HANXIUTANG

ANHUI HANXIUTANG BIOLOGICAL CO., LTD.

Mask (Non Medical)

Qualification Certificate and Introduction

CATALOG

HANXIUTANG

Business License

HANXIUTANG

统一社会信用代码
91340800MA2NW4WE5C(2-2)

营业执照
（副本）

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　安徽翰修堂生物科技有限公司

类　　型　有限责任公司（自然人独资）

法定代表人　程启娟

经营范围　生物技术研发、技术服务；营养健康咨询服务；会展服务；保健食品、食品、化妆品、洗涤用品、日用百货、体育用品、机械设备、服装、鞋帽、五金交电、家用电器、工艺美术品的销售；医疗器械研发、生产及销售；卫生消毒用品（不含危化品）、生物制品、劳动防护用品、口罩（非医用）、纺织品生产及销售；货物及技术进出口（但国家限定公司经营或禁止进出口的商品及技术除外）。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　壹仟万圆整

成立日期　2017年08月03日

营业期限　/长期

住　　所　安徽省安庆市大观区湖心中路一期综合楼13-31号

登记机关　安庆市大观区市场监督管理局

2020　06　04

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示

国家市场监督管理总局监制

Product Inspection Report

HANXIUTANG

检验检测报告

TEST REPORT

STFWT202012466G

Product Name: Filtering half mask

Trust Unit: ANHUI HANXIUTANG BIOTECHNOLOGY CO.,LTD

Manufacturer: ANHUI HANXIUTANG BIOTECHNOLOGY CO.,LTD

Test Category: Entrusted Inspection

江苏省特种安全防护产品质量监督检验中心

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

Test Report

STFWT202012466G page 1 of 10

Product Name	Filtering half mask	Specification Type	HXT-01
		Trademark	HANXIUTANG
Trust Unit	ANHUI HANXIUTANG BIOTECHNOLOGY CO.,LTD	Tel	13713710928
Manufacturer	ANHUI HANXIUTANG BIOTECHNOLOGY CO.,LTD	Sample Grade	FFP2
Sample Quantity	100 pcs	Sample Receiving Date	2020-05-05
Test Category	Entrusted inspection	Serial Number	20200421-1
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	EN 149：2001+A1：2009 (*Respiratory protective devices -Filtering half masks to protect against particles-Requirements，testing，marking*)		
Test Conclusion	The samples were tested, the items tested meet the requirements of EN 149:2001+A1:2009 standard for FFP2 level. Signature Date：2020-06-10		
Remarks	No. STFWT202012466G instead of No. STFWT202012466 test report, the original report is invalid The head harness of the mask provided by the applicant is ear hanging. Compatibility with skin is not recognized by the center. The test data are only for reference. The sample is not marked for reuse and does not require testing for blocking performance. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. The results apply to the sample as received.		

Approver 陈.赵 Examiner 杨森 Major tester 丁欣

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

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7.5 Material Pass[1]

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.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

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.

Note1: Refer to Annex A for test data.

7.6 Cleaning and disinfecting N/A[2]

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.

Note2: Non-reusable respirator.

7.7 Practical performance Pass[3]

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

Note3: Refer to Annex A for test data.

7.8 Finish of parts Pass

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

7.4 Package Pass

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.

Note1: The visual inspection was carried out as per required by the manufacturer and the standard.

Product Inspection Report

HANXIUTANG

7.9.1 Total inward leakage Pass[4]

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:

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

Note4: Refer to Annex A for test data.

7.9.2 Penetration of filter material Pass[5]

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

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

Note5: Refer to Annex A for test data.

7.10 Compatibility with skin Pass[6]

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.

Note6: Refer to Annex A for test data.

7.11 Flammability Pass[7]

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.

Note7: Refer to Annex A for test data.

7.12 Carbon dioxide content of the inhalation air Pass[8]

The carbon dioxide content of the inhalation air (dead space) shall not exceed an

Note8: Refer to Annex A for test data.

7.13 Head harness Pass[9]

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

Note9: Refer to Annex A for test data.

7.14 Field of vision Pass[10]

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

Note10: Refer to Annex A for test data.

7.15 Exhalation valve N/A[11]

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.

Note11: Valve-less respirator.

7.16 Breathing resistance Pass[12]

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

Note12: Refer to Annex A for test data.

7.17 Clogging N/A[13]

7.17.2 Breathing resistance N/A[13]

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

7.17.3 Penetration of filter material

	Sodium chloride test 95	Paraffin oil test 95 l/min	
FFP1	≤20%	≤20%	N/A[13]
FFP2	≤6%	≤6%	
FFP3	≤1%	≤1%	

Note13: Non-reusable respirator.

7.18 Demountable parts N/A[14]

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

Note14: No demountable parts.

