

भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS

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Haryana Branch Office

पंजीकृत – पावती

दिनांकः 31/07/2*0*20

हमारा संदर्भः हरियाणा शाखा का०/सी एम/एल-9100139207 /

विषयः भा0 मा0 ब्यूरो प्रमाणन मुहर लाइसेंस

उत्पाद : मेडिकल टेक्सटाइल सर्जिकल फेस मास्क - विशिष्टि

भा0 मा0 संख्याः 16289:2014

01-07-2020 से 30-06-2021 तक लागू ।

मैसर्स ए वी ए इंटरनेशनल प्राइवेट लिमिटेड, प्लॉट नंबर 235, सेक्टर 56, फेज 5, कुंडली, औद्योगिक एस्टेट, सोनीपत हरियाणा -131028

महोदय.

उपरोक्त दर्शाये गये अनुसार आपके द्वारा उत्पाद उपरोक्तानुसार पर ब्यूरो मुहर लगाने के लिए मा0 मा0 ब्यूरो प्रमाणन मुहर लॉइसेंस संलग्न है।

- 2. लाइसेंस यह मानते हुए स्वीकृत किया जा रहा है कि आप केवल प्रमाणन के समानुकूल वाले सारे उत्पादन पर इसे मुहरांकित करेंगें । ब्यूरो कभी भी लाइसेंस समाप्त करने का अधिकार सुरक्षित रखता है ।
- 3. यह स्पष्ट करना चाहेंगे कि परीक्षण एवं निरीक्षण योजना का पूर्णतः पालन करना जरूरी होगा ।
- 4. परीक्षणों एवं निरीक्षणों के सभी रिकार्ड एवं रद्दीकरण के दस्तावेज भी ठीक ढंग से रखे जाने चाहिए । जब कभी भी हमारे निरीक्षण अधिकारी आपकी फैक्टरी में आयें एवं भा0 मा0 ब्यूरो के मांगने पर ये रिकार्ड दिखाये जाने चाहिए ।
- 5. लाइसेंस में प्रदान स्कोप के अलावा कोई भी वैराइटी मार्क करना आई एस आई का दुरूपयोग माना जाएगा व नियमानुसार कार्रवाई की जाएगी । यदि वैरायटी जोड़नी है तो आवेदन कर सकते है।
- 6. अनुरूपता के प्रमाणपत्र की शर्ते संलग्न है।

कृपया पावती भेजें ।

भवदीय.

संलग्नकः उपरोक्तानुसार

प्रमुख (एच आर बी ओ) (हरियाणा शाखा कार्यालय)

भारतीय मानक ब्यूरो Bureau of Indian Standards

मानक चिहन के उपयोग के लिए अनुज्ञप्ति Licence for the use of Standard Mark

लाइसेंस सं सीएम/एल-9100139207 Licence No. CM/L-9100139207

यह ब्यूरो, भारतीय मानक ब्यूरो अधिनियम, 2016 (2016 का 11) द्वारा प्रदत शक्तियों के आधार पर By virtue of the power conferred on it by the Bureau of Indian Standards Act, 2016 (11 of 2016) the Bureau hereby grants to

मैसर्स ए वी ए इंटरनेशनल प्राइवेट लिमिटेड, प्लॉट नंबर 235, सेक्टर 56, फेज 5, कुंडली, औद्योगिक एस्टेट, सोनीपत हिरयाणा -131028

M/s. AVA International Private Limited, Plot No.235, Sector 56, Phase 5, Kundli, Industrial Estate, Sonipat Haryana -131028

को (जिसे इसमें आगे अनुज्ञप्तिधारी कहा गया है) इसकी प्रथम अनुसूची के पहले स्तंभ में विनिर्दिष्ट मानक चिहन का, इस अनुसूची के तीसरे स्तंभ में दी गई किस्मों पर, उपयोग करने के लिए यह अनुज्ञप्ति प्रदान करता है। इन उत्पादित किस्मों पर चिहन का उपयोग उक्त अनुसूची के द्वितीय स्तंभ में समय-समय पर संशोधित अथवा पुनरीक्षित/संदर्भित संबद्ध भारतीय मानक (मानकों) के अनुसार/अनुरूप विनिर्मित हो।

(hereinafter called the Licensee) this licence to use the Standard Mark set out in the first column of the Schedule hereto, upon or in respect of the varieties set out in the third column of the said Schedule which is manufactured in accordance with/conforms to the related Indian Standard(s) referred to in the second column of the said Schedule as from time to time amended or revised.

