

ULR-TC578720000014606P

Test Report No. GGN/T(A)/20/014606A1/1-2

Dated 2020-08-08



South Asia

Applicant

: **DR. SEVEN JOINT STOCK COMPANY**  
**Headquarter:** 25/1, Nhieu Tu Street, Ward 07, Phu Nhuan District, Ho Chi Minh City, Vietnam  
**Manufactory :**24/5 Ha Huy Giap Street, Thanh Loc Ward, District 12, Ho Chi Minh City, Vietnam  
: Received on 2020-07-27 3:49 PM  
: From 2020-07-27 to – 2020-08-07  
: Sample A: DR. SEVEN (4- Ply face mask)

Test Sample

Test Period

Sample Description

Color

Mfg./Exp. Date

: Blue  
: Manufacturing date: June 22<sup>nd</sup> 2020  
Expiry date: June 22<sup>nd</sup> 2023

Sample Quantity

Lot No./Batch No.

Country Of Origin

Name of the Buyer / Destination

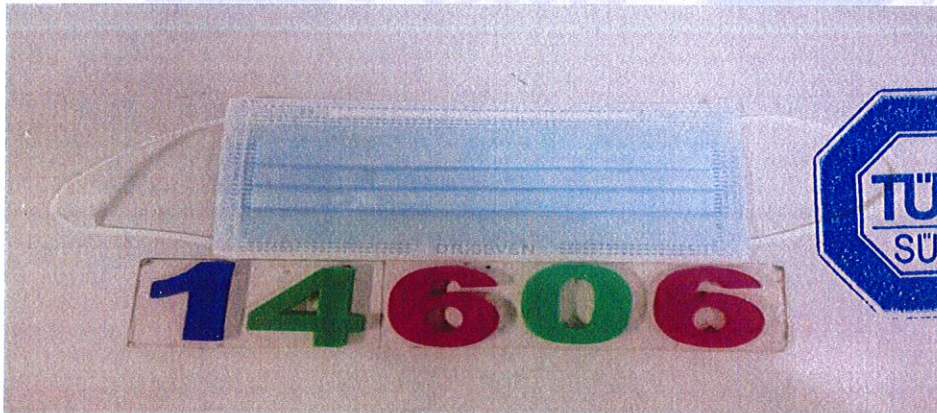
Testing Standard Followed

: 50 pcs/box; 7 Boxes  
: 220620-01  
: VIETNAM  
: / USA, EUROPE  
: **As per ASTM F2100-19, EN 14683:2019+AC:2019**  
**The test specification is followed as per ASTM F2100 – 19, Level 3 Barrier and EN 14683:2019+AC:2019 type IIR**

Note: 1. the submitted samples are Not Drawn by the Laboratory

2. Requested tests are performed

### Sample Photo



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**The test report is electronically generated. Hence original signature is not required.**

Note: (1) The results relate only to the items tested. (2) The test report shall not be reproduced except in full without the written approval of the laboratory, (3) Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production. For further details, please see testing and certification regulation, chapter A-3.4.

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### Summary of Results

Sl. No.	Tests	Test Method	Specification	Observation	Conclusion
1.	Differential pressure (Breathability)	EN 14683:2019+AC:2019 (E) Annex C	<6 mmH <sub>2</sub> O/cm <sup>2</sup>	0.12 mmH <sub>2</sub> O/cm <sup>2</sup>	Pass
2.	Synthetic blood penetration (Splash resistance test)	ASTM F1862/F1862M - 17 (120 mmHg)	No visible penetration of synthetic blood at the end of test period. 29 masks out of 32 masks should pass the test to quality this parameter.	32 Specimens are Passing out of 32 Specimens	Pass
3.	Synthetic blood penetration (Splash resistance test)	ASTM F1862/F1862M - 17 (160 mmHg)	No visible penetration of synthetic blood at the end of test period. 29 masks out of 32 masks should pass the test to quality this parameter.	32 Specimens are Passing out of 32 Specimens	Pass
4.	Sub-micron Particulate Filtration Efficiency: (ASTM F2299/F2299M - 03 (Reapproved 2017))	ASTM F2299 (Average particle size (0.1 μ))	≥98%	98.9%	Pass
5.	Flammability	16 CFR Part 1610	Burning time should be ≥3.5 seconds to categorized as Class 1	Class1	Pass
6.	Differential pressure (Breathability)	EN 14683:2019+AC:2019 (E) Annex C	<60Pa/cm <sup>2</sup>	1.16 Pa/cm <sup>2</sup>	Pass
7.	Synthetic blood penetration (Splash resistance test)	(ISO 22609:2004)	No visible penetration of synthetic blood at the end of test period. 29 masks out of 32 masks should pass the test to quality this parameter.	32 Specimens are Passing out of 32 Specimens	Pass
8.	Microbial Cleanliness (Bioburden)	EN ISO 11737-1:2018, Annex D	≤30CFU/g	4CFU/g	Pass

