Arya HC
Health Care

LE FFP2 CE 2163 NON SONO TUTTE UGUALI!!!

LE NOSTRE MASCHERINE FFP2 ARYA HC HZ96 SONO SICURE PER LA TUA SALUTE

Le mascherine distribuite da *T-Tex Srl* **modello commerciale ARYA HC HZ96** produttore *Shenzhen Hezheng Industrial Development Co. Ltd*, sono in regola con tutte le Normative vigenti e:

- Sono **Conformi** alla Normativa UNI EN 149:2001+ A1 2009 e rispondono a tutte le Direttive del Regolamento EU 2016/425
- Sono in possesso di **CERTIFICATO VALIDO E RICONOSCIUTO** a livello Europeo
- Sono state **testate per ben 3 volte** da 3 differenti Laboratori Accreditati che le certificano come FFP2 con BFE **≥94%**.

CHIEDI QUI TUTTA LA DOCUMENTAZIONE OPPURE SCANSIONA IL QR CODE

T-Tex Srl - Via Boggia 9, 28013 - Gattico (NO), www.t-tex.it

T-TEX srl

SEDE OPERATIVA: Via Boggia 9 - 28013 Gattico - Fraz. Maggiate Sup. (NO) Italy
SEDE LEGALE: Via Posorti 10 - 21029 Vergiate (VA) Italy
ph. +39.0331.946107 fax +39.0331.942514 www.ttex.it info@ttex.it
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Reg. Soc. Trib. Busto Arsizio 17382 - Cap. Soc. €. 10400 i.v. UNI EN ISO 9001:2008

ARYA HC MASCHERINE FFP2 CODICE PRODOTTO HZ96

Con la presente la **T-Tex Srl importatore** e **distributore** della mascherina in oggetto, rende noto al solo scopo chiarificatore, che le **mascherine FFP2** da Noi distribuite;

MODELLO COMMERCIALE: ARYA HC FFP2
CODICE PRODOTTO: HZ96
PRODUTTORE: SHENZEN HEZHENG INDUSTRIAL DEVELOPMENT & CO.

CATEGORIA DPI: III
CERTIFICATO DI CONFORMITA': CE 2163 HZ96

Sono conformi alla Normativa UNI EN 149:2001+ A1 2009 e le stesse rispettano tutte le Direttive del Regolamento EU 2016/425.

I Test Report elencati ed in allegato, effettuati sul modello **ARYA HC FFP2 HZ96** da noi commercializzato, ne attestano la **capacità batterica filtrante ≥ al 94%.**

- Test Report n. 178139783a001 TUV RHEINLAND
- Test Report n. KZ2022265 NINGBO CUSTOMS DISTRICT TECHNOLOGY CENTER
- Test Report n. WSZ FHL NO.6182 JIANGSU GUOJIAN TESTING TECHNOLOGY CO., LTD

Si tratta di laboratori le cui Certificazioni non possono essere messe in discussione.

Qualsiasi illazione solo basata su supposizioni come quelle di questi giorni NON ha alcun valore se non comprovata da prove tecniche emesse da SOLI laboratori accreditati.

Chiediamo quindi di rendere disponibili alle **Autorità di Controllo** e a tutti i **Clienti** che la richiedono, la presente dichiarazione e tutti i test report in allegato. (disponibili anche sul sito http://www.t-tex.it/ffp2/ sezione HZ96).

In fede

Ing. Giuseppe Tamborini
A.U. T-Tex Srl

Gattico, lì 03/03/2021

federfarma
federazione nazionale unitaria
dei titolari di farmacia italiani

Roma, 4 marzo 2021
Uff.-Prot.n° UE – AA/3518/127/F7/PE
Oggetto: Mascherine FFp2
CE 2163.

ALLE ASSOCIAZIONI PROVINCIALI

ALLE UNIONI REGIONALI

Questa Federazione facendo seguito alla pubblicazione di articoli su quotidiani a carattere nazionale ed alla diffusione di analoghe notizie sui mass-media concernenti la reale efficacia protettiva e la rispondenza ai requisiti tecnici vigenti di alcune mascherine FFP2, segnatamente quelle riportanti il marchio CE 2163, ha ritenuto necessario chiedere urgenti indicazioni alle Amministrazioni competenti al riguardo, a tutela della salute pubblica, al fine di poter fornire corrette e tempestive indicazioni alle farmacie di tutto il territorio.

Con l'occasione, si ritiene necessario evidenziare che fino al ricevimento delle richieste indicazioni da parte delle Amministrazioni competenti, la scrivente non può che considerare tuttora vendibili tali dispositivi, non avendo sinora ricevuto alcun provvedimento di contenuto contrario.

Si assicura sin d'ora il tempestivo aggiornamento in merito alla vicenda.

Cordiali saluti.

ILSEGRETARIO
Dott. Roberto TOBIA

IL PRESIDENTE
Dott. Marco COSSOLO

Questa circolare viene resa disponibile anche per le farmacie sul sito internet www.federfarma.it contemporaneamente all'inoltro tramite e-mail alle organizzazioni territoriali.

