



# गणेश वैज्ञानिक अनुसंधान संस्थापन

(भारत सरकार के साथ तेल आयुक्त एवं दिल्ली सरकार के खाद्य मंत्रालय द्वारा अनुमोदित)

## GANESH SCIENTIFIC RESEARCH FOUNDATION

(Approved Competent Laboratory by Government of India and Delhi Govt.)



### TEST CERTIFICATE

Issued to: M/s BIO MEDICAL DEVICES	Report No.:13894
Address – Plot No 13, Village Gadaipur , Randhawa Masanda Road Focal Point Jalandhar, 144004	Date of Issue: 08.10.2020
	Reference: Client's Letter
	Kind Atten.: M/s BIOMEDICAL DEVICES
	Format TCF-GSRF/09/2019

### SAMPLE PARTICULARS

Nature of Sample: FACE MASK N95 (AIR RESPIRATOR without Exhalation Valve)	Test Start: 01.10.2020
Model No: N95 FACE MASK	Test Completed: 08.10.2020
Brand Name: BIO MEDICAL DEVICES	Samples Qty: 120
Sampling done by Manufacturer/Client	Date of sample receipt: 01.10.2020

<p>Description - a) Complies to FFP2, Equivalent to NIOSH, N95 Mask Criteria, Multi-layer design, Breathable and Comfortable with Components – i) Adjustable nose clip (Aluminium or eq.) ii) Nose comfort iii) Welded headband and ear loops.</p> <p>b) Colour – Multicolour, without exhalation valve.</p> <p>The sample meets the criteria as per the below tests for mentioned reference standards in this test certificate.</p>	<p>Sample Complies as per EN 149 approved FFP2 Mask with-out Exhalation Valve rating EN 14683. 2019, ASTM F2101, ASTM F1862/ISO 22609 Meets NIOSH 42 CFR 84 N95 requirements for a minimum 95% filtration efficiency against solid aerosols</p> <p>Meets N95 Respirator with Antimicrobial/Antiviral Agent Filtering Respirator.</p> <p>Meets - RESPIRATORY PROTECTIVE DEVICES, FFP2 (BIS 9473:2002)</p>
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S. No	Parameter	Results	Specifications	Method
1	Visual Inspection	Pass	Sample complies for proper marking and instructions for use.	IS 9473:2002
2	16 CFR Part 1610: Flame Spread (Flammability)	Class 1, Passes the Test	A standardized flame shall be applied to the surface near the lower end of the specimen for 1 second, and the time required for the flame to proceed up the fabric a distance of 127 mm (5 in) shall be recorded. (Class 1 and Class 2). Mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	16 CFR Part 1610
3	Carbon dioxide Content	0.62	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 percent (by volume).	IS 9473:2002
4	Breathing resistance			





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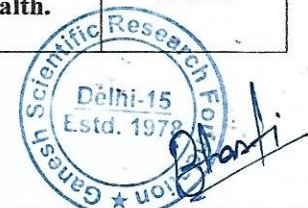
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(4.1)	Exhalation Resistance (25 cycles/min and a 2.0 l/stroke or a continuous flow of 160 l/min.)	2.4(Pass)	Permitted resistance mbar, Max (Exhalation @ 160 l/min) 3 for FFP2, NIOSH	IS 9473:2002, EN 14683, ASTM F2299, NIOSH N95, EN 149 FFP2
(4.2) a	Inhalation (Resistance 30 l/min)	0.6(Pass)	Permitted resistance mbar, Max (Inhalation @ 30 l/min) 0.7 for FFP2	IS 9473:2002, EN 14683, ASTM F2299, NIOSH N95, EN 149 FFP2, IS16289:2014
(4.2) b	Inhalation (Resistance 95 l/min)	2.1(Pass)	Permitted resistance mbar, Max (Inhalation @ 95 l/min) 2.4 for FFP2, NIOSH	IS 9473:2002, EN 14683, ASTM F2299, NIOSH N95, EN 149 FFP2, IS16289:2014
5	PFE, High (Particulate) Filtration Efficiency Test or Particle filter penetration {testing filters against 95 l/min, penetration with NaCl aerosol %}	98.9%(Pass)	NLT 95% for FFP2	ASTM F2299M-03 2010, IS 9473:2002
6	Leakage Test {The sodium chloride aerosol test LWD of Face & W of mouth Taken Normal (Test solution Flow rate of 0.12 m/s.)} %	7.6%(Pass)	NMT 11 percent for FFP2, NIOSH	IS 9473:2002
7	Clogging test Performance	Pass	Performance tests, with Dolomite	IS 9473:2002
8	Practical Performance			IS 9473:2002
	a) Head harness comfort	Pass	Pass/Fail	
	b) Security of fastenings,	Pass	Pass/Fail	
	c) Field of vision	Pass	Pass/Fail	
	8.1 Walking Test(6km/h,10mins)	Pass	Pass/Fail	
	8.2 Work Simulation Test (20 min test)	Pass	Pass/Fail	
9	Mechanical Strength (simulating rough usage of filter) (10Kgt, 2000 Rotation min in 20 minutes)	Pass	Pass/Fail	
10	Compatibility with Skin	Pass	Materials that may come into contact with the wearer's skin shall not be known to have potential to cause irritation or any adverse effect to health.	IS 9473:2002, ISO 10993-1:2018