- 2 इस अनुज्ञप्ति में अनुबंध अनुज्ञप्ति की शर्तों के लिए अनुज्ञप्तिधारी उत्तरदायी हैं। यह अनुज्ञप्ति पहली अनुसूची में यथा-उल्लिखित नाम, कारखाना के पते ओर अवधि के लिए विधिमान्य होगा ओर इसे स्कीम-1 में निर्दिष्टानुसार नएकृत कराया जा सकता है।
- 2. This Licence carries obligations on part of the licensee as conditions of licence which are given in Annexure attached herewith. This licence shall be valid for the name, factory address and period as mentioned in the schedule and may be renewed as specified in the scheme-I

अनुसूची Schedule

(अनुज्ञप्ति सं सीएम एल- 9100139207) (Licence No.CM/L-9100139207) /

नाम : मैसर्स ए वी ए इंटरनेशनल प्राइवेट लिमिटेड

Name: M/s. AVA International Private Limited

कारखाने का पताः प्लॉट नंबर 235, सेक्टर 56, फेज 5, कुंडली, औद्योगिक एस्टेट, सोनीपत, हरियाणा -131028

Factory Address: Plot No.235, Sector 56, Phase 5, Kundli, Industrial Estate, Sonipat, Haryana -131028

विधिमान्यताः एक जुलाई दो हजार बीस से तीस जून दो हजार इक्कीस तक

Validity: From First July Two Thousand Twenty to Thirtieth June Two Tho

मानक चिहन		venty to Thirtieth June Two Thousand Twenty On	
	भारतीय मानक	अनुज्ञप्ति का विषय क्षेत्र	मुहरंकन शुल्क
Standard Mark	Indian Standard(s)	Scope of Licence	Marking Fee
(1)	(2)	(3)	(4)
IS 16289 CM/L-9100139207	भा. मा. 16289:2014 IS 16289:2014 मेडिकल टेक्सटाइल सर्जिकल फेस मास्क - विशिष्टि Medical Textiles Surgical Face Masks - Specification	कक्षा 1 का सर्जिकल फेस मास्क Surgical Face Masks of Class 1	एक वर्ष की प्रचालन अवधि के दौरान न्यूनतम मुहरंकन शुल्क रु. 63000/- के साथ सभी इकाइयों के लिए रु. 0.20 प्रति इकाई = 100 पीस एक प्रचालन वर्ष के लिए न्यूनतम चिहनांकन शुल्क अग्रिम में देय होगी जो
आज वर्ष 202(अगले नवीकरण में अग्रनीत होगी। Rs. 0.20 per unit for all the units with a minimum marking fee of Rs. 63000/- during an operative period of one year. Unit = 100 Piece Minimum marking fee for one operative year payable in advance which will be carried over to next renewal(s)

Signed, Sealed and Dated this

day of

31

July

ताराख का हस्ताक्षारत, मुहरबंद किया गया month of Year 2020

भारतीय मानक ब्यूरो के लिए

For Bureau of Indian Standards

प्रमुख(एच आर बी ओ) Head (HRBO)



THE SOUTH INDIA TEXTILE RESEARCH ASSOCIATION

CENTRE OF EXCELLENCE FOR MEDICAL TEXTILES

Physical, Chemical & Biological Testing Laboratories

(ISO/IEC 17025 NABL ACCREDITED)

13/37, Avinashi Road, Aerodrome Post, Coimbatore - 641 014, INDIA



TEST REPORT

XXVII / A / E / 12650 / 20

Test Report No : **O2000657**Sample Received On : **14-08-2020**

ULR: TC694420010000525P

Inward Date: 14-08-2020

Tested on: 17.08.2020 to 20.08.2020

Report Date: 20-08-2020

To
Ava International Pvt Ltd
235,Sec 56,Phase-V
Industrial Eastat,Kundli Sonipat,Haryana

Sonipat, Haryana, India Pincode: 131028

Contact No(s): 9811799523

Dear Sir / Madam,

This has reference to the sample(s) submitted by you for testing vide your letter reference no : dt 06.08.2020.

The results pertaining to your sample(s) are enclosed herewith.

