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TEST REPORT

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Product Testing Service

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Test report No Date of Issue Sample Booking/Recipt Date: Date of start of testing Date of completion of test Sample Description:	 ATL0690022021 15/03/2021 10/03/2021 10/03/2021 15/03/2021 PRIMA MEDIX-N95
Client Name Address: Sample Code Std Reference	 PT Prima Medix Nusantara MidPlaza 2, 8th Floor JI Jendral Sudirman 10-11 Jakarta 10220 – Indonesia BL21021002 EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles
Test Method Test Environment Relative Humidity Sample Condition Expiry Date Manufacturing date Contact Person	 Refer Test results 25±2°C 60±5%RH Good 10 FEB 2023 10 FEB 2021 Mr. Andy Soeharsono

Submitted sample Image



Signed for and On Behalf of INTEGRATED ASSESSMENT SERVICES PVT LTD

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TECHNICAL HEAD

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Test Results

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S. No.	Parameters	Clause	Specified Requirement	Observed Value	Result	
1 Packaging 7.4			Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination	Satisfactory	Satisfactory	
2	Material	7.5	before use. Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After undergoing the conditioning, none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps. Three particle filtering half masks shall be tested. When conditioned, particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Satisfactory	Satisfactory	
3	Cleaning & Disinfection	Cleaning & If the particle filtering half mask is designed to be re-usable, the materials used shall Not applicable				
4	Practical performance	77	The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be Determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests Which revealed these imperfections.	Satisfactory	Satisfactory	
5	Finish of parts	7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Satisfactory	Satisfactory	
6 Total inward 7.9.1 leakage		7.9.1	The tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1 8 % for FFP2	Total Inward Leakage was less than 11% for 25 out of 25 exercise. 5 out of 5 individual wearer arithmetic mean for total Inward Leakage found less than 8%	Satisfactory	

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				2 % for FFP3.					
			filtering half ma	tion of the filter of the particle ask shall meet the requirements of Table n chloride test 95 l/min	Observed value of % Leakage as follows: Mask % Leakage(NACL)				
7	Penetration of filter material.	7.9.2	Classification	Ma	sk	% Leakage		Satisfactor	
	AR (3 samples)		FFP1	test aerosol %			(NaCI)		
			FFP2	6	M		5.66		
			FFP3	1	M: M:		5.50 5.81		
				tion of the filter of the particle	171	5	5.01		
	Penetration of		Sodiur	ask shall meet the requirements of Table n chloride test 95 l/min	Ma	ask % Leakage			
7.a	filter material		Classification	Maximum penetration of	М	1	(NaCI) 5.20		Satisfactor
	SW (3 samples)			test aerosol %	M		5.80		
			EFP1	20	M		5.91		
			FFP2 FFP3	6 	101	0	0.01		
				tion of the filter of the particle					
				ask shall meet the requirements	Ma	ek	%		
	Penetration of			of Table n chloride test 95 l/min	IVIA	SN	/₀ Leakage (NaCl)		
7.b	filter material		Classification	Maximum penetration of	М	1	5.96		Satisfactor
	MS (3 samples)		EFP1	test aerosol %	M		5.77		
	T 7				M	3	5.98		
			FFP2 FFP3	6			0.00		
8	Compatibility with skin	7.10	wearer's skin s cause irritatior	may come into contact with the hall not be known to be likely to or any other adverse effect to health.	tatio	, material dio n or any adv to health		Satisfactory	
9	Flammability	7.11	for the wear f When tested, shall not burr After remova	sed shall not present a danger rer and shall not be of highly lammable nature. the particle filtering half mask or not to continue to burn for more than 5 s al from the flame. The particle ask does not have to be usable after the test.	Satisfactory				Satisfactory
10	CO2 Content of the inhalation air (AR- 3 Samples)	7.12	(dead space)	xide content of the inhalation air shall not exceed an average of ,0 % (by volume).				Satisfactor	
			the particle filte ar	ness shall be designed so that ering half mask can be donned nd removed easily.					
11	Head Harness	7.13	The head harness shall be adjustable or self- adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device					Satisfactor	
12	Field of vision	7.14		ion is acceptable if determined actical performance tests	Acceptable when checked in practical performance tests as per 8.4				Satisfactor
13	Exhalation valve(s)	7.15	more exhalatio corre If an exhalatio	ing half mask may have one or n valve(s), which shall function ctly in all orientations. on valve is provided it shall be ainst or be resistant to dirt and	No Exhalation valve available in the submitted mask				Satisfactory

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			may inclue necessary fo	shrouded or hat may be half mask to									
			Exhalation operate corre flow of 3										
			When the ex to the face- tensile f										
			tensile force of 10 N applied for 10 s. The breathing resistances apply to valved and valve less particle filtering half masks and shall				MASK	AR	SW	MS			
	Breathing		Classification	Classification Maximum permitted resistance (mbar)				0.12	0.15	0.18			
14	Resistance Test AR (3 samples)	7.16		Inhal 30 l/min		Exhalation 160 l/min	@ lpm Inh 95 @ lpm	0.59	0.61	0.65	Satisfactory		
			FFP1 FFP2	0.6 0.7	<u>2.1</u> 2.4	3.0 3.0	Inh 160 @ lpm	1.18	1.20	1.25			
			FFP3	1.0	3.0	3.0							
			The breathin	ig resistan	ces apply t	o valved and							
				the requir		isks and shall Table	MASK	AR	SW	MS			
	Breathing Resistance Test AC (3 samples)	7.16	Classification		im permitted (mbar)		Inh 30 @ lpm	0.18	0.23	0.25			
14.a				Inhal 30 l/min	ation 95 l/min	Exhalation 160 l/min	Inh 95 @ lpm	0.63	0.65	0.60	Satisfactory		
			FFP1	0.6	2.1	3.0	Inh 160	1.25	1.23	1.21			
			FFP2	0.7	2.4	3.0	@ lpm						
			FFP3	1.0	3.0	3.0		m					
	Breathing Resistance Test 7.16 SW (3 samples)	tance Test 7.16	The breathin valve less pa	MASK	AR	sw	MS						
			ince Test 7.16	Classification	the require Maximu	im permitted (mbar)		Inh 30 @ lpm	0.25	0.22	0.20		
14.b					Inhal	. /	Exhalation	Inh 95	0.58	0.63	0.65	Satisfactory	
				30 l/min	95 l/min	160 l/min	@ lpm	4.00	4.05	1.00			
				FFP1	0.6	2.1	3.0	Inh 160 @ lpm	1.22	1.25	1.23		
	10		FFP2	0.7	2.4	3.0			-				
			FFP3	1.0	3.0	3.0			_				
15	Demountable Parts	7.18		and secur		all be readily possible by	No demo in the						
16	Visual inspection	8.2	The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests										
17	Marking	Annex A	For parts, which cannot reasonably be marked, the relevant information shall be included in the information to be supplied by the manufacturer.										
			the manufacturer need not be marked but the relevant information have to be given in the information to be supplied by the manufacturer										

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