Notizie, informazioni, aggiornamenti sul mondo della farmacia ogni giorno su la web TV di Federfarma

FEDERFARMA channel

Via Emanuele Filiberto, 190 - 00185 ROMA
Tel. (06) 70380.1 - Telefax (06) 70476587 - e-mail:box@federfarma.it
Cod. Fisc. 01976520583

AGENZIA DOGANE MONOPOLI

DIREZIONE REGIONALE LOMBARDIA
Ufficio delle Dogane di Varese
Sezione Operativa Territoriale di Busto Arsizio

PROCESSO VERBALE DI CONSTATAZIONE
Articolo 15-16 DL 18 del 17 marzo 2020

[Dispositivo Protezione Individuale (DPI) con marchio CE valido]

Protocollo 4066/RI del 18/11/2020

Il giorno 18/11/2020

Il sottoscritto Sergio D'ADAMO

funzionario In servizio presso l'Ufficio In intestazione ed all'uopo delegato, procede alla redazione del presente processo verbale per dare atto delle attività di verifica condotte relativamente al marchio CE ed all'applicazione dell'articolo 15 del DL 18/2020:

Dichiarazione doganale 4T n. 6845/U del 17/11/2020

Dichiarante (campo 8 della dichiarazione) T-Tex Srl

P. IVA 02450600123

Rappresentante (campo 14 della dichiarazione) CAD Battaglino Srl

P. IVA 11600320151

Prodotto verificato

Tipo MASCHERINE FFP2 Modello HZ96

Marca CE 2163 Produttore SHENZHEN HEZHENG INDUSTRIAL DEVELOPMENT CO., LTD

21052 – Busto Arsizio (VA), Via Dogana 2
0332/1822395
pec dogane.varese@pec.adm.gov.it/e-mail dogane.varese.bustoarsizio@adm.gov.it

AGENZIA DOGANE MONOPOLI

DIREZIONE REGIONALE LOMBARDIA
Ufficio delle Dogane di Varese
Sezione Operativa Territoriale di Busto Arsizio

Modulo Svincolo

Diretto ☐ Destinatario_____
PEC_____

Celere ☐

Estremi Certificato Marcatura CE 2163-PPE-1400/01

Validità del Certificato

SI ☒

NO ☐

IL VERBALIZZANTE

Sergio D'ADAMO

LA PARTE

Per avvenuta notifica
(Data, qualifica, e firma leggibile)

18/11/2020 A.U.

T-TEX s.r.l.
Via Posorti, 10 - Tel. 0331 946107
21029 VERGIATE (VA)
P.IVA: 02450680123
Cod. Fisc.: 01223920128

Via Pec trasmesso al destinatario utilizzatore della merce.

21052 – Busto Arsizio (VA), Via Dogana 2
0332/1822395
pec dogane.varese@pec.adm.gov.it/e-mail dogane.varese.bustoarsizio@adm.gov.it

EU DECLARE OF THE CONFORMITY	CE

We

Company name:	Shenzhen Hezheng Industrial Development Co., ltd
Postal address:	601 Zhaoye Workshop, No.172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China
Postcode:	518110
City:	Shenzhen

Declare that the DoC is issued under our sole responsibility and belongs to the following products:

Apparatus model/Product:	HZ96
Type:	Filtering half mask

Object of the declaration(identification of apparatus allowing traceability. It may include a colour image of sufficient clarity where necessary for the identification of the appearance)

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

Personal protective equipment Regulation(EU)2016/425

The following harmonised standards and technical specifications have been applied:

Title, Date of standards/specification:

EN149:2001 +A1 :2009

Notified body (where applicable)	4 digit notified body number
UNIVERSAL CERTIFICATION AND SURVEILLANCE SERVICE TRADE LTD. CO.	2163
Certificate Number:	2163-PPE-1400
Technical report numbered:	2163-KKD-1400

Signed for and on behalf of

Guangdong,China	Sep.07.2020	黄海阳
Place of issue	Date of issue	Name;function,signature General Manager

TÜVRheinland®
Precisely Right.

Test Report No.: 178139783a 001

Client: **Shenzhen Hezheng Industrial Development Co., Ltd**
601 Zhaoye workshop, No. 172, huanguanzhong Road, Songyuanxia community, Guanhu street, Longhua District, Shenzhen

Contact Person: Fang Fang

Sample Description As Declared :

No. Of Sample	:	90 Pcs
Product Description	:	KN95 Particulate Respirator(HZ96)
Colour	:	White
Country of Origin	:	China
Sales Destination(country)	:	US/ EU(country name not provided)
Product End Use	:	Protection
Test type	:	Partial Test
Product type	:	Single shift use only
Claimed Classification	:	**FFP2 NR**

Sample obtaining method: Sending by customer

Sample Receiving date: 2020-05-06
Delivery condition: *Apparent good, Samples tested as received*
Test Period: 2020-05-09 to 2020-06-19

Test specification:	***Test result:***
Particulate respirator-half facepiece EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking^	Please refer to result page

For and on behalf of
TÜV Rheinland / CCIC (Qingdao) Co., Ltd.

2020-06-22 Alex Zhou / Senior Manager

Date *Name/Position*

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material list

Material	Color	Location
Textile	White	White folding mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

7.4 **Package^** **PASS [1]**

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.
Note 1: In accordance with the requirement.

7.5 **Material^** **PASS [2]**

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 described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the 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.
Note 2: In accordance with the requirement.
Specimens -08, -20, -37 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -14, -28, -44 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 **Cleaning and disinfecting^** **NAp [3]**

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.
Note 3: Single shift use only.

7.7 **Practical performance^** **PASS** [4]

The particle filtering half mask shall undergo practical performance tests under realistic conditions

Note 4: No imperfections.

Specimen and subject details:

Specimen	Subject
-47	SM
-63	LCF

7.8 **Finish of parts^**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. **PASS** [5]

Note 5: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 **Total inward leakage^** **PASS** [6]

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, 2% for FFP3.