Encl: Bill

This is a computer generated report, hence does not require signature.

IMPORTANT

This report is strictly CONFIDENTIAL. Its use for publicity, arbitration or as evidence in legal disputes is forbidden. Reference of sample(s) given by the party. Samples are not drawn by the laboratory. The above results are related to the samples tested. The report shall not be reproduced except in full, without the written approval of the laboratory. Authenticity of the report may be verified from our website www.lab.sitraonline.org.

ENCE

Test Report No: O2000657

THE SOUTH INDIA TEXTILE RESEARCH ASSOCIATION

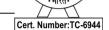
CENTRE OF EXCELLENCE FOR MEDICAL TEXTILES

Physical, Chemical & Biological Testing Laboratories

(ISO/IEC 17025 NABL ACCREDITED)

13/37, Avinashi Road, Aerodrome Post, Coimbatore - 641 014, INDIA

ULR: TC694420010000525P



Report Date: 20-08-2020

Ava International Pvt Ltd

Ref: dt 06.08.2020

Splash Resistance-ASTM F1862

ASTM F1862/F1862M-2017

Result at 160mmHg

Pass

O2000657-1
Sample Particulars: Three Ply Facemask Sample
Staphylococcus aureus ATCC 6538
5 x 10 ⁵ CFU/mL
Tryptic soya agar
Peptone water
37 ^o C for 24 h
Face mask 10 x 10 cm
Face side
28.5 L / min
3.0 ± 0.3 micron
1814
0
99.7
99.8
99.4
99.6
99.8
2091
0

Breathability - Differential pressure-EN 14683**	O2000657-1
EN 14683:2014(E) Annex C	Sample Particulars: Three Ply Facemask Sample
Pa/cm ²	42.30

^{*} Test(s) not covered under NABL Scope.

method.

- End of Report -

(This is a computer generated report, hence does not require signature.)



भारतीय मानक व्यूरो BUREAU OF INDIAN STANDARDS

Address: Plot No 4-A, Madhya Marg,

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Phones: 0172-2650290

0172-2659065 Fax:

E-Mail: mdchl@bis.org.in

http://www.bis.org.in web:

Haryana Branch Office

Our Ref :HRBO/CM/L 9100143610

Dated: 17 8/2020

Subject: Grant of BIS Certification Marks Licence No 9100143610 as per IS 9473:2002.

- Reed -

M/s. AVA International Pvt. Ltd.

Plot No.235, Secror-56

Phase-5, Industrial Estate, Kundli

Distt: Sonipat Haryana131028

Dear Madams(s)/Sir,

With reference to your application, we are pleased to inform you that the Certification Marks Licence has been granted to you to use the Standard Mark in respect of the followings:

Product:- Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles

Grade/Class/Type/Variety

Class FFP2, Sub-Class S (solid), Type: Without Valves, For single use only, Without resistance to clogging

As Per IS 9473:2002

- 1. The licence is granted on the explicit condition that you will mark entire/substantial production which conforms to the Indian Standards.
- 2. The number assigned to this licence is CM/L- 9100143610 which has been made operative from 2020-08-19 and is valid upto 2021-08-18. The licence number should invariably be referred to in your future correspondence.

According to sub-regulation (1) &(3) of Paragraph 5 of scheme I of Schedule II under Bureau of Indian Standards (Conformity of Assessment) Regulation, 2018, the annual licence fee of Rs. 1000,00 and the marking fee for use of standard mark as per Annexure-I of Scheme I of BIS(Conformity assessment) Regulation 2018 is payable by you with effect from 2020-08-19 for the period of validity of the licence in advance.

- 3. Minimum marking fee stipulated in Annexure -I of scheme I of BIS (Conformity Assessment) Regulation 2018 is payable by you regardless of the whether you actually mark your product or not with the Standard Mark.Our Receipt No. 0091PC2020000994 dated 2020-08-19 for the licence fee and the minimum marking fee Rs.37000 for the first operative period is already issued separately.
- 4. This advance minimum marking fee will be carried over to the next year on every renewal. The actual marking fee calculated on the unit rate on the production marked or the minimum marking fee, whichever is higher shall be payable by you at the time of renewal.

