FFP2 NR Atemschutzmaske

XTDC-2022-FF02

Persönliche Schutzausrüstung (PSA)
der Kategorie III

CE 2443

EN 149:2001+A1:2009

Hersteller: Xiantao Dingcheng Nonwoven Products Co., Ltd.

Executive Summary

Hochleistungs-Atemschutz für professionelle Anforderungen

Die XTDC-2022-FF02 ist eine ventillose, filtrierende Halbmaske und wurde für den zuverlässigen Schutz vor feinen Partikeln und Aerosolen entwickelt. Sie bietet ein deutlich höheres Schutzniveau als chirurgische Masken und ist für professionelle Einsatzbereiche im Gesundheitswesen, in der Industrie und in der pharmazeutischen Produktion konzipiert.

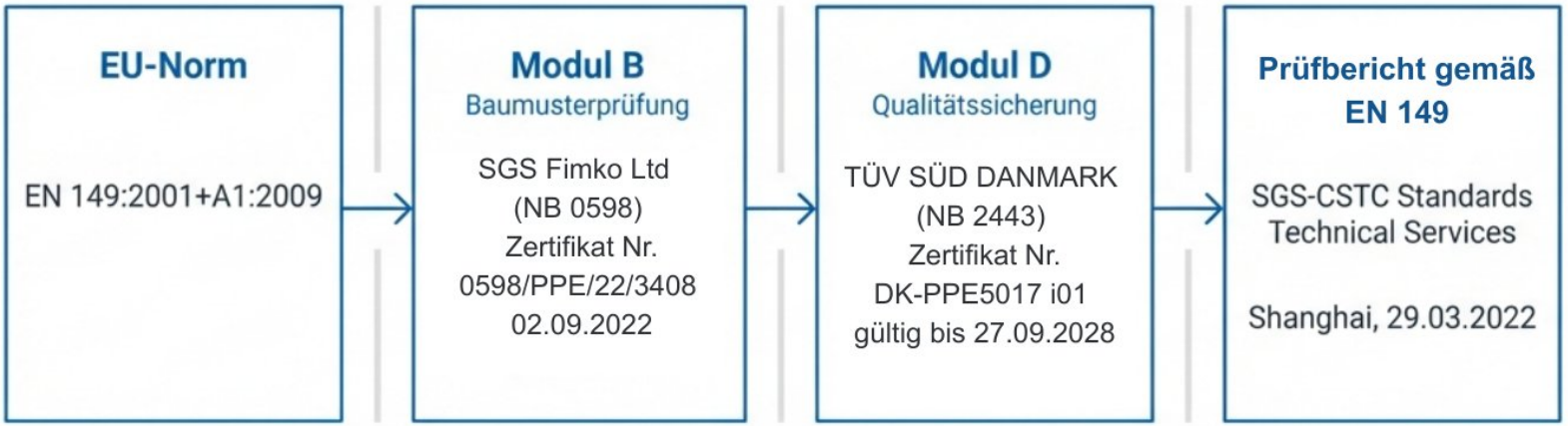
Zertifiziert gemäß EU-Verordnung (EU) 2016/425.

Filterleistung ≥ 95% (nicht-ölige luftgetragene Partikel).

Kategorie III: Schutz gegen tödliche Gefahren oder ernste, irreversible Gesundheitsschäden.

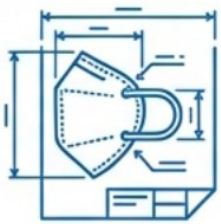
Validierte Konformität und Zertifizierung

Die Maske erfüllt alle Anforderungen der europäischen Normen für persönliche Schutzausrüstung gemäß Verordnung (EU) 2016/425, bestätigt durch notifizierte Stellen.



Technische Spezifikationen im Detail

Modell	XTDC-2022-FF02
Klassifizierung	FFP2 NR (nicht wiederverwendbar)
Material	100 % latexfreier Vliesstoff (Non-woven Fabric)
Filterleistung	≥ 95% für nicht-ölige Partikel
Farbe	Weiß
Herstellungsdatum	Produktionsdatum: chargenabhängig
Haltbarkeit	3 Jahre
Norm	EN 149:2001+A1:2009



Ergonomie und Tragekomfort für lange Einsätze

Hautfreundliche Tragekomfort

Angenehme Materialien für den direkten Hautkontakt.

Ventillose Ausführung

Ohne Ausatemventil, geeignet für hygienisch sensible Einsatzbereiche.

Hygienische Einzelverpackung

Einzeln verpackt für sichere Lagerung und Ausgabe.