Note 6: 46 out of the 50 individual exercise results were not greater than 11%; 8 of the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Table 7.9.1-A Inward leakage test data

Test specification: EN149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head Up/down(%)	Talk(%)	Walk(%)	Mean(%)
LZM	-09	A.R.	2.4	6.5	10.8	6.4	3.5	5.9
YZF	-22	A.R.	5.0	9.0	9.9	10.5	5.5	8.0
GJB	-36	A.R.	5.8	8.1	5.8	6.1	2.9	5.7
JLX	-56	A.R.	4.7	9.4	6.6	5.0	4.9	6.1
TLX	-74	A.R.	3.6	12.6	11.6	7.6	7.2	8.5
TS	-13	T.C.	3.8	10.3	5.6	7.3	5.5	6.5
SM	-29	T.C.	6.3	10.3	8.6	7.2	6.1	7.7
LCF	-43	T.C.	7.0	14.3	14.7	8.2	6.7	10.2
ZH	-62	T.C.	6.5	8.5	8.1	4.4	6.3	6.8
YB	-80	T.C.	2.9	8.1	6.7	6.0	4.2	5.6
Maximum permitted			11					8

Table 7.9.1-B Facial dimension

Subject	Face length(mm)	Face width(mm)	Face Depth(mm)	Mouth Width(mm)
LZM	118	157	124	44
YZF	113	151	106	48
GJB	109	154	109	57
JLX	119	152	109	59
TLX	104	153	112	40
TS	97	146	102	51
LCF	119	165	121	56
SM	116	144	109	49
ZH	102	152	113	55
YB	112	150	119	66

7.9.2 **Penetration of filter material^** **PASS**

The penetration of the filter of the particle filtering half mask shall meet the requirements of below:

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	⩽ 20%	⩽ 20%
FFP 2	⩽ 6%	⩽ 6%
FFP 3	⩽ 1%	⩽ 1%

Table 7.9.2- Penetration of filter material

Test specification: EN149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			After 3 minutes	Max. during exposure	
Sodium chloride test	A.R.	-17	0.39		PASS
		-27	0.16		
		-64	0.25		
	S.W.	-19	0.11		
		-46	0.40		
		-68	0.16		
	M.S. + T.C.	-23	0.63	0.70	
		-51	0.39	0.39	
		-72	0.42	0.42	
Paraffin oil test	A.R.	-30	0.25		
		-52	0.45		
		-75	0.24		
	S.W.	-35	0.24		
		-55	0.32		
		-04	0.37		
	M.S. + T.C.	-42	0.38	0.83	
		-58	0.43	0.93	
		-03	0.51	1.07	
Maximum permitted		6			
Flow conditioning: Single filter: 95.0 L/min					

7.10 **Compatibility with skin^** **PASS** [7]

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note 7: Specimens -10, -21, -38, -53, -69 (A.R.) and specimens -15, -33, -45, -61, -73 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 **Flammability^** **PASS**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Table 7.11- Flammability

Test specification: EN149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
A.R.	-24	Burn for 0.4 s	PASS
	-39	Burn for 0.8 s	
T.C.	-31	Burn for 0.5 s	
	-50	Burn for 0.6 s	

7.12 **Carbon dioxide content of the inhalation air^** **PASS**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Table 7.12- Carbon dioxide content of the inhalation air

Test specification: EN149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
A.R.	-18	0.42%	PASS
	-54	0.43%	
	-60	0.46%	
Maximum permitted		1.0%	

7.13 **Head harness^** **PASS** [8]

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

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.

Note 8: Specimens -12, -26, -49, -65, -76 (A.R.) and specimens -16, -34, -59, -71, -05 (T.C.) were tested. Head harness (ear straps) can be donned and removed easily, adjustable or self-adjusting, have sufficiently robust to hold the face mask firmly enough to satisfy the total inward leakage requirements. See 7.9.1 for results.

7.14 **Field of vision^** **PASS** [9]

The field of vision is acceptable if determined so in practical performance tests.

Note 9: Specimens -41 and -67 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 **Exhalation valve^** **NAp**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

7.16 **Breathing resistance^** **PASS** [10]

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min x 2.0 l/stroke)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Note 10: FFP2 Filtering face mask. Test result are shown in below Table.

Table 7.16 Breathing resistance (mbar)

Test specification: EN149-2001 Clause 8.9

Specimen	Condition	Inhalation resistance(mbar)		Exhalation resistance(mbar)				
		At 30 l/min	At 95 l/min	Breathing machine(25 cycles/min x 2.0 l/stroke)				
				A	B	C	D	E
-11	A.R.	0.36	1.34	2.92	2.91	2.93	2.94	2.91
-25		0.37	1.36	2.95	2.92	2.91	2.96	2.95
-32		0.38	1.38	2.96	2.98	2.92	2.91	2.94
-40	T.C.	0.35	1.29	2.87	2.86	2.86	2.84	2.81
-48		0.36	1.31	2.87	2.86	2.81	2.81	2.85
-57		0.35	1.30	2.89	2.92	2.87	2.83	2.81
-66	S.W.	0.36	1.34	2.92	2.89	2.91	2.87	2.86
-70		0.37	1.36	2.98	2.92	2.83	2.93	2.95
-79		0.35	1.31	2.91	2.87	2.85	2.89	2.85
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		0.7	2.4	3.0				

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side.

7.17 **Clogging^** **NRq [11]**

7.17.2 **Breathing resistance**

Valved particle filtering half masks:
After clogging, the inhalation resistances shall not exceed,
FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95 l/min continuous flow;
The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Valveless particle filtering half masks:
After clogging the inhalation and exhalation resistances shall not exceed:
FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95 l/min continuous flow.

7.17.3 **Penetration of filter material**

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	⩽ 20%	⩽ 20%
FFP 2	⩽ 6%	⩽ 6%
FFP 3	⩽ 1%	⩽ 1%

Note 11: Single shift use only.

7.18 **Demountable parts^** **NAp [12]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note 12: No demountable parts were used.

9 **Marking^** **NRq**

9.1 **Packaging**

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". ID This letter shall follow the classification marking preceded by a single space.

9.2 **Particle filtering half mask^**

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space(see 9.2.4).