5. With a view to streamlining the reporting of quantity marked, calculation and collection of marking fee on the unit rate basis, fees will be calculated on the production marked during the first nine months of operation of the licence at the time of first renewal, and on the production marked during twelve months comprising the last three months of the previous operative year and the first nine months of the current operative year, at the time of the second and subsequent renewals. In case the licence expires, the entire production marked till the expiry date shall be taken into account for calculating the marking fee payable.

6.The Scheme of Testing and Inspection (Ref: Annex C of PM/9473/3 June 2020) as specified by BIS will have to be implemented by your organization strictly and completely. This supervision of the operation of the Scheme shall be done by a person responsible for the quality control function in your organization. Kindly inform us the name and designation of the person who will be held responsible for the operation and maintenance of the Scheme. Any future change in this respect will have to be communicated by you to us as and when these take place.

7. We are enclosing a sheet giving the preferred dimensions of the Standard Mark to enable you to prepare the designs of the Standard Mark for marking the above product Photographic reduction in any size is permissible. This will ensure the relative proportions of the different dimensions maintained. Preferred dimensions be used as far as possible.

8.On commencement of marking of your product for which you are licensed, you may advertise your product with Standard Mark in various media only during the validity of your licence. The use of Standard Mark on letterheads and publicity literature will be permitted only on receipt of your assurance that in the event of cancellation or lapsing of your licence, the Standard Mark on your letterheads, publicity literatures etc. will be destroyed/obliterated.

9.This licence is granted for your factory situated at Plot No. 235, Sector 56, Phase 5, Kundli Industrial, Estate, Sonipat, Haryana 131028. Privileges under the licence shall not be exercised by any other firm company/factory etc. This licence is not transferable in the event of shifting the manufacturing and testing equipment from the licensed premises to some other place, use of Standard Mark shall be stopped till the new premises are inspected and found to be satisfactory by us in respect of manufacturing and testing facilities available there and the address of the new premises is endorsed in the licence.

Thanking You,

ell

Scientist E & Head

☎: 0751- 2341960, 2343972 2390160, 2390211

Fax: 0751-2341148

E-Mail: director@drde.drdo.in



भारत सरकार, रक्षा मंत्रालय Govt. of India, Ministry of Defence रक्षा अनुसंधान एवं विकास स्थापना (डी.आर.डी.ई.) Defence R&D Establishment (DRDE) झांसी मार्ग, ग्वालियर - 474002 (म.प्र.) Jhansi Road, Gwalior- 474 002 (M.P.)

No. DRDE/MASK/2020

By email

Date: 13 July 2020

To M/s AVA International Pvt. Ltd., 235, Sector 56, Phase 5, Kundli Industrial Area, Haryana-131028. e-mail: info@careview.in

Sub: Test report of N95 mask without exhalation valve.

Ref: Your letter No. Nil dated 15 June 2020.

With reference to the above, kindly find enclosed herewith the test report (Particulates Filtration Efficiency) of the mask samples submitted by you for testing at DRDE, Gwalior.

Dr. M. Boopathi Scientist F

Encl: As above (One page)



Test Report No DRDE/MASK/1331

Date: 13 July 2020

Defence Research and Development Establishment (DRDE),

Govt. of India, Ministry of Defence

Jhansi Road, Gwalior-474002

Phone: 0751-2341550, Fax: 0751-2341148

Email: director@drde.drdo.in

		The state of the s
Manufacturer / Developer	M/s AVA International Pvt. Ltd., Kundli Industria	l Area, Haryana-131028.
Letter No. & date	Nil & 15 June 2020	
Manufacturer's code if any	Nil	
Category of Masks submitted	N95 without exhalation valve	
DRDE sample code	PD-1331	
Date of receipt of sample	18 June 2020	
Period of testing	25 June 2020 to 13 July 2020	
Remarks (if any)	Nil	

Test Results

1. Particulates Filtration Efficiency (PFE)

Test Method	Test Conditions	R	esults	Remarks 3
		Specified	Observed	Constitution of the state of th
NaCl aerosol with	As received		99.13 %	
laser based measurement	Conditioned for 24 hrs at +70±3° C	≥ 95 %	99.14 %	Meets the requirement as specified.
	Conditioned for 24 hrs at -30±3° C		99.21 %	

Note:

- i. The test results shall not be treated as an endorsement/Certification of the product. The DRDE/DRDO Logo or "Approved by DRDE/DRDO" cannot be used on product or any promotional document or otherwise.
- ii. The test results are valid for the samples tested and the documented test conditions.
- iii. The test report shall not to be published in any form without the written approval of the Director, DRDE in case of Commercial Testing Samples.
- iv. Samples are not drawn by the DRDE, Gwalior. The results relate to the sample submitted by the client.
- v. Test report is meant for guidance and not be used for litigation.
- vi. Remnant Sample storage up to 60 days only.