Allergikerfreundlich

100 % latexfrei, nickelfreier verstellbarer Nasenbügel.

Ergonomische Passform

Passform für verschiedene Gesichtsformen.

Sichere Befestigung

Doppelte elastische Ohrschlaufen ohne Metallklammern.

Nutzungsdauer

FFP2 NR – ausgelegt für eine komplette Arbeitsschicht.

Primäre Anwendungsbereiche und Zielgruppen

Konzipiert für Umgebungen, in denen wirksamer Schutz vor luftgetragenen Partikeln essenziell ist.

Gesundheitswesen

Medizinisches Fachpersonal, Pflegekräfte, Labore (Exposition gegenüber luftgetragenen Partikeln).

Industrie & Handwerk

Bau, Metallverarbeitung, chemische Industrie (Staub- und Partikelbelastung).

Pharma

Pharmazeutische und technische Produktionsumgebungen.

Notfall

Temporäre Situationen mit erhöhter Partikelbelastung.

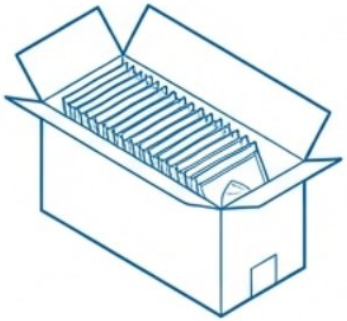
Zielgruppen: Medizinisches Fachpersonal, Industrie- und Bauarbeiter, Sicherheitskräfte.

Verpackungshierarchie und Logistikdaten

Einzelverpackung

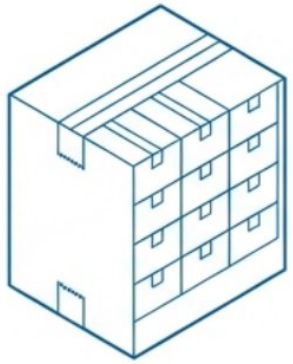
1 Maske pro versiegeltem Polybeutel (Hygienisch)

Box (Verkaufsverpackung)



45 Masken in Einzelverpackungen

Umkarton (Versand)



50 Boxen (Total: 2250 Masken)

Logistikdaten Umkarton

- Maße: 57 × 33 × 67 cm
- Gewicht: 17 Kg
- Lagerung: Staubdichte, stapelbare Kartons, geeignet für trockene Lagerbedingungen. Lagerung kühl, trocken und lichtgeschützt.

EU TYPE-EXAMINATION CERTIFICATE
Regulation (EU) 2016/425, MODULE B
0598/PPE/22/3408 Issue 1
0598/PPE/22/3408

Product	Filtering half masks
Model	XTDC-2022-FF02 Filtering half mask , XTDC-2022 Fish Type Protective mask
Trademark	-
Certificate Holder / Manufacturer	Xiantao Dingcheng Nonwoven Products Co., Ltd. Liukou Industrial Park, Xiantao, Hubei, China
	Product complies with the applicable essential health and safety requirements of Regulation (EU) 2016/425 and standard(s) mentioned below
Standard(s)	EN 149:2001 + A1:2009
Other Information	Respiratory protective devices. Filtering half masks to protect against particles, with a device classification of FFP2 NR. This certificate shall be used in conjunction with conformity assessment procedure module C2 or D.
Validity	This certificate is valid until 2027-09-02.
Date of issue	2022-09-02
	SGS Fimko Ltd
Signature	Mikko Hirvonen Senior Specialist

SGS Fimko Ltd is a Notified Body (0598) according to the Personal Protective Equipment Regulation (EU)

SGS Fimko Ltd
Takomotie 8, FI-00380 Helsinki, Finland
t. +358 9 696 361 www.sgs.fi
Business ID 0978538-5 Member of the SGS Group (SGS SA)

Additional information XTDC-2022-FF02 Filtering Half Mask / XTDC-2022 Fish Type Protective mask, consisting of a white five layer (polypropylene) disposable particle filtering half mask, with aluminium / metal silver nose clip, polyester / elastane ear loop.

Contract No: SSL-CERT220700105/ GB-202207002405

Technical File: Filtering Half Mask XTDC-2022-FF02 / Fish Type Protective mask XTDC-2022, Version 2, Dated: 2022-08-21

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

SGS Fimko Ltd
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DANAK
PROD Reg.No. 7035
Member of EA MLA

TÜV SÜD
Danmark

EU PPE Module D Quality System Certificate

No. DK-PPE5017 i01

Holder of Certificate: **Xiantao Dingcheng Non-woven Products Co., Ltd**
Liukou Industrial Park
433000 Xiantao, Hubei
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): **Xiantao Dingcheng Non-woven Products Co., Ltd**
Liukou Industrial Park, 433000 Xiantao, Hubei, PEOPLE'S REPUBLIC OF CHINA

Scope of Certificate: Production control of personal protective equipment category III product(s) described in the EU Type Examination Certificates (Module B) as listed in the Annex to this Certificate.