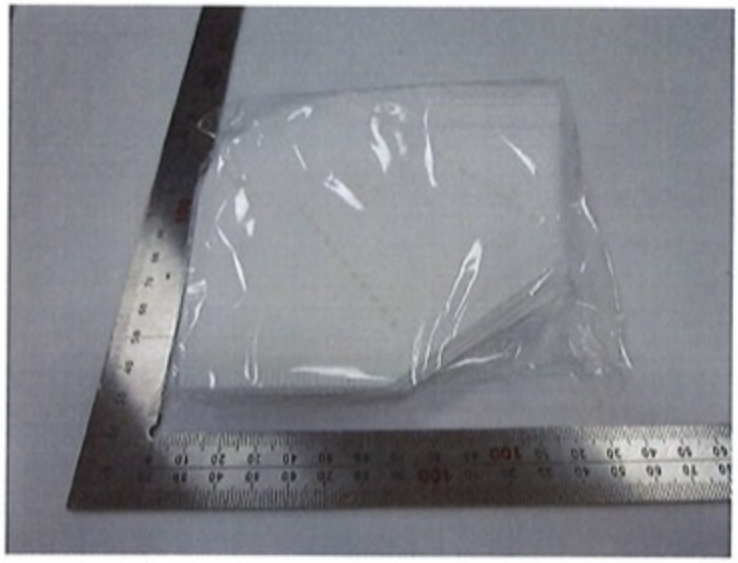
Example FFP3 NR D, FFP2 R D.

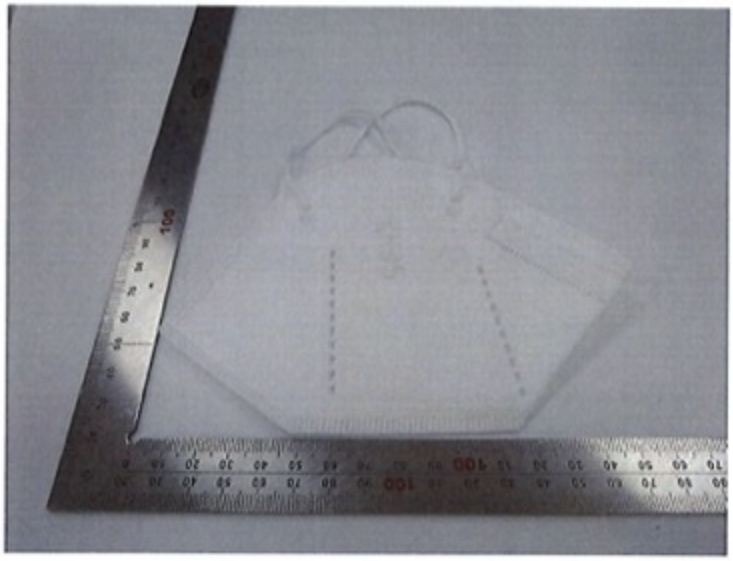
9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

10	**Information to be supplied by the manufacturer^**	**NRq**
10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package.	
10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on application/limitations; the meaning of any colour coding; checks prior to use; donning fitting; use; maintenance(e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.	
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	
10.5	Warning shall be given against problems likely to be encountered, for example: — fit of particle filtering half mask (check prior to use); — it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; — air quality (contaminants, oxygen deficiency); — use of equipment in explosive atmosphere.	
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.	
10.7	For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.	

Remark: "^" indicates that the test is sub-contracted to the lab China Academy of Safey Science and Technology which complies with the requirement of ISO/IEC 17025:2017, the registration No. CNAS L0118.

Photo:





- END -

General Terms and Conditions of Business of TÜV Rheinland in Greater China

1. Scope

1.1 These General Terms and Conditions of Business of TÜV Rheinland in Greater China ("GTCB") is made between the client and one or more member entities of TÜV Rheinland in Greater China as applicable as the case may be ("TÜV Rheinland"). The Greater China hereof refers to Mainland China, Hong Kong and Taiwan. The client hereof includes:

(i) a natural person capable to form legally binding contracts under the applicable laws who concludes the contract not for the purpose of a daily use;

(ii) the incorporated or unincorporated entity duly organized, validly existing and capable to form legally binding contracts under the applicable law.

1.2 The following terms and conditions apply to agreed services including consultancy services, information, deliveries and similar services as well as ancillary services and other secondary obligations provided within the scope of contract performance.

1.3 Any standard terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractual terms and conditions of the client shall form part of the contract even if TÜV Rheinland does not explicitly object to them.

1.4 In the context of an ongoing business relationship with the client, the GTCB shall also apply to future contracts with the client without TÜV Rheinland having to refer to them separately in each individual case.

2. Quotations

Unless otherwise agreed, all quotations submitted by TÜV Rheinland can be changed by TÜV Rheinland without notice prior to its acceptance and confirmation by the other party.

3. Coming into effect and duration of contracts

3.1 The contract shall come into effect for the agreed term upon the quotation letter of TÜV Rheinland or a separate contractual document being signed by both contracting parties, or upon the works requested by the client being carried out by TÜV Rheinland. [illegible]

3.2 [illegible]

3.3 [illegible]

4. Scope of services

4.1 [illegible]

4.2 [illegible]

4.3 [illegible]

4.4 [illegible]

4.5 [illegible]

4.6 [illegible]

4.7 [illegible]

5. Performance periods/dates

5.1 [illegible]

5.2 [illegible]

5.3 [illegible]

5.4 [illegible]

5.5 [illegible]

6. The client's obligation to cooperate

6.1 The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to TÜV Rheinland.

6.2 Design documents, supplies, auxiliary staff, etc. necessary for performance of the services shall be made available free of charge by the client. Moreover, collaborative action of the client must be undertaken in accordance with legal provisions, standards, safety regulations and accident prevention instructions. And the client represents and warrants that:

a) it has required statutory qualifications;

b) the product, service or management system to be certified complies with applicable laws and regulations; and

c) it doesn't have any illegal and dishonest behaviours or is not included in the list of Enterprises with Serious Illegal and Dishonest Acts of People's Republic of China.