#### Conclusion:

1. This product achieved **Level 3 Barrier** according to ASTM F2100-19, standard specification for performance of materials used in medical face masks.
2. This product achieved **type IIR** according to EN 14683:2019+AC:2019, standard specification for performance of materials used in medical face masks.

The report no GGN/T(A)/20/014606 dated 2020-08-07 has been superseded. The test report is amended in terms of split test report.

Authorized By

Venu Gopala Krishna Rayudu  
(Authorised Signatory)

Authorized By

Ashutosh Kumar Pathak  
(Authorised Signatory)



South Asia

**Test Result(s):**

<b>1. Differential Pressure (Breathability): (EN 14683:2019+AC:2019(E) Annex C)#</b>						
<b>Test Condition:</b> Specimen Size: Diameter 25 mm (Area: 4.9 cm <sup>2</sup> ), Sample Exposure Side: Face Side, Flow Rate: 8 L/min, Airflow Direction: From the Inside of the Mask to the Outside of the Mask						
<b>Observations:</b>						
Specimens	:	1	2	3	4	5
Test Results (mmH <sub>2</sub> O/cm <sup>2</sup> )	:	0.10	0.11	0.10	0.12	0.15
Average Test Results (mmH <sub>2</sub> O/cm <sup>2</sup> )	:	0.12				
Requirement	:	<6 mmH <sub>2</sub> O/cm <sup>2</sup>				
Conclusion	:	PASS				
Note: The test requirement is taken as per ASTM F2100 – 19, Level 3 Barrier						

<b>2. Synthetic blood penetration (Splash resistance test): (ASTM F1862/F1862M - 17)#</b>									
<b>Test Condition:</b> Fluid Pressure: 120 mmHg									
<b>Observations:</b>									
Specimens	:	1	2	3	4	5	6	7	8
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	9	10	11	12	13	14	15	16
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	17	18	19	20	21	22	23	24
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	25	26	27	28	29	30	31	32
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Final Test Result	:	32 Specimens are Passing out of 32 Specimens							
Requirement	:	Minimum 29 specimens pass out of 32 specimens tested							
Conclusion	:	PASS							
Note: The test requirement is taken as per ASTM F2100 – 19, Level 2 Barrier									



South Asia

3. Synthetic blood penetration (Splash resistance test): (ASTM F1862/F1862M – 17)#									
Test Condition: Fluid Pressure:160 mmHg									
<b>Observations:</b>									
Specimens	:	1	2	3	4	5	6	7	8
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	9	10	11	12	13	14	15	16
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	17	18	19	20	21	22	23	24
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	25	26	27	28	29	30	31	32
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Final Test Result	:	32 Specimens are Passing out of 32 Specimens							
Requirement	:	Minimum 29 specimens pass out of 32 specimens tested							
Conclusion	:	PASS							
Note: The test requirement is taken as per ASTM F2100 – 19, Level 3 Barrier									

4. Sub-micron Particulate Filtration Efficiency: (ASTM F2299/F2299M – 03 (Reapproved 2017)#						
Test Condition: Particle Size: 0.1 micron						
<b>Observations:</b>						
Positive Control Particle Count [A]	:	16715				
Negative Control Particle Count [B]	:	287				
Specimens	:	1	2	3	4	5
Particle Count With Specimens [C]	:	537	625	425	360	440
Particle Filtration Efficiency (%), $E=[1-(C-B)/A]*100$	:	98.50	97.97	99.17	99.56	99.08
Avg. Particle Filtration Efficiency (%)	:	98.9				
Requirement	:	>=98%				
Conclusion	:	PASS				
Note: The test requirement is taken as per ASTM F2100 – 19, Level 3 Barrier						