This is to certify that TÜV SÜD DANMARK ApS did undertake the relevant conformity to type assessment procedures as specified in Annex VIII of Personal Protective Equipment Regulation (EU) 2016/425 for the quality system under the control of the manufacturer for the equipment identified in the Annex to this Certificate which was found to be in conformity with the type described in the EU type-examination certificate based on quality assurance of the production process and satisfied with the applicable requirements under the Implementing Regulation (EU) 2016/425 . The Conditions for the validity of this certificate are listed in the Annex and requires periodical surveillance.
For details see: www.tuvsud.com/ps-cert

Assessment Report no.: PPE5017 AR 2025

Valid until: 2028-09-27

Date, 2025-09-28

(Wei (Peter) Ye)

This certificate has been issued in accordance with the TÜV SÜD Testing, Certification, Validation and Verification Regulations of TÜV SÜD DANMARK ApS and constitutes the main page(s) of the combined Certificate and Annex.
For further details, related to this certification please contact babt@tuvsud.com

TÜV SÜD DANMARK ApS is Notified Body according to Regulation (EU) 2016/425 on personal protective equipment with the identification number 2443.

TÜV®

EU Declaration of Conformity

Annex IX PPE Regulation (EU)2016/425

This EU Declaration of conformity refers to the following products

Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
FFP2 NR MASK W/O VALVE	XTDC-2022-FF02	FFP2 NR	XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD

The Manufacturer's name and address is as follows:

Name:	XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO.,LTD
Address:	LIUKOUINDUSTRIALPARK,XIANTAOCITY,HUBEIPROVINCE,CHINA

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

Detailed description of the PPE to allow traceability/identification of the PPE.

XTDC-2022-FF02: White folding particle filtering half mask without valve.

The article identified in product category is in conformance with the relevant Union Harmonization Legislation Regulation (EU)2016/425.

References to the relevant harmonized standards used,including the date of the standard,or references to the other technical specifications,including the date of the specification,in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149:2001+A1:2009

☑SGS Fimko Ltd CE0598 performed the EU Type Examination(Module B) and issued the Type Examination Certificate Number:Module B

No.	EU Type Examination(Module B)Certificate Number
1	0598/PPE/22/3408

Product Category:

□ **This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervalsa and is under the surveillance of SGS Fimko Ltd**

CE 0598

☑ **This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of TÜV SÜD DANMARK ApS CE2443**

Certificate No: DK-PPE5017 i01

Signature : Date: 2025/10/13

Company stamp :

XIANTAO DINGCHENG NON-WOVEN PRODUCTS CO., LTD
LIUKOU INDUSTRIAL PARK 433000 XIANTAO CITY - HUBEI

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A) Filtering half mask
Sample Color	:	(A)White
Composition	:	(A)Non-woven melt-blown
Style No.	:	XTDC-2022-FF02
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Mar 11, 2022
Testing Period	:	Mar 14, 2022 - Mar 29, 2022
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

SGS does not verify authenticity of any Brand/Trademark of products. Buyers must check if the product is genuine with the Brand/Trademark owner directly.

Test Result

Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking

EN 149:2001+A1:2009

Clause 7.4 Packaging
(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
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.	Comply	Pass

Clause 7.5 Material
(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
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.	Comply	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting
(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
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.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance
(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfection	Pass

Clause 7.8 Finish of Parts
(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage
(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3	Detail refer to Appendix 1	Meet FFP1 Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	4.23	4.43	4.17	4.56	4.20	4.32
Luo	2	A.R.	4.52	5.19	5.00	5.54	5.40	5.13
Lu	3	A.R.	4.36	4.74	4.28	4.90	4.19	4.49
Wang	4	A.R.	3.38	3.10	3.02	3.44	3.38	3.26
Bao	5	A.R.	5.39	4.25	5.30	5.99	5.70	5.33
Ding	6	T.C.	3.01	3.43	3.58	4.28	3.22	3.50
Li	7	T.C.	5.63	5.10	5.80	6.05	5.03	5.52
Chen	8	T.C.	3.44	3.33	3.94	4.05	3.55	3.66
Song	9	T.C.	4.55	4.46	4.75	5.11	4.74	4.72
Ye	10	T.C.	5.44	6.01	5.17	6.22	5.19	5.61

Facial Dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50
Ding	134	150	110	52

Liu	120	135	117	50
Ye	126	137	105	52

Note: A panel of ten clean-shaven persons (without beards or sideburns) were selected covering the spectrum of facial characteristics of typical users of the filtering half masks submitted by applicant (excluding significant abnormalities). It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects shall not be used for testing particle filtering half masks.