If the client breaches the aforesaid representations and warranties, TÜV Rheinland is entitled to i) immediately terminate the contract/order without prior notice; and ii) withdraw the issued testing report/certificates if any.

6.3 The client shall bear any additional cost incurred on account of work having to be redone or being delayed as a result of late, incorrect or incomplete information provided by or lack of proper cooperation from the client. Even where a fixed or maximum price is agreed, TÜV Rheinland shall be entitled to charge extra fees for such additional expense.

7. Prices

7.1 [illegible]

7.2 Unless otherwise agreed, work shall be invoiced according to the progress of the work.

7.3 [illegible]

8. Payment terms

8.1 All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts and rebates shall be granted.

8.2 Payments shall be made to the bank account of TÜV Rheinland as indicated on the invoice, stating the invoice and client numbers.

8.3 [illegible]

8.4 [illegible]

8.5 [illegible]

8.6 [illegible]

8.7 TÜV Rheinland shall be entitled to demand appropriate advance payments.

8.8 [illegible]

8.9 Only legally established and undisputed claims may be offset against claims by TÜV Rheinland.

9. Acceptance of work

9.1 [illegible]

9.2 [illegible]

9.3 [illegible]

9.4 [illegible]

9.5 [illegible]

9.6 [illegible]

10. Confidentiality

10.1 [illegible]

10.2 [illegible]

10.3 [illegible]

10.4 [illegible]

10.5 [illegible]

10.6 [illegible]

10.7 [illegible]

11. Copyrights and rights of use, publications

11.1 [illegible]

11.2 [illegible]

11.3 [illegible]

11.4 [illegible]

11.5 [illegible]

11.6 [illegible]

11.7 [illegible]

12. Liability of TÜV Rheinland

12.1 [illegible]

12.2 [illegible]

12.3 [illegible]

12.4 [illegible]

12.5 [illegible]

12.6 [illegible]

12.7 [illegible]

13. Export control

13.1 [illegible]

13.2 [illegible]

14. Data protection notice

TÜV Rheinland processes personal data of the client for the purpose of fulfilling this contract. In addition, TÜV Rheinland also processes the data for other legal purposes in accordance with the relevant legal basis. The personal data of the client will only be disclosed to other natural or legal persons if the legal requirements are met. This also applies to transfers to third countries. The personal data will be deleted immediately as soon as a corresponding reason for deletion arises. Data subjects may exercise the following rights: right of information, right of rectification, right of deletion, right of processing limitation, right of objection, right of data transferability. In addition, persons concerned by the data processing have the right to revoke their consent at any time with effect for the future, as well as the right to file a complaint with the competent data protection supervisory authority. For further details on the processing of personal data by TÜV Rheinland as the person responsible or contract processor, please refer to the respective data protection information. You can contact the Group Data Protection Officer of TÜV Rheinland by e-mail at datenschutz@de.tuv.com or by post at the following address: TÜV Rheinland AG, c/o Group Data Protection Officer, Am Grauen Stein, 51105 Cologne, Germany.

15. Test material: transport risk and storage

15.1 [illegible]

15.2 [illegible]

15.3 [illegible]

15.4 [illegible]

16. Termination of the contract

16.1 [illegible]

16.2 [illegible]

16.3 [illegible]

16.4 [illegible]

17. Partial invalidity, written form, place of jurisdiction and dispute resolution

17.1 [illegible]

17.2 [illegible]

17.3 [illegible]

17.4 [illegible]

May 2019

TÜV Rheinland / CCIC (Qingdao) Co., Ltd. · 6F, No.2 Bldg., No.175 Zhuzhou Rd., Qingdao 266101, Shandong, P.R. China
Tel.: +86- 532- 8870 6655 · Fax: +86- 532- 8870 6669· Email: info@qd.chn.tuv.com · Web:www.tuv.com

161019130764

Test Report

Report No.: [2020] WSZ FHL NO.6182

Product Name Filtering half mask

Applicant Shenzhen Hezheng Industrial Development Co.,Ltd

Manufacturer Shenzhen Hezheng Industrial Development Co.,Ltd

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.

3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

Test Report

Product name	Filtering half mask	Model name	HZ96
		Brand	Dr.HZ
Laboratory/ Add.	Jiangsu Guojian Testing Technology Co., Ltd./ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/ Add/Tel	Shenzhen Hezheng Industrial Development Co.,Ltd/601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen, China/—		
Manufacturer/ Add/Tel	Shenzhen Hezheng Industrial Development Co.,Ltd/601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen, China/—		
Sample classification	FFP2	Sample number	GW6182-2020
Sample quantity	120 pcs	Date of receipt of sample	25/05/2020
Test type	Entrusted inspection	Article/Batch/Style number	—
Date (s) of performance of tests	10/06/2020~19/06/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testing	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking		
Test items	Packaging, material, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The samples upon testing comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-11. Date of issue: 22/06/2020		
Note	The test results presented in this report relate only to the submitted sample as received.		

Lu Bing
Approver (name, signature)

Wan Heng
Reviewer (name, signature)

Yang Ying
Chief Tester (name, signature)

Sample description:	—
Test item particulars:	
Type of use	☐ re-useable particle filtering half mask ☒ single shift only particle filtering half mask
Classes of devices.....	☐ FFP1 ☒ FFP2 ☐ FFP3
Exhalation valve(s).....	☐ Yes ☒ No
Inhalation valve(s).....	☐ Yes ☒ No
Designed to protect against both solid &liquid aerosols.	☒ Yes ☐ No
Possible test case verdicts:	
- Test case does not be required to the test object.....	NRq（Not required）
- Test case does not apply to the test object.....	N/A (Not Applicable)
- Test object does meet the requirement.....	P (Pass)
- Test object does not meet the requirement.....	F (Fail)
General remarks:	
The test results presented in this report relate only to the submitted sample as received. This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context. Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods. Throughout this report a ☐ comma / ☒ point is used as the decimal separator.	
Environmental condition of the testing in this report:	
1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C; 2) T.C. Temperature conditioned: a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C; and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.	

