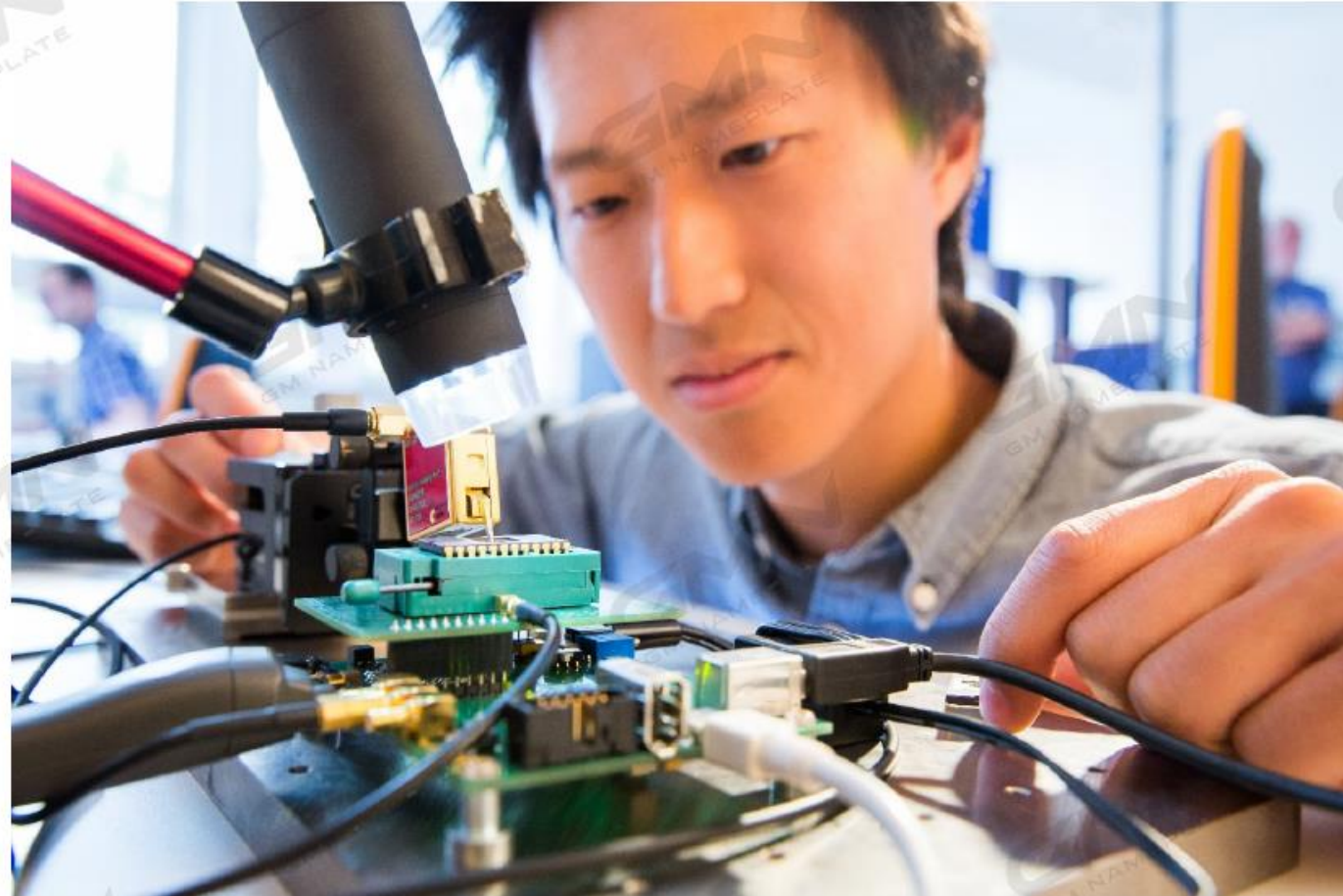
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July 2011



TEST REPORT

Test and classification of PPE-091 Single-Use Medical face masks
according to EN 14683 : 2019 + AC : 2019

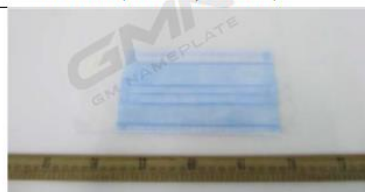


Medical Face Mask Test Report



Test Report No.: TNSG-C-0025/PPE091/AZ0021577(0)-3

Page 2 of 5

Certification Authority	TÜV NORD (Thailand) Ltd. (Singapore Branch) 25 International Business Park, #03-107, Singapore 609916		
Testing Laboratory	Yan Hing Centre, 9-13 Wong Chuk Yueng St., Fo Tan, Shatin, New Territories, Hong Kong		
Applicant	GM Nameplate Asia Pte Ltd 53 Joo Koon Circle Singapore 629103		
Legal Manufacturer	Same as applicant		
Sample Description	One (1) submitted mask sample(s) stated to be:		
	Item Name	Single-Use Medical Face Mask	
	Item No.	PPE-091 (formerly AM001)	
			