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 2	Meet FFP1 Meet FFP2 Meet FFP3

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	Penetration test (As received)	1	0.121
		2	0.110
		3	0.137
	Penetration test （Simulated wearing treatment）	4	0.146
		5	0.125
		6	0.138
	Exposure test （Mechanical strength +Temperature conditioned）	7	0.235
		8	0.279
		9	0.262
Paraffin oil test	Penetration test (As received)	10	0.201
		11	0.179
		12	0.225
	Penetration test （Simulated wearing treatment）	13	0.214
		14	0.222
		15	0.208
	Exposure test （Mechanical strength +Temperature conditioned）	16	0.393
		17	0.384
		18	0.405
Flow conditioning：Single filter: 95.0 L/min			

Clause 7.10 Compatibility with Skin

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
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.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

A

As Received	No. 1	No. 2	Requirement
After Flame Time(s)	0	0	Max.5s
Temperature Conditioned	No. 1	No. 2	Requirement
After Flame Time(s)	0	0	Max.5s

Remark: Test shall be performed on 2 individual particle filtering half mask for each conditioning (as received & temperature conditioned)

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result	
As received	1	0.5621	Mean value:0.56
	2	0.5634	
	3	0.5633	

Clause 7.13 Head Harness

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
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.	Comply	

Clause 7.14 Field of Vision
(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)
(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to No exhalation valve	N.A.
(b) 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.	Not applicable due to No exhalation valve	
(c) 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.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	

Clause 7.16 Breathing Resistance
(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement	Results	Comment
The breathing resistance of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 5	Meet FFP1 Meet FFP2 Meet FFP3

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

Appendix 5: Summarization of Test Data

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中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Breathing resistance (mbar)

			1					2					3				
	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 l/min	0.4	0.3	0.4	0.4	0.4	0.4	0.3	0.4	0.3	0.3	0.4	0.4	0.4	0.4	0.4
		95 l/min	1.4	1.4	1.4	1.4	1.3	1.4	1.3	1.3	1.4	1.4	1.3	1.4	1.3	1.4	1.4
	Exhalation	160 l/min	2.5	2.5	2.4	2.4	2.5	2.5	2.5	2.4	2.4	2.5	2.5	2.4	2.5	2.5	2.5
			4					5					6				
	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Simulated wearing treatment	Inhalation	30 l/min	0.4	0.4	0.3	0.3	0.3	0.4	0.3	0.4	0.4	0.4	0.3	0.3	0.4	0.4	0.3
		95 l/min	1.4	1.3	1.4	1.4	1.4	1.3	1.4	1.3	1.3	1.3	1.4	1.3	1.4	1.4	1.4
	Exhalation	160 l/min	2.4	2.5	2.5	2.5	2.5	2.4	2.4	2.5	2.4	2.4	2.4	2.4	2.5	2.4	2.5
			7					8					9				
	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	Inhalation	30 l/min	0.3	0.3	0.4	0.3	0.3	0.4	0.4	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3
		95 l/min	1.4	1.3	1.3	1.3	1.3	1.4	1.4	1.3	1.4	1.3	1.3	1.4	1.3	1.3	1.3
	Exhalation	160 l/min	2.4	2.4	2.4	2.4	2.5	2.4	2.4	2.4	2.4	2.5	2.5	2.5	2.4	2.4	2.4

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

Clause 7.17 Clogging

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

<table>
<tr><th>Test Requirement</th><th>Results</th><th>Comment</th></tr>
<tr><td>Clause 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 95L/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 95L/min continuous flow</td><td>Optional for single shift device only</td><td>N.A.</td></tr>
<tr><td>Clause 7.17.3 Penetration of filter material
All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.
<table>
<tr><th rowspan="3">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr>
<tr><th>Sodium chloride test 95 l/min</th><th>Paraffin oil test 95 l/min</th></tr>
<tr><th>%
max.</th><th>%
max.</th></tr>
<tr><td>FFP1</td><td>20</td><td>20</td></tr>
<tr><td>FFP2</td><td>6</td><td>6</td></tr>
<tr><td>FFP3</td><td>1</td><td>1</td></tr>
</table>
</td><td>Optional for single shift device only</td><td>N.A.</td></tr>
</table>

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Clause 7.18 Demountable Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No demountable parts	N.A.