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
1 (7.3)	Visual inspection	Marking/ information	—	Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10	The clause were not required	NRq
2 (7.4)	Packaging	Visual inspection	—	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Particle filtering half masks packaged and protected against mechanical damage and contamination.	Pass
3 (7.5)	Material	Visual inspection	—	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.	Materials were suitable withstand handling and wear.	Pass
			—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure	
					Sample 2: neither facepiece nor straps have mechanical failure	
					Sample 3: neither facepiece nor straps have mechanical failure	
			—	After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse.	Sample 4: no collapse	
					Sample 5: no collapse	
					Sample 6: no 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.	Not constitute a hazard or nuisance for the wearer	
4 (7.6)	Cleaning and disinfecting		—	Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.	☐ Fulfil the requirements after testing, or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	N/A
			—	With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11.	☐ Tests results refer to S. No. 7(7.9.2), or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result				Single item decision
5 (7.7)	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1: has the feeling of comfortable wearing				Pass
					Sample 2: has the feeling of comfortable wearing				
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm				
					Sample 2: All fastenings are firm				
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field				
					Sample 2: Having a wider visual field				
6 (7.8)	Finish of parts	Visual inspection	—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs				Pass
7 (7.9.2)	Leakage— Penetration of filter material	Sodium chloride	—	≤**6%**	A.R.[1]	0.1%	0.1%	0.2%	Pass
					S.W.[1]	0.1%	0.2%	0.1%	
					M.S+ T.C.[2]	0.2%	0.3%	0.2%	
		Paraffin oil	—	≤**6%**	A.R.[1]	0.2%	0.3%	0.3%	Pass
					S.W.[1]	0.3%	0.3%	0.2%	
					M.S+ T.C.[2]	0.8%	0.7%	0.9%	
		[1] average penetration over a time of 30s, beginning 3 min after the start of the test reported [2] max. penetration during exposure test reported; Note: The penetration of the filter of the particle filtering half mask shall meet the requirements below: Maximum penetration of sodium chloride aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1% Maximum penetration of paraffin oil aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%							

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result		Single item decision
8 (7.10)	Compatibility with skin	—	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	A.R.	5 pcs all don't cause irritation	Pass
				T.C.	5 pcs all don't cause irritation	
9 (7.11)	Flammability	—	When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.1s	Pass
					The Sample is burning. Burning time:0.1s	
				T.C.	The Sample is burning. Burning time:0.1s	
					The Sample is burning. Burning time:0.1s	
10 (7.12)	Carbon dioxide content of the inhalation air	—	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume). Remark: 3 half masks (S1, S2 and S3) A.R. tested.	Sample 1	0.7057%	Pass
				Sample 2	0.7015%	
				Sample 3	0.7027%	
				average	0.70%	
11 (7.13)	Head harness	—	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. 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.	A.R.	All of 5 pieces particle filtering half mask meet the requirements	Pass
				T.C.	All of 5 pieces particle filtering half mask meet the requirements	
12 (7.14)	Field of vision	—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field		Pass

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
13 (7.15)	Exhalation valve(s)	Visual inspection	—	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No exhalation valve(s)	N/A
			—	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage, and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	No exhalation valve(s)	
		Flow conditioning	—	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	No exhalation valve(s)	
		Strength of attachment of exhalation valve housing	—	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	No exhalation valve(s)	
14 (7.17)	Clogging— Breathing resistance & Penetration of filter material		—	Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3.	☐ Tests results refer to Table C&D, or ☒ Tests not requested for single shift use face mask	N/A
15 (7.18)	Demountable parts		—	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No demountable parts	N/A

Table A- Leakage—Total Inward Leakage

S.No. (Cl.No.)	Test item	Unit	Technical requirements[1)]	Test result							Single item decision
16 (7.9.1)	Leakage—Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than **11%**; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than **8%.**	Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	Pass
				A.R.	3.4	4.2	4.8	4.9	3.4	4.1	
					3.2	3.9	4.5	4.7	3.3	3.9	
					3.6	4.3	5.0	5.1	3.8	4.4	
					3.1	3.8	4.0	4.3	2.6	3.6	
					3.9	5.1	5.7	6.1	4.4	5.0	
				T.C.	3.3	4.1	4.4	4.7	3.4	4.0	
					2.9	3.7	3.9	4.5	2.4	3.5	
					2.9	3.7	4.0	4.2	3.0	3.6	
					4.0	4.5	5.2	5.5	3.5	4.5	
					3.1	4.1	4.5	4.6	2.7	3.8	

Note 1:
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
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 2 % for FFP3.

Table A-1- Test subjects—Facial dimension

Test Subject No.	Length of face (mm)	Width of face (mm)	Depth of face (mm)	Width of mouth (mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	120	135	125	50