Date Received by Testing Laboratory	18 May 2020		
Test Period	18 May 2020 to 29 May 2020		
Tests Requested	Test In Accordance to EN 14683:2019, incorporating corrigendum August 2019 – Medical Face Masks – Requirements and Test Methods (Requirements for Type IIR Classification)		Result
	Bacterial Filtration Efficiency (BFE)		Refer to Test Report
	Differential Pressure Test (Pa/cm ²)		
	Microbial cleanliness (Bioburden)		
	Splash Resistance		

Compiled by:	<u>Tang Chi Lin</u> TÜV NORD Singapore	Approved by:	<u>Gaurava Mishra</u> TÜV NORD Singapore
Date	<u>4th June 2020</u>	Date	<u>4th June 2020</u>
Signature		Signature	



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Page 3 of 5

No.	Test Specifications	Test Method	Test Result	
1	Bacterial Filtration Efficiency (BFE) <i>Staphylococcus ATCC 6538</i>	EN 14683 : 2019 + AC : 2019 (E), 5.2.2 and Annex B (See Note 1 and Remark 2)	<u>Trial</u>	<u>%</u>
			1	99.54%
			2	99.39%
			3	99.65%
			4	99.59%
			5	99.59%
			Average	99.55%
			<u>Classification</u> Meets requirement for Type IIR ≥ 98%	
2	Differential Pressure Test (Pa/cm ²)	EN 14683 : 2019 + AC : 2019 (E), 5.2.3 and Annex C (See Note 2 and Remark 3)	<u>Trial</u>	<u>Pa/cm²</u>
			1	26.57
			2	26.3
			3	26.85
			4	26.02
			5	26.49
			<u>Classification</u> Meets requirement for Type IIR < 60 Pa/cm ²	
3	Microbial cleanliness	EN 14683 : 2019 + AC : 2019 (E), 5.2.5 and Annex D EN ISO 11737-1:2018 (See Remark 4)	<u>Trial</u>	<u>cfu/g</u>
			1	15.9
			2	14.5
			3	15.0
			4	15.9
			5	13.1
			Average	14.9
			<u>Classification</u> Meets requirement for Type IIR ≤ 30 cfu/g	

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Page 4 of 5

4	Splash Resistance	EN 14683 : 2019 + AC : 2019 (E), 5.2.4 ISO 22609 : 2004 (32 specimens) Pressure : 16.0 kPa (See Remark 5 and 6)	<u>Trial</u>	<u>Result</u>
			1	None Seen
			2	None Seen
			3	None Seen
			4	None Seen
			5	None Seen
			6	None Seen
			7	None Seen
			8	None Seen
			9	None Seen
			10	None Seen
			11	None Seen
			12	None Seen
			13	None Seen
			14	None Seen
			15	None Seen
			16	None Seen
			17	None Seen
			18	None Seen
			19	None Seen
			20	None Seen
			21	None Seen
			22	None Seen
			23	None Seen
			24	None Seen
			25	None Seen
			26	None Seen
			27	None Seen
			28	None Seen
			29	None Seen
			30	None Seen
			31	None Seen
			32	None Seen
			<u>Classification</u>	
			Meets requirement for Type IIR ≥ 16.0 kPa	

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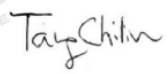




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Page 5 of 5

Notes	1) Control average: 1973 CFU • Mean particle size: 3.0 µm • Testing side: outside of specimen 2) Differential Pressure takes 5 masks for testing
Remarks	1) Notation: % denotes Percentage CFU denotes Colony Forming Unit µm denotes Micrometre cm ² denotes Square Centimetre Litre/min denotes Litres per Minute Pa/cm ² denotes Pressure per square Centimetre cfu/g denotes Colony Forming Unit per gram 2) Bacterial filtration efficiency requirement stated in EN 14683-2019 + AC: 2019 (E) ≥ 95% for Type I ≥ 98% for Type II ≥ 98% for Type IIR 3) Differential Pressure requirement stated in EN 14683-2019 + AC: 2019 (E) < 40 Pa/cm ² for Type I < 40 Pa/cm ² for Type II < 60 Pa/cm ² for Type IIR 4) Microbial cleanliness requirement stated in EN 14683-2019 + AC : 2019 (E) ≤ 30 cfu/g for Type I, Type II and Type IIR 5) Splash Resistance, minimum pressure in kPa requirement stated in EN 14683-2019 + AC : 2019 (E) Not required for Type I and Type II ≥ 16.0 for Type IIR 6) Splash Resistance, an acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results (i.e. "None Seen")

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