An ISO 9001:2015 Certified Company

Office: Plot No-576, Opp. ITS College, Loni Road, Mohan Nagar, Ghaziabad (UP)-201007 Regd. Off.: D-17/573, East Gokulpur, Amar Colony, Delhi-110094 | Email: hslabs83@gmail.com

Mob: +917053533000, + 917530853802



TEST REPORT

Page 1 of 2

Issued To	:	AVA International Pvt. Ltd.		Report No.	:	HSL200508:01
		235, Sector 56, Phase V, Kundli		Date of Receiving	:	08/05/2020
		Sonepat-131028		Date of Testing Start	:	09/05/2020
				Date of Completion	:	12/05/2020
Description	:	N95 Mask (CV1221)				
Customer Ref. No.	:	CV/124				
Brand Name	:	CareView	Sa	ample Quantity		: 20 Pcs
Sample Drawn By	:	Party	Sa	ample Package		: Corrugated Box
Lot No.	:	052031	Be	est Before Date		: May, 2023
Mfd. Date	:	May, 2020	Aı	ny Other Information	ì	: N.S.

S.No	Test Parameters	Test Result	Specification as per Party	Test Method/ Test Standard
1	Description	Well Fitted, Non Collapsible & without Valve, Provide good breathability.	Should be well fitted, non- collapsible & good breathability.	Visually
2.	Layers, Ply	6	6	Visually
3.	Check for integrity	Complies	All Layers stitched	Visually
4.	Weight, g	6.78	Thi Bayers stitemed	v is during
5.	GSM g/m ²			
A	Layer 1	34.82	35 ± 5 % GSM spun bonded PP fabric SSS Grade.	By measurement
В	Layer 2	25.21	25 ± 5% GSM spun bonded PP fabric SS Grade.	By measurement
С	Layer 3	25.30	25 ± 5% GSM Melt blown fabric PP.	By measurement
D	Layer 4	74.75	75 ± 5% GSM Thermal bonded media PP and Polyester	By measurement
Е	Layer 5	25.36	25 ± 5% GSM melt blown fabric PP.	By measurement
F	Layer 6	25.21	25 ± 5% GSM spun bonded PP fabric SSS Medical Grade.	By measurement
6.	Absorbency test, %	6.75		By weighing
7.	Heavy metal ion test, ppm	Complies	Not more than 1	By chemical method
8.	Breathability	Complies	To comply	BY Appling Pressure
9.	Splash Resistance Pressure, mmHg	Complies	Not less than 120	ISO 22609:2004
10.	Bacterial Filtration Efficiency, %	99.25	≥ 95	IS:16288:2014



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TEST REPORT

Page 2 of 2

Issued To		AVA International Pvt. Ltd.	Report No.	:	HSL200508:01
		235, Sector 56, Phase V, Kundli	Date of Receiving	:	08/05/2020
		Sonepat-131028	Date of Testing Start	:	09/05/2020
		Date of Completion		:	12/05/2020
Description	:	N95 Mask (CV1221)			
Customer Ref. No.	:	CV/124			
Brand Name	:	CareView	Sample Quantity		: 20 Pcs
Sample Drawn By	:	Party	Sample Package		: Corrugated Box
Lot No.	:	052031	Best Before Date		: May, 2023
Mfd. Date	:	May, 2020	Any Other		: N.S.
			Information		

Summary: The BFE Test is performed to determine the efficiency of test article compared to bacteria counts. A suspension of Staphylococcus aureus NCIM2127 was aerosolized onto the test article at a constant flow rate. The challenged delivery is maintained at 3.4 - $4.5*10^4$ colony forming units with mean particle size of $3.0 \, \mu m \pm 0.3 \, \mu m$. The procedure shows reproducible bacteria challenge to be delivered to the test materials.

Remarks: This sample conforms Quality compliant with standards for medical N95 respirator-NIOSH N95, EN 149 FFP2 or equivalent.