Table B- Breathing Resistance

S.No. (Cl.No.)	Test item		Unit	Technical requirements[1)]	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
17 (7.16)	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.3	0.4	0.4	0.3	0.4	Pass
						0.4	0.4	0.5	0.4	0.4	
						0.3	0.4	0.4	0.4	0.3	
					S.W.	0.4	0.4	0.3	0.4	0.3	
						0.3	0.3	0.4	0.4	0.3	
						0.3	0.4	0.3	0.4	0.3	
					T.C.	0.3	0.4	0.4	0.3	0.4	
						0.3	0.4	0.4	0.3	0.4	
						0.3	0.4	0.4	0.4	0.3	
		Inhalation 95 L/min		≤2.4	A.R.	1.3	1.4	1.4	1.4	1.3	Pass
						1.3	1.4	1.4	1.3	1.4	
						1.4	1.5	1.4	1.5	1.4	
					S.W.	1.4	1.5	1.5	1.4	1.4	
						1.4	1.5	1.5	1.4	1.4	
						1.4	1.5	1.4	1.5	1.4	
					T.C.	1.4	1.4	1.5	1.4	1.4	
						1.3	1.4	1.4	1.4	1.4	
						1.3	1.4	1.5	1.4	1.4	
		Exhalation 160 L/min		≤3.0	A.R.	2.3	2.4	2.4	2.3	2.4	Pass
						2.3	2.3	2.4	2.4	2.3	
						2.4	2.4	2.3	2.4	2.3	
					S.W.	2.3	2.4	2.4	2.3	2.4	
						2.3	2.4	2.3	2.4	2.4	
						2.4	2.3	2.4	2.4	2.3	
					T.C.	2.3	2.4	2.4	2.4	2.4	
						2.3	2.4	2.4	2.4	2.4	
						2.4	2.3	2.4	2.4	2.4	

Note 1: Limitation may need be changed according to classification, refer to Table 2 — Breathing resistance of EN 149:2001 +A1:2009 for the Technical requirements.

Table C- Clogging Test—Breathing resistance

S.No. (Cl.No.)	Test item[1) 2)]		Unit	Technical requirements[1) 2)] (mbar)	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
18 (7.17)	Clogging test— Breathing resistance	Inhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						
		Exhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						
Note 1: Valved particle filtering half masks After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 L/min continuous flow; The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow.											
Note 2: Valveless particle filtering half masks After clogging the inhalation and exhalation resistances shall not exceed FFP1: 3 mbar, FFP2: 4 mbar FFP3: 5 mbar at 95 L/min continuous flow.											

Table D- Clogging Test—Penetration of filter material

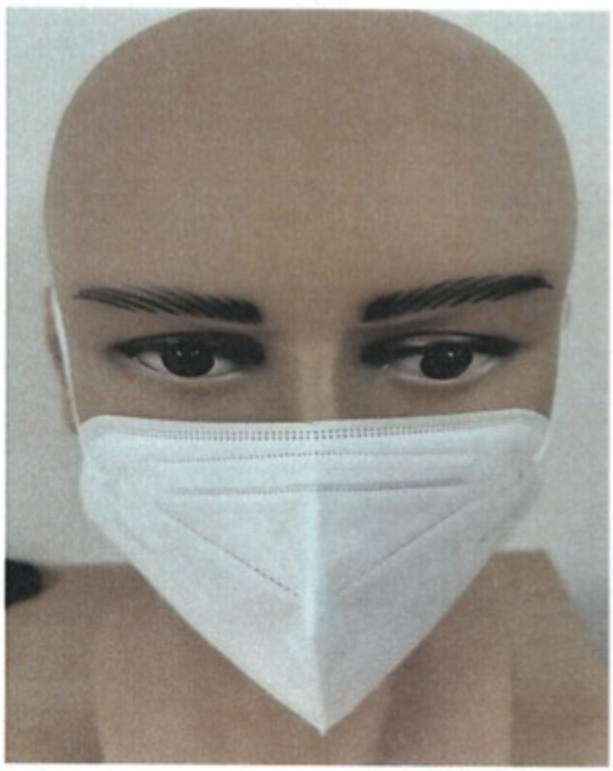
S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result		Single item decision
19 (7.17)	Clogging test- Penetration of filter material	Paraffin oil	—	—	A.R.		N/A
					T.C.		
					T.C.		
Note: Maximum penetration of test aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%							

Abbreviations :		
A.R. As received	M.S. Mechanical strength	S.W. Simulated wearing treatment
T.C. Temperature conditioned	F.C. Flow conditioned	C.D. Cleaning and Disinfecting

Annex A- Estimates of the uncertainty of measurement

Test item	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

Annex B- Sample Photo



The end

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TESTING
CNAS L0317

The Testing Center is accredited for compliance with ISO/IEC17025:2017.

The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.

CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

Selected test items from EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirements, testing, marking
According to supervised product checks procedure at random intervals (C2)

The following samples were submitted and identified on behalf of the client as:

Product	:	**Particle Filtering Half Mask**
Report No.	:	**KZ2022265**
Client	:	**Universal Certification and Surveillance Service Trade Ltd.Co.**
Model(s)	:	**HZ96**
Number of samples	:	**20**
Received date	:	**2020.09.21**
Date(s) of tests	:	**2020.09.21-2020.09.22**

DESCRIPTION OF SAMPLES

General information	**Classification**	**Main components**
	FFP2	White folding mask
Manufacturer	Shenzhen Hezheng Industrial Development Co., Ltd.	
Manufacturer address	601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China	

Chief Tester: 冯云 Feng Yun

Reviewer: 傅丹华 Fu Danhua

Approve: 傅科杰 Fu Kejie
Authorized Signatory,
Lab Director

Issued: 2020.09.22

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Test Report No.KZ2022265

Conditions:

The test results presented in this report relate to the samples tested only.

This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.

The authenticity of this test report and its contents can be verified by contacting the laboratory.

Conclusion

Test Items

Clause 7.9.2	Penetration of filter material	Pass
Clause 7.16	Breathing resistance	Pass

Remarks: Pass = Meet EN 149:2001+A1:2009 FFP2 Requirement
Fail = Below EN 149:2001+A1:2009 FFP2 Requirement
N/A = Not Applicable

Disclaimer Measurement Uncertainty:
Unless otherwise agreed upon, Pass or Fail verdicts are given based on the measured values without any considerations of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO/IEC 17025 requirements.
By taking measurement uncertainties into account it might happen that measured values can neither be assessed as Pass nor as Fail.