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%

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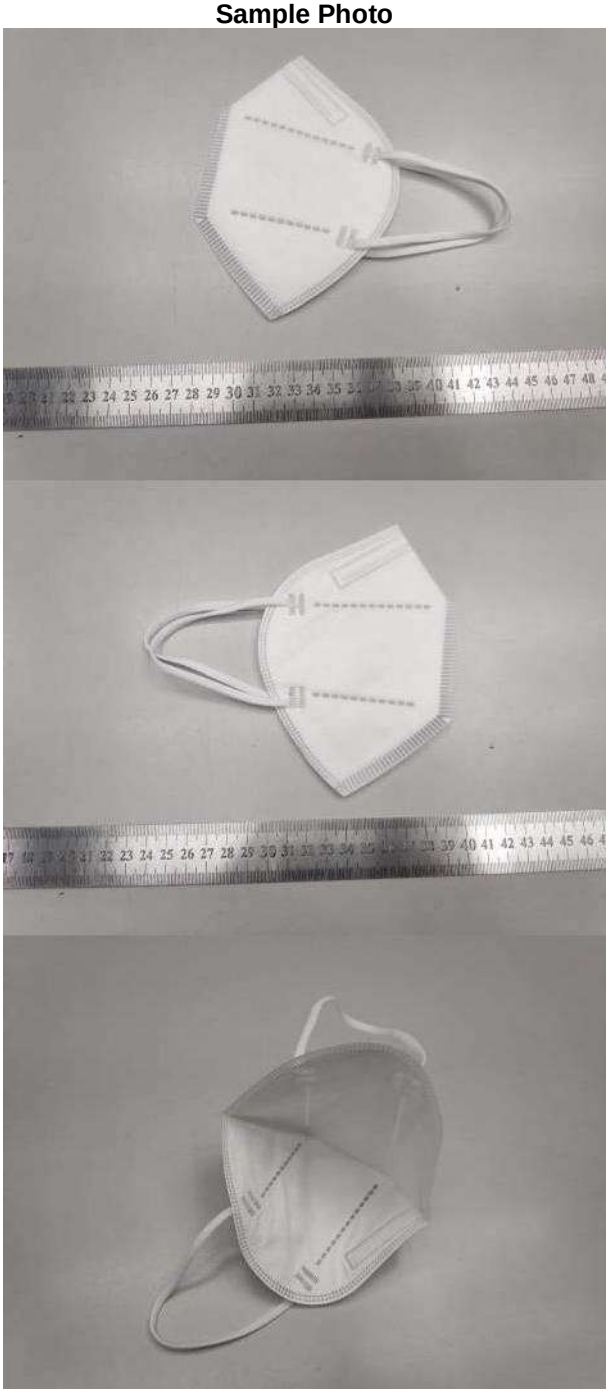
Sample Photo



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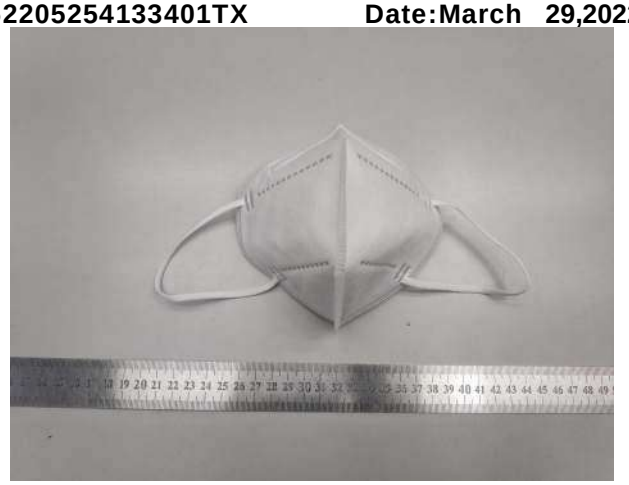

Product information is provided by applicant without verification or authentication of the brand.