5.0 FLAMMABILITY\*:  
 16 CFR 1610

Sample A -Upper				
Fabric Surface: Plain				
Preliminary Testing: Original: Lengthwise;				
	Original state		After Refurbishing	
	Flame spread(sec.)	Burn Code	Flame spread(sec.)	Burn Code
(1)	-	IBE	-	-
(2)	-	IBE	-	-
(3)	-	IBE	-	-
(4)	-	IBE	-	-
(5)	-	IBE	-	-
Average	-	-	-	-
(6)	-	-	-	-
(7)	-	-	-	-
(8)	-	-	-	-
(9)	-	-	-	-
(10)	-	-	-	-
Average	-	-	-	-
Flammability Classification: <b>Class 1</b>				
Refurbishing	N/A			
Remark:	<p><b>Class 1 - Normal Flammability</b>                      Textiles meeting these requirements are generally accepted by the trade as having no unusual burning characteristics.</p> <p><b>Class 2 - Intermediate Flammability</b>                      Textiles meeting these requirements are recognized by the trade as having flammability characteristics between normal and rapid and intense burning.</p> <p><b>Class 3 - Rapid and intense Burning</b>                      Such textiles are considered dangerously flammable and recognized by the trade as being unsuitable for clothing because of their rapid and intense burning.</p> <p>IBE=Ignited but extinguished                      *IBE=Ignited but extinguished, denotes a burn that goes under the cord without breaking the cord                      -- Sec =Actual Burn Time Measured and Recorded by timing device                      DNI=Did not ignite                      BB = Base burns.                      SFuc = Surface flash under the code but does not break the cord.                      SFpw = Surface flash, part way                      SFpoi = Surface flash at point of impingement only.                      SFonly = Time in second, surface flash only.                      SFBB = Time in seconds, surface flash base burn.                      SFBBpoi = Time in seconds, surface flash base burn starting at the point of impingement.</p>			

Note: 1. Test after refurbishing is not applicable as per clause 16CFR 1610.35(a)(2)



South Asia

<b>6. Differential Pressure (Breathability): (EN 14683:2019+AC:2019(E) Annex C)#</b>						
<b>Test Condition:</b> Specimen Size: Diameter 25 mm (Area: 4.9 cm <sup>2</sup> ), Sample Exposure Side: Face Side, Flow Rate: 8 L/min, Airflow Direction: From the Inside of the Mask to the Outside of the Mask						
<b>Observations:</b>						
Specimens	:	1	2	3	4	5
Test Results (Pa/cm <sup>2</sup> )	:	1.02	1.11	1.02	1.22	1.43
Average Test Results (Pa/cm <sup>2</sup> )	:	1.16				
Requirement	:	<60 Pa/cm <sup>2</sup>				
Conclusion	:	PASS				
Note: The test requirement is taken as per EN 14683:2019+AC:2019 Type IIR						

<b>7. Synthetic blood penetration (Splash resistance test): (ISO 22609:2004)#</b>									
<b>Test Condition:</b> Fluid Pressure: 16.0 KPa (120 mmHg), Fluid Velocity: 550 cm/s									
<b>Observations:</b>									
Specimens	:	1	2	3	4	5	6	7	8
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	9	10	11	12	13	14	15	16
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	17	18	19	20	21	22	23	24
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Specimens	:	25	26	27	28	29	30	31	32
Test Results	:	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Final Test Result	:	32 Specimens are Passing out of 32 Specimens							
Requirement	:	Minimum 29 specimens pass out of 32 specimens tested							
Conclusion	:	PASS							
Note: The test requirement is taken as per EN 14683:2019+AC:2019 Type IIR									

<b>8. Microbial Cleanliness (Bioburden): (EN 14683:2019+AC:2019(E) Annex D / EN ISO 11737-1:2018)*</b>						
<b>Test Condition:</b> Plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.						
<b>Observations:</b>						
Specimens	:	1	2	3	4	5
Total Microbial Cleanliness (CFU/g)	:	3	4	8	7	6
Average Microbial Cleanliness (CFU/g)	:	4CFU/g				
Requirement	:	<= 30 CFU/g				
Conclusion	:	PASS				
Note: The test requirement is taken as per EN 14683:2019+AC:2019 Type IIR						

Remarks:

- # The identified tests are performed in our ISO 17025 accredited subcontract laboratory.
- \* The test is under the scope of ISO 17025 accreditation.

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===== END OF REPORT =====