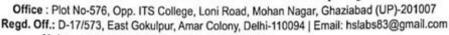
Note: The above report is concerned only to the samples submitted by the customers to our Laboratory. These results may not be indicative of the results of bulk lot. It is the duty of supplier/ customer to maintain the traceability between the sample submitted for testing and the bulk lot supplied.

This report is generated to let the customer know about the quality of their product and to help them improve their products quality.

Qualitative Test: Realise on the wearer's ability to taste or smell a test agent.



An ISO 9001:2015 Certified Company



Mob: +917053533000, +917530853802



TEST REPORT

Report No.: HSL200508:01
Sample Name: N95 Mask (CV1221)

Combined Results of Five Participants

A. Dr. AnirudhB. Ankit AgarwalC. Vishal MittalD. Vishal BansalE. Udit Dixit

Duration of Test: 10 Minutes

Test Agent: Sodium Chloride Aerosol

1 cst Age	ent: Sodium Chloride Aerosoi																										
S.No.	Activities to perform by		A	ble	to			Al	Able to Fe						l		Small						T	ast	te		
	participant for 60 seconds		inhale				ex	ha	le		irritation					Aerosol						Aerosol					
	after	Properly						pro	pe	rly	,	in															
	injecting aerosol											n	ose	/sn	eez	ze											
	Participants Name Code	A	В	C	D	E	A	В	C	D	E	A	В	C	D	\mathbf{E}	A	В	C	D	\mathbf{E}	A	В	\mathbf{C}	D	\mathbf{E}	
1.	Normal Breathing	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
2.	Deep Breathing	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
3.	Stand Fixed in a place and	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	move head side to side between											. 1	e.	7.1												1	
	the												ν,													ı	
	extreme positon of each side																									1	
4.	Move Head up and Down	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	Ν	N	N	N	N	N	N	N	N	N	N	
5.	Recite counting 1 to 100 and	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
	backwards slowly and loudly												-													i	
	so that it could be heard by																									i	
	test								١.																	i	
	conductor																										
6.	Bend and Touch your feet 10	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	Ν	N	N	N	N	N	N	N	N	N	N	
	times and then jog at your place																									ı	
7.	Breathe Normally	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	



An ISO 9001:2015 Certified Company

Office: Plot No-576, Opp. ITS College, Loni Road, Mohan Nagar, Ghaziabad (UP)-201007

Regd. Off.: D-17/573, East Gokulpur, Amar Colony, Delhi-110094 | Email: hslabs83@gmail.com

Mob: +917053533000, +917530853802



TEST REPORT

Points we consider while selecting the participants for test: -

- 1. Participant didn't smoke, eat or drink (except water) at least 20 minutes before the test.
- 2. Participants were clean shaved i.e. hadn't have facial hair.
- 3. Participants were medically fit and had no respiratory problem.

Conclusion: For qualitative test 5 participants were chosen and they were asked to perform some activities for 60 seconds each. After studying their collective response, we can conclude that the samples doesn't allow the aerosol to pass through it in the amount that could hinder the inhalation and exhalation process of participant.

Remarks: The result of qualitative testing show that the sample provides good breathability and protection against aerosol particles.





Certificate of Compliance

We hereby declare that the technical of the product compiled with the requirement of the EN 149:2001 + A1:2009.

Manufacturer

Name : AVA International Private Limited

Address : Plot No. 235, Sector-56, Phase-V, HSIIDC, Industrial Estate Kundli, Sonipat, Haryana - 131028, India

Product: "MANUFACTURING OF SURGICAL MASKS, 2PLY MASKS, 3 PLY MASKS (CV 1121), KN95 MASKS, N95 MASKS (CV 1221, CV 1221H, CV 1221HV, CV 1221V) AND 6 LAYER MASKS"

The certification body has performed an audit of the above product quality system covering the design, manufacture and the final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the **EN 149:2001 + A1:2009**.

This certification is issued under following conditions

- It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design of type examination procedures, if requested.
- 2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
- 3. The certificate validity is conditioned by positive results or surveillance audits.
- 4.After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
- 5. The CE mark as shown above can be used, under the responsibility of the manufacturer,

This certificate is issued on the basis of assessment carried out as per technical specifications,. The testing analysis is verified by random sample & this certificate does not assure quality in regular production.