End of Report

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Personal Protective Equipment- Module D Assessment Report

Client Name	Xiantao Dingcheng Non-woven Products Co., Ltd
Client Number	PPE5017
Facility Number	2426
Visit Number	13779
Holder Number	2426
Certificate Number	DK-PPE5017 i01
Audit type	☒ Initial ☐ Annual Surveillance ☐ Re-certification ☐ Transfer (Surveillance) ☐ Transfer (Re-certification) ☐ Special
Audit Method	☐ Remote ☒ On-site
Standard/ Normative Document(s) (Note: please delete/strikethrough the not applicable standard/normative document)	☐ Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 ☒ Personal Protective Equipment Regulation (EU) 2016/425
Audit date/(-s)	2025-09-02 to 2025-09-05
Client Address (Street / P.O. Box)	Liukou Industrial Park,
Postal/ zip code / state / city	Xiantao, Hubei, China
Contact phone number	+8618007229722
Contact e-mail	chengqin1977@qq.com; 1930467324@qq.com
Site(s)/Location(s) visited: (include name and address, if relevant)	Xiantao Dingcheng Non-woven Products Co., Ltd Liukou Industrial Park, Xiantao, Hubei, China
Certification Type	☒ Single site ☐ Multi-site with site sampling (see multi-site certification plan) ☐ Multi-site without site sampling (see multi-site certification plan) ☐ Combined certification
Client representative	Ms. Cheng Qin
Lead auditor/auditor	Xie, Yukun
Other audit team members	Remote TE support TE: Zhang, Jamie for PPE clothing; Liu, Qi (Adam) for PPE masks
Observer/ trainee	n.a.
Interpreter	n.a.
Audit language	Chinese + English
Next audit date scheduled	2026 Sept 02
Assessment report number* (*only applicable to audits, where new certificate is issued)	PPE5017 AR 2025

Authorized representative details (only to be completed where Authorised representative is used)

Name of the Authorised representative	Riomavix S.L.
Address of the Authorised representative	Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
Email	leis@riomavix.com

Telephone number	+34 658 396 230

Implementation of the audit

Duration of audit	32hours
Particularities	n.a.
Specific information about the client	n.a.

Types of Product within the scope of the Certification (add more rows as required)

Type of PPE	Type of Risk
Protective Clothing	substances and mixtures which are hazardous to health
Respiratory protective equipment	harmful biological agents

Site details (copy the table below, if required to record additional sites for multi-site certifications)

Facility name/ address	
Facility Type	☐ Headquarters/central functions ☒ Manufacturing site with central functions ☐ Manufacturing site without central functions ☐ Design site without central functions or manufacturing ☐ Test Site ☐ Other: Click or tap here to enter text.
Name of the Management Representative at the site	Ms. Cheng Qin
Position of the Management Representative at the site	GM and Quality Dept Manager.
Number of Full Time Equivalent Employees	34
Total Involved in production	13
Total area of the site	30000
Area of the Facility	20000
Production related areas (incl. Stores)	15000
Number of shifts operated	1
Number of total shifts	1
Are all shifts performing the same work?	n.a.
If more than one, which shift(s) were audited:	n.a.
If more than one, they differed as follows:	n.a.

Key personnel seen during the assessment (add more rows as required)

Name	Position
Cheng Qin	GM, Management Representative
Wang Hongli	Production Department Representative.
Li Xiufang	Quality Department Supervisor
Chen Cuicui	Material Department
Du Wanjun	Storage/Warehouse
Tang Min	Sales, Marketing

Li Quan	HR, Department Office

Objectives of Initial audit:

- Determination of the extent of conformity of the management system, or those parts applicable of it, with audit criteria;
- Determination and evaluation of the capability of the management system to ensure compliance with applicable statutory, regulatory and contractual requirements;
- Determination and evaluation of the effectiveness of the management system to ensure the client organization is continually meeting its specified objectives;
- Identification of areas for potential improvement of the management system;
- Evaluation of the management´s responsibility for the company´s policies;
- Evaluation of the links between the standard requirements and the management system requirements;
- Evaluation of the operational control of processes, including internal audits and management review.

Objectives of Surveillance audit:

- Evaluation of internal audits and management review;
- Review of actions taken on nonconformities identified during the previous audit;
- Review of complaints handling;
- Evaluation of effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system;
- Review of the progress of planned activities aimed at continual improvement;
- Evaluation of continuing operational control;
- Review of any changes;
- Review of the use of marks and/or any other reference to certification

Objectives of Recertification audit:

- Evaluation of the effectiveness of the management system in its entirety;
- Review of internal and external changes and its continued relevance and applicability to the scope of certification;
- Evaluation of demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;
- Review the effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the management system.

Significant changes since the last audit

Topic	Changes
Management system / documented information	☐ No ☐ Yes *-if yes, please describe-* ☒ n.a. as initial audit
Scope of certification	☐ No ☐ Yes *-if yes, please specify the change and the sites affected by it-* ☒ n.a. as initial audit
Number of employees	☐ No ☐ Yes *- if yes, please specify the change and the sites affected by it-* ☒ n.a. as initial audit
Miscellaneous *e.g. products/services, processes, facilities, equipment, infrastructure, criteria of multi-site certification with/without site sampling*	*-if applicable, please specify the change and the sites affected by it-* ☒ n.a. as initial audit

Changes compared with audit planning

Are there changes with regard to the information given in the client´s application questionnaire (or similar documents):

☒ No

☐ Yes:

Topic	Confirmed change:
Scope of certification	n.a.
Number of (effective) employees	n.a.
Scheduled audit time	n.a.
Others	n.a.