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11	Bacterial Filtration Efficiency (BFE)	99.3(Pass)	Min 95% {With aerosol impact Staphylococcus aureus at flow rate of 28.3 l/min}	ASTM F2101
12	Resistance against penetration by Synthetic Blood (fixed volume, horizontally projected)	22.9 kPa or 171.8 mm hg	Resistance against penetration by Synthetic Blood (fixed volume, horizontally projected) ( $\geq 16$ kPa)	ASTM F1862/ISO22609
13	Breathability (Differential Pressure)	< 60.0 (Pass)	The differential pressure is an indicator of the breathability of the mask, expressed in a differential pressure ( $\Delta P$ ) in mm H <sub>2</sub> O/cm <sup>2</sup> or Pascal/cm <sup>2</sup> . < 40 or < 60.0 Pascal/cm <sup>2</sup> is required	Point 5.2.2 of the EN 14683 standard (description in annex C)  NIOSH
14	The bio-burden or microbial charge (Microbial Cleanliness)	< 10 (Pass)	< 30 cfu/g	EN ISO 11737-1:2018



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ESTD 1978

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15	Penetration of Filter Material			
15.1	Particle filter penetration {testing filters against 95 l/min, penetration NaCl aerosols test %	4.3 (Pass)	Max 6.0% for FFP2	EN149/IS9473:2002
15.2	Paraffin Oil test, penetration of paraffin oil @ 95 l/min, %	1.9 (Pass)	Max 2.0% for FFP2	EN149/IS9473:2002
16	Cytotoxicity (Biocompatibility Tests)	≤ 2 (Pass)	Observing the cells under a microscope and assigning a cytotoxic grade (0-4). The grade is based on an estimated percent lysis (death) and on the morphology (appearance) of the cells. Test materials pass the assay if the cytotoxic score is ≤ 2 (≤ 50% lysis).	ISO 10993-5, USP <87>
17	Sensitizing (Disperse Dyes and Carcinogenic Dyes) (Biocompatibility Tests)	No Reaction Found (Passes the Test)	The Sensitization test is used for the determination of sensitizing activity of chemicals and medical devices. These tests are assessing the potential of a material or product to cause a delayed hyper-sensitivity reaction	ISO 10993-1
18	Skin Irritation (Biocompatibility Tests)	No Irritation Found (Passes the test)	The Irritation test(s) can be used to determine if a material or chemical will cause local irritation in the skin, mucosal, or ocular tissues	ISO 10993-1
19	Viral Penetration Test	22.9 kPa (Pass)	Virus Pressure Stimulation Exposure pressure [kPa]  20.0 (Class 6)	ASTM F1671  ISO 16604



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			Resistance penetration by blood-borne pathogens using a bacteriophage ("virus" penetration simulation) –	
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ANALYST  
NOTE:

AUTHORISED SIGNATORY

- Results# shows the performance tested under laboratory conditions for the submitted sample by the client, please note that the test may not reflect the reality of use.
- Laboratory is not responsible for safety of the users in any case, these results do not purport to address all of the safety concerns, if any associated with use of the final product.
- Users are responsible to establish safety and determine the applicability of the PPE's as per the regulatory requirements and uses, the test does not conform to all blood borne pathogens exposure.
- Methods\* are mentioned for reference purposes, as laboratory have developed inhouse methods to perform the tests

### Current Updates

- Our laboratory ([gsrf.co.in](http://gsrf.co.in)) tech partner Progenbiolab Technologies Pvt. Ltd which is in association (Transfer of Technology) with DRDO for **Production of Equipment for Combating of Covid 19**. Find us at DRDO website <https://drdo.gov.in/counter-covid-19-technologies>. For more details call@9599974780

End of the Report (Total 5 pages)