To verify this certificate, please visit at https://gaafs.us/certified-organizations/#

Certificate No: QVA-AVAL-20-050240

Date of Certification : 18 May 2020 Date of Issue : 18 May 2020 Date of Surveillance 1 : 17 May 2021 Date of Surveillance 2 : 17 May 2022

Date of recertification: 17 May 2023



Authorised Signatory







QVA Certification

CAB Address: Maryland Avenue, SW Washington, D.C. 20202, USA

Validity of this certificate is subject to annual surveillance audits to be done successfully

This certificate is the property of QVA Certification and shall be return immediately on request

QVA Certification an independent Management System, Products and Personal assessment Body, QVA Certification is accredited by GAAFS.US,



Certificate of Compliance This is to certify that

AVA INTERNATIONAL PRIVATE LIMITED

PLOT NO. 235, SECTOR-56, PHASE-V, HSIIDC, INDUSTRIAL ESTATE KUNDLI, SONIPAT, HARYANA, 131028.

has been assessed and Certified by KBN Certification System

CE Mark

For the following scope of activities:

PRODUCTS :- MANUFACTURING & TRADING OF SURGICAL MASKS, 2/3/6 PLY FACE MASKS, KN95 FACE MASKS, N95 FACE MASKS, PPE KIT, COVERALLS, SHOE COVER, GOGGLES, GLOVES AND FACE SHIELDS.

The Certification body has performed a technical file review of the above product technical file covering the design, manufacturer and final inspection of the certified products. The technical file has been assessed approved and is subject to continuous surveillance according to Directive: 93/42/EEC

This Certificate issued the following conditions:

- 1. It apply to the technical file maintained in the manufacturer of the about referenced models and it does not substitute the design or type examination procedures, if requested
- 2. The certificate remain valid until the manufacturing condition or the technical file are changed.
- 3. The certificate validity is conditioned by positive result or surveillance audit.
- 4. After fulfilling the relevant EU legislation of Directive the manufacturer shall affix to each device of the referenced work
- 5. The CE mark as shown above can be used, under the responsibility of the manufacturer after the completion of an EU declaration of conformity and compliance with all relevant EC Directives in product. The statement is based on a single evaluation of one sample of above mentioned products. It dose not imply assessment of the whole production.

Date of Registration: 18/05/2020 1st Surveillance Date: 17/05/2021 Re-Certification Due: 17/05/2023 2nd Surveillance Date: 17/05/2022

Certificate No:- 2412180520

To Verify this certificate please visit at www.kbncertification.com











KBN Certification System

Validity of this Certificate is Subject to annual Surveillance audits done successfully

this certificate of Registration remains the property of KBN Certification System and shall be returned immediately Upon request
Office Address:- E-49, First Floor, Mansa Ram Park, Near Kali Mata Mandir,
Uttam Nagar, New Delhi - 110059 (INDIA).
Address:- 305, High Street, Purley, London, United Kingdom.
Email:- info@kbncertification.com Website:- www.kbncertification.com



Certificate of Compliance

This is to certify that the management system of

AVA International Private Limited

Plot No. 235, Sector-56, Phase-V, HSIIDC, Industrial Estate Kundli, Sonipat, Haryana - 131028, India

has been accessed and found to be accordance with the requirements of the standard given below

FDA

(US FDA Regulatory Guidelines for Scientific and Medical Instruments)

For the following scope:

"Manufacturing and Trading of Surgical Masks, 2/3/6 Ply Face Masks, KN95 Masks, N95 Masks, PPE Kit, Coveralls, Shoe cover, Goggles, Gloves and Face Shields."

The Technical Document maintained by the organization has been reviewed and found to comply with the requirement and found to comply with the requirements of section 701(h)(1)(C)(i) of the U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)).

Note: This certificate is issued on the basis of assessment carried out as per technical specifications. The testing analysis is verified by random sample & this certificate does not assure quality in regular production.