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Test Report No.KZ2022265

Test Results

7.9.2 Penetration of filter material **Pass[1]**

The penetration of the filter of the particle filtering half mask shall meet the following requirements.

	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note 1: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.16 Breathing resistance **Pass[2]**

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 L/min	95 L/min	160 L/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note 2：FFP2 respirator. Test results are shown in Annex A Table 7.16.

End of Test Results

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Test Report No.KZ2022265

Annex A: Summarization of Test Data

Table 7.9.2 Penetration of filter material

Test specification: EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	01	0.44	Pass
		02	0.62	
		03	0.70	
Paraffin oil test	As received	04	0.62	
		05	0.54	
		06	0.77	
Flow conditioning: single filter: 95.0 L/min				

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

	Flow rate		07					08					09				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 L/min	0.65	0.63	0.62	0.65	0.68	0.65	0.68	0.67	0.64	0.64	0.63	0.67	0.65	0.68	0.62
		95 L/min	1.50	1.55	1.58	1.53	1.57	1.57	1.53	1.51	1.57	1.53	1.58	1.50	1.57	1.53	1.51
	Exhalation	160 L/min	2.51	2.51	2.45	2.43	2.49	2.49	2.51	2.46	2.59	2.50	2.47	2.45	2.51	2.47	2.51
Assessment			Pass														

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

End of Annex A

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Test Report No.KZ2022265

Annex B: Photos of sample

End of Annex B

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1400

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Shenzhen Hezheng Industrial Development Co., Ltd.

601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: Dr.HZ **Model:** HZ96
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **02/09/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1400/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Shenzhen Hezheng Industrial Development Co., Ltd.

601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
Dr. HZ / HZ96	FFP2 NR	2163-PPE-1400	02.09.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **29/09/2020** and will be valid for one year, until **28/09/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

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Director

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 02.09.2020 / 2163-KKD-1400

Manufacturer: Shenzhen Hezheng Industrial Development Co., Ltd.

Address: 601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Guojian Testing Technology Co., Ltd. accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L10118 for the product identified below, dated 22.06.2020 with Serial Id (2020)WSZ FHL NO.6182 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 28 August, 2020 Version 01 provided by the manufacturer.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask

Classification: FFP2 NR

Brandname: Dr.HZ **Model:** HZ96

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ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permessible user impediment

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3 Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

1.4. Information supplied by the manufacturer

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

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2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.
The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.
The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

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Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements	
Article 5	**Classification:** Particle Filtering Half Mask The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as; Filtering Efficiency and Maximum Total Inward Leakage: Classified as **FFP2** Mask is classified for single shift use, NR
Article 7.4	**Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.
Article 7.5	**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users. Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.
Article 7.6	**Cleaning and Disinfection:** Particle filtering half mask is not designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.
Article 7.7	**Practical Performance:** The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfactions reported during total inward tests about the comfort, field of vision and fastening issues.

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
2.Head harness comfort	2	0	Positive results are obtained from the test subjects No imperfections
3.Security of fastenings	2	0	
5.Field of vision	2	0	

Conditioning: (A.R.) As Received, original

Article 7.8	**Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.
Article 7.9.1	**Total Inward Leakage:** The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report. It was reported that: All 50 exercise measurement results are smaller or equal to 11%, the values varies between 2.4% and 6.1%. All 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 3.5% and 5.0%. **According to the reported results, the product meets the limits for FFP2 classification.**

Article 7.9.2

Penetration of filter material: Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0.1	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2 and FFP3 classes.**
(A.R.)	-	0.1		
(A.R.)	-	0.2		
(S.W.)	-	0.1		
(S.W.)	-	0.2		
(S.W.)	-	0.1		
(M.S. T.C.)	-	0.2		
(M.S. T.C.)	-	0.3		
(M.S. T.C.)	-	0.2		

95 L/min = 1,6 $dm^3.sn^{-1}$

Conditioning: (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

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Article 7.9.2

Penetration of filter material: Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0.2	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2 and FFP3** classes.
(A.R.)	-	0.3		
(A.R.)	-	0.3		
(S.W.)	-	0.3		
(S.W.)	-	0.3		
(S.W.)	-	0.2		
(M.S. T.C.)	-	0.8		
(M.S. T.C.)	-	0.7		
(M.S. T.C.)	-	0.9		

Conditioning: (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.10

Compatibility with skin: In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

Article 7.11

Flammability:

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	Burn for 0.1s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfill requirements of the standard
(A.R.)	-	Burn for 0.1s		
(T.C.)	-	Burn for 0.1s		
(T.C.)	-	Burn for 0.1s		

Conditioning: (A.R.) As Received, original
(T.C.) Temperature Conditioning

Article 7.12

Carbon dioxide content of the inhalation air:

Condition	No. of Sample	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0.7057	0.70[%]	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfil requirements of the standard
(A.R.)	-	0.7015			
(A.R.)	-	0.7027			

Conditioning: (A.R.) As Received, original

Article 7.13

Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

Article 7.14

Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

Article 7.15

Exhalation Valve(s): The model under inspection have no valves.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 simulated wearing treatment complies with the limits given in the standard for **FFP1, FFP2 and FFP3** classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

Passed.

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Article 7.17	**Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. ***(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)***
Article 7.18	**Demountable Parts:** There are no demountable parts on the product.
Article 8	**Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.
Article 9	**Marking – Packaging:** Necessary markings are available on the product package (box). The name and trademark of the manufacturer is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the the year of end of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing HZ96. The mask template (drawing) indicates that the mask will carry information about the name and the brandname (Shenzhen Hezheng Industrial Development Co., Ltd. / Dr.HZ) of the manufacturer, type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested samples by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model HZ96 drawing exists in the techaical file of the manufacturer, Annex 6 of technical file.
Article 10	**Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate, Annex 8. The manufacturer shall include this documented user information text in every smallest commertially available package.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** Director

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