ESTD 1978

गणेश वैज्ञानिक अनुसन्धान संस्थापन

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

GANESH SCIENTIFIC RESEARCH FOUNDATION

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

ISO 9001 2015 CERTIFIED

TEST CERTIFICATE

Issued to: M/s BIO MEDICAL DEVICES **Address – Plot No 13, Village Gadaipur ,** **Randhawa Masanda Road** **Focal Point Jalandhar, 144004**	Report No.:**13895** 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 with 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**

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 loop **b) Colour – Multicolour, with exhalation valve.** **The sample meets the criteria as per the below tests for mentioned reference standards in this test certificate.**			**Sample Complies as per EN 149 approved FFP2 Mask with 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** **Meets N95 Respirator with Antimicrobial/Antiviral Agent Filtering Respirator.** **Meets - RESPIRATORY PROTECTIVE DEVICES, FFP2 (BIS 9473:2002)**	
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**	**0.55**	**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**			

Ganesh Scientific Research Foundation Delhi-15 Estd. 1978

Office : 64-65, Satguru Ram Singh ji Marg, Kirti Nagar Industrial Area, New Delhi-110 015
Mobile : 9268933883, Ph. : (0) 011-25102814, 25195045
E-mail : info@gsrf.co.in, gsrfdelhi@gmail.com I Website : www.gsrf.co.in

(4.1)	Exhalation Resistance (25 cycles/min and a 2.0 l/stroke or a continuous flow of 160 l/min.)	2.0(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)	0.4(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)	1.9(Pass)	Permitted resistance mbar, Max (Inhalation @ 95 l/min)2.4 for FFP2, NIOSH	
5	PFE, High (Particulate) Filtration Efficiency Test or Particle filter penetration {testing filters against 95 l/min, penetration with NaCl aerosol %	98.4%(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.)} %	8.0%(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) (10Kgwt, 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

Ganesh Scientific Research Foundation ★ Delhi-15 Estd. 1978

11	Bacterial Filtration Efficiency (BFE)	99.8(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)	22.5 kPa or 168.8 mm hg	Resistance against penetration by Synthetic Blood (fixed volume, horizontally projected) (≥ 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 (ΔP) in mm H2O/cm2 or Pascal/cm2. < 40 or < 60.0 Pascal/cm2 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

Ganesh Scientific Research Foundation ★ Delhi-15 Estd. 1978

15	Penetration of Filter Material				
15.1	Particle filter penetration {testing filters against 95 l/min, penetration NaCl aerosols test %		4.8 (Pass)	Max 6.0% for FFP2	EN149/IS9473:2002
15.2	Paraffin Oil test, penetration of paraffin oil @ 95 l/min, %		1.95 (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	22.7 kPa (Pass)	Virus Pressure Stimulation Exposure pressure [kPa] 20.0 (Class 6)		ASTM F1671 ISO 16604

Ganesh Scientific Research Foundation Delhi-15 Estd. 1978

			Resistance penetration by blood-borne pathogens using a bacteriophage ("virus" penetration simulation) –	
20	**Strength of attachment of Exhalation Valve**	**Complies**	**An axial tensile force of 10 N shall be applied to the valve (housing) for 10 s.**	**IS 9473:2002/EN 149**
21	**Exhalation Valve Leakage Test**	**<30(Pass)**	**Leakage between the valve and valve seat shall not exceed 30 millimeters per minute**	**Subpart K of [42 CFR 84], NIOSH/EN149**

ANALYST

AUTHORISED SIGNATORY

NOTE:

- 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) 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)