Particular aspects of the audit

Deviations from the audit plan	☒ No ☐ Yes Click or tap here to enter text.
Significant issues impacting the audit program *(activities planned in the course of the certification cycle)*	☒ No ☐ Yes Click or tap here to enter text.
Changes in audit objectives or audit criteria	☒ No ☐ Yes Click or tap here to enter text.
Any unresolved issues, if identified	n.a.
Other special features:	n.a.

Products covered by the Certification in production during the assessment.

Filtering half masks:

- XTDC-2022-FF02 Filtering half mask
- XTDC-2022 Fish Type Protective mask

Disposable isolation gown:

- DC4016A PP+PE (35gsm)

Chemical protective clothing:

- DC4017A SMS (35gsm)

Chemical protective coverall:

- DCM702
- DCM703
- DCM702Y

Chemical protective coverall:

- DCS 702B
- DCS 702
- DCS 703B
- DCS 703

Protective Clothing Disposable coverall:

- DCMPH100

Production Testing witnessed during the assessment and / or demonstrated capability for Production Testing:

Sampled 3 products, rest types have the same or similar tech and production way.

Filtering half masks:

- XTDC-2022-FF02 Filtering half mask

Disposable isolation gown:

- DC4016A PP+PE (35gsm)

Chemical protective coverall:

- DCM702

Quality Checks/Inspections witnessed during the assessment and / or demonstrated capability for Production:

Witnessed online general checking (size, marking, package, metal needle)
Onsite selected(products), strength testing, respiratory resistance test and water resistance test are demonstrated in factory lab.

Detail any issues raised on the observation reports/action list generated during the last visit that have not been satisfactorily resolved:

As initial audit, n.a.

Assessment Coverage Reference Charts (*Delete not applicable one*)

PPE UKCA Module D		(√)	No. of findings
2.	**Manufacturing**	☐	
3	**Quality System**	☐	
3.1	Application	☐	
3.2	Quality system	☐	
3.4	Fulfil obligations	☐	
3.5	Changes to quality system	☐	
5	**Conformity Marking and Declaration of Conformity**	☐	
5.1	Affixing UKCA mark	☐	
5.2	UK Declaration of Conformity	☐	
6	**Documentation Keeping**	☐	
8	**Authorised Representative (if any)**	☐	

PPE CE Module D		(√)	No. of findings
2.	**Manufacturing**	✓	
3	**Quality System**	✓	
3.1	Application	✓	
3.2	Quality system	✓	**2OFI**
3.4	Fulfil obligations	✓	**1NC**
3.5	Changes to quality system	✓	**1 NC**
5	**Conformity Marking and Declaration of Conformity**	✓	
5.1	Affixing CE mark	✓	
5.2	EU Declaration of Conformity	✓	
6	**Documentation Keeping**	✓	**2 NC**
8	**Authorised Representative (if any)**	✓	

See BABT AF091 Action List for details of findings.

Auditor's Comments (PPE (Regulation (EU) 2016/425 and PPE (Enforcement) Regulations 2018) / Personal Protective Equipment Regulation (EU) 2016/425

PPE5017 Xiantao Dingcheng Non-woven Products Co., Ltd established and well developed from 2009, in the non-woven industry. The audited facility and address: Liukou Industrial Park, Xiantao, Hubei, China. The audit was based on the Personal Protective Equipment Regulation (EU) 2016/425. The PPE products are Filtering half masks:XTDC-2022-FF02 Filtering half mask & XTDC-2022 Fish Type Protective mask; Disposable isolation gown:DC4016A PP+PE (35gsm); Chemical protective clothing: DC4017A SMS (35gsm); Chemical protective coverall: DCM702, DCM703, DCM702Y; Chemical protective coverall: DCS 702B, DCS 702, DCS 703B, DCS 703; Protective Clothing Disposable coverall: DCMPH100.

The quality system is based on Quality Manual, DC-QM-2023 C/0 and related Quality Procedures and Work Instructions and records as they are documented well.

I have found 4NC and 2 OFI during the audit. (details refer to Action List AF091 and correction and corrective actions, evidence, plans, etc.)