To verify this certificate, please visit at https://gaafs.us/certified-organizations/#

Certificate No: QVA-AVAL-20-050239

Date of Certification : 18 May 2020 Date of Issue : 18 May 2020 Date of Surveillance 1 : 17 May 2021 Date of Surveillance 2 : 17 May 2022

Date of recertification: 17 May 2023











QVA Certification

CAB Address : Maryland Avenue, SW Washington, D.C. 20202

Validity of this certificate is subject to annual surveillance audits to be done successfully
This certificate is the property of QVA Certification and shall be return immediately on request
QVA Certification an independent Management System, Products and Personal assessment Body, QVA Certification is accredited by GAAFS.US.,



Certificate of Registration

This is to certify that

AVA INTERNATIONAL PRIVATE LIMITED

PLOT NO. 235, SECTOR-56, PHASE-V, HSIIDC, INDUSTRIAL ESTATE KUNDLI, SONIPAT, HARYANA, 131028.

has been assessed and Certified by KBN Certification System

ISO 9001:2015

Quality Management System

Corporate Member Of Quality Council Of India (QCI)

For the following scope of activities:

MANUFACTURING & TRADING OF SURGICAL MASKS, 2/3/6 PLY FACE MASKS, KN95 FACE MASKS, N95 FACE MASKS, PPE KIT, COVERALLS, SHOE COVER, GOGGLES, GLOVES AND FACE SHIELDS.

Date of Registration: 18/05/2020 1st Surveillance Date: 17/05/2021 Re-Certification Due: 17/05/2023 2nd Surveillance Date: 17/05/2022

Certificate No:- 2409180520

To Verify this certificate please visit at www.kbncertification.com









Authorised Signatory

KBN Certification System

ValidityofthisCertificateisSubjecttoannualSurveillanceauditsdonesuccessfully

this certificate of Registration remains the property of KBN Certification System and shall be returned immediately Upon request

Office Address:- E-49, First Floor, Mansa Ram Park, Near Kali Mata Mandir, Uttam Nagar, New Delhi - 110059 (INDIA).

Address:- 305, High Street, Purley, London, United Kingdom.

Email:- info@kbncertification.com Website:- www.kbncertification.com



Certificate of Registration

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AVA INTERNATIONAL PRIVATE LIMITED

PLOT NO. 235, SECTOR-56, PHASE-V, HSIIDC, INDUSTRIAL ESTATE KUNDLI, SONIPAT, HARYANA, 131028.

has been assessed and Certified by KBN Certification System

ISO 13485:2016

Medical Devices Management System

Corporate Member Of Quality Council Of India (QCI)

For the following scope of activities:

MANUFACTURING & TRADING OF SURGICAL MASKS, 2/3/6 PLY FACE MASKS, KN95 FACE MASKS, N95 FACE MASKS, PPE KIT, COVERALLS, SHOE COVER, GOGGLES, GLOVES AND FACE SHIELDS.

Date of Registration: 18/05/2020 1st Surveillance Date: 17/05/2021 Re-Certification Date: 17/05/2023 2nd Surveillance Date: 17/05/2022

Certificate No:- 2410180520

To Verify this certificate please visit at www.kbncertification.com









KBN Certification System

Validity of this Certificate is Subject to annual Surveillance audits done successfully this certificate of Registration remains the property of KBN Certification System and shall be returned immediately Upon request

Office Address:- E-49, First Floor, Mansa Ram Park, Near Kali Mata Mandir, Uttam Nagar, New Delhi - 110059 (INDIA).

Accreditation Address:- 305, High Street, Purley, London, United Kingdom. Email:- info@kbncertification.com Website:- www.kbncertification.com



Certificate of Compliance

This is to certify that

AVA INTERNATIONAL PRIVATE LIMITED

PLOT NO. 235, SECTOR-56, PHASE-V, HSIIDC, INDUSTRIAL ESTATE KUNDLI, SONIPAT, HARYANA, 131028.

has been assessed and Certified by KBN Certification System

GMP

Good Manufacturing Practice

For the following scope of activities:

MANUFACTURING & TRADING OF SURGICAL MASKS, 2/3/6 PLY FACE MASKS, KN95 FACE MASKS, N95 FACE MASKS, PPE KIT, COVERALLS, SHOE COVER, GOGGLES, GLOVES AND FACE SHIELDS.

Date of Registration: 18/05/2020 1st Surveillance Date: 17/05/2021 Re-certification Date: 17/05/2023 2nd Surveillance Date: 17/05/2022

Certificate No:- 2411180520

To Verify this certificate please visit at www.kbncertification.com









KBN Certification System

Validity of this Certificate is Subject to annual Surveillance audits done successfully

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