PPE5017 Xiantao Dingcheng Non-woven Products Co., Ltd has a quality management system fits for EU PPE regulation based on certified ISO 9001:2015. The management review and internal audit records found to be good and commitment of the top management, continues conformity with legal requirement and standards. The employees are well managed and trained for the manufacturing processes and roles. A continual improvement and awareness were demonstrated during the interviews. It is willing to improve both the quality of the products and level of the management system.

Only applicable to multi-site certification (with / without site sampling):

Additional aspects for multi-site audits:	
All requirements by the certification body for conducting a multi-site audit were	☐ fulfilled ☐ not fulfilled[1)2)]
Under consideration of all audit reports from all sites, the management system of the organization is:	☐ effective ☐ not effective [1)2)]
When planning corrective actions for non-conformances, all sites of the organization were considered in order to detect systematic errors:	☐ fulfilled ☐ not fulfilled[1)]
The organization effectively uses information from corrective actions from each individual site in order to increase the overall effectiveness of the management system:	☐ fulfilled ☐ not fulfilled[1)]
Strengths and weaknesses of the MS:	

1) Listed as a nonconformity in the action list (BABT AF091) *2) Certification cannot yet be recommended*

Non-conformities

Effectiveness verification of corrective actions from previous audit	
The audit team evaluated the corrective action taken to address the nonconformities / areas of concern from the previous audit.	☐ Effective ☐ Not effective (☐ MiN or ☐ NC) ☒ Not applicable (no existing MiNs or NCs) Initial audit
In the case of re-certification audits, the audit team considered the audit reports for the last two audits in the audit planning / performance of the audits and checked the nonconformities / areas of concerns in particular.	☐ Effective ☐ Not effective (☐ MiN or ☐ NC) ☒ Not applicable (no existing MiNs or NCs) Initial audit
The Corrective actions were found to be:	☐ Effective ☐ Not effective (☐ MiN or ☐ NC) ☒ Not applicable (no existing MiNs or NCs) Initial audit

Total number of identified audit findings during this audit			
Major Non-conformities	Minor nonconformities	Opportunities for improvement	Positive aspects
4	n.a.	2	n.a.

Summarized evaluation of management-system

Refers to strengths and weaknesses, degree of maturity of the management system, commitment by top management, ensuring continuous conformity with legal and other requirements, application of performance indicators, continual improvement, achievement of objectives, employee expertise, effectiveness of internal audits and management reviews.

PPE5017 Xiantao Dingcheng Non-woven Products Co., Ltd has a quality management system fits for EU PPE regulation based on certified ISO 9001:2015. The management review and internal audit records found to be good and commitment of the top management, continues conformity with legal requirement and standards. The employees are well managed and trained for the manufacturing processes and roles. A continual improvement and awareness were demonstrated during the interviews. It is willing to improve both the quality of the products and level of the management system.

Recommendation

The evidence collected during the audit demonstrates that the organization uses certificates and certification marks in conformity with the applicable requirements: *Note – Use of the UKAS/ DANAK mark / logo on manufacturers documentation and products is prohibited*	☒ fulfilled ☐ not fulfilled (NC) ☐ not applicable (in the case of initial certification)
Audit results	☒ The audit objectives for the management system (MS) have been fulfilled; ☒ The scope of certification is appropriate; ☒ A (centrally) managed MS is in place; ☒ Release / maintenance of certificate recommended (subject to effective closure of nonconformities)
	☐ The audit objectives for the MS have NOT been fulfilled; ☐ Certificate change of scope is recommended; ☐ Special audit is required; ☐ Suspension / withdrawal of certificate recommended; certification cannot be granted or maintained

Signature of Lead/Reporting Auditor	Xie Yukun	**Date**	**12/09/2025**

Additional remarks.

Disclaimer statement

Auditing is based on a sampling process of the available information. Any audit recommendations are subject to an independent review prior to a decision concerning the awarding or renewal of certification.

Management system certification audits (initial certification, surveillance or re-certification audits) are not legal compliance audits (ISO 17021 9.2.1.2; IAF MD22:2019, APPENDIX A).

Duty of information

The Certification Body shall be notified by the client without delay of all changes that may impact on the management system's capability to continue to fulfill the requirements of the relevant standard now and in the future.

These matters include major changes regarding:

- legal, commercial, organizational status or ownership
- organization and management (e.g. key managerial, decision-making, or technical staff)
- addresses and sites
- scope of operations under the certified management system

Due dates

The due date (last day of the certification audit) must be considered for the planning of any additional audit. The respective due dates should be coordinated with the lead auditor.

Confidentiality

The Certification Body will treat all received documented information related to the certification process as strictly confidential.

Copies to:

- Members of the audit team
- Certification Body
- Customer