Product Inspection Report

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Annex A: Summarization of Test Data

Clause		Result			Assessm
7.5	Material	Simulated wearing treatment	1#	No mechanical failure	Pass
			2#	No mechanical failure	
			3#	No mechanical failure	
		Temperature conditioned	4#	No mechanical failure	
			5#	No mechanical failure	
			6#	No mechanical failure	
7.9	Practical performance	As received	7#	No mechanical failure	Pass
			8#	No mechanical failure	
7.9.1	Total inward leakage	Individual exercise result			Pass
		As received	9#	47 out of the 50 individual exercise results ≤ 11%	
			10#	47 out of the 50 individual exercise results ≤11%	
			11#	47 out of the 50 individual exercise results ≤ 11%	
			12#	47 out of the 50 individual exercise results ≤11%	
			13#	47 out of the 50 individual exercise results ≤ 11%	
		Temperature conditioned	14#	47 out of the 50 individual exercise results ≤11%	
			15#	47 out of the 50 individual exercise results ≤ 11%	
			16#	47 out of the 50 individual exercise results ≤11%	
			17#	47 out of the 50 individual exercise results ≤ 11%	
			18#	47 out of the 50 individual exercise results ≤11%	
		Individual wearer arithmetic means			
		As received	9#	9 individual wearer arithmetic means≤ 8%	
			10#	9 individual wearer arithmetic means≤ 8%	
			11#	9 individual wearer arithmetic means≤ 8%	
			12#	9 individual wearer arithmetic means≤ 8%	
			13#	9 individual wearer arithmetic means≤ 8%	
		Temperature conditioned	14#	9 individual wearer arithmetic means≤ 8%	
			15#	9 individual wearer arithmetic means≤ 8%	
			16#	9 individual wearer arithmetic means≤ 8%	
			17#	9 individual wearer arithmetic means≤ 8%	
			18#	9 individual wearer arithmetic means≤ 8%	

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCT

Clause		Result			Assessment
7.9.2	Penetration of filter material/%	Sodium chloride test(95L/min)			Pass
		As received	19#	0.31	
			20#	0.34	
			21#	0.36	
		Simulated wearing treatment	22#	0.39	
			23#	0.42	
			24#	0.44	
		M.S.+T.C.	25#	0.47	
			26#	0.49	
			27#	0.54	
		Paraffin oil test(95L/min)			
		As received	28#	1.14	
			29#	1.19	
			30#	1.22	
		Simulated wearing treatment	31#	1.27	
			32#	1.33	
			33#	1.36	
		M.S.+T.C.	34#	1.41	
			35#	1.44	
			36#	1.49	
7.10	Compatibility with skin	As received	9#	No irritation or any other adverse effect to health	Pass
			10#	No irritation or any other adverse effect to health	
			11#	No irritation or any other adverse effect to health	
			12#	No irritation or any other adverse effect to health	
			13#	No irritation or any other adverse effect to health	
		Temperature conditioned	14#	No irritation or any other adverse effect to health	
			15#	No irritation or any other adverse effect to health	
			16#	No irritation or any other adverse effect to health	
			17#	No irritation or any other adverse effect to health	
			18#	No irritation or any other adverse effect to health	
7.11	Flammability	As received	37#	Didn't burn	Pass
			38#	Didn't burn	
		Temperature conditioned	39#	Didn't burn	
			40#	Didn't burn	

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

Clause		Result				Assessment
7.12	Carbon dioxide content of the inhalation air/%	As received				Pass
		41#	42#	43#	Mean value	
		0.55	0.54	0.53	0.54	
7.13	Head hardness	As received				Pass
		9#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		10#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		11#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		12#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		13#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		Temperature conditioned				
		14#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		15#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		16#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		17#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		18#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
7.14	Field of vision	As received	7#	Passed the practical performance tests		Pass
			8#	Passed the practical performance tests		

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

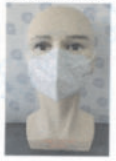
Product Inspection Report

HANXIUTANG

Clause				Result			Assessment
				Inhalation		Exhalation	
				30 l/min	95 l/min	160 l/min	
		As received					
7.16	Breathing resistance (mbar)	41#	A	0.5	1.8	2.7	Pass
			B	0.5	1.8	2.7	
			C	0.6	1.9	2.8	
			D	0.5	1.8	2.7	
			E	0.5	1.8	2.7	
		42#	A	0.5	1.8	2.7	
			B	0.6	1.9	2.7	
			C	0.5	1.8	2.7	
			D	0.5	1.8	2.8	
			E	0.5	1.8	2.7	
		43#	A	0.5	1.8	2.7	
			B	0.5	1.8	2.7	
			C	0.5	1.8	2.7	
			D	0.5	1.9	2.7	
			E	0.6	1.8	2.8	
		Simulated wearing treatment					
		44#	A	0.5	1.8	2.7	
			B	0.6	1.9	2.7	
			C	0.5	1.8	2.8	
			D	0.5	1.8	2.7	
			E	0.5	1.8	2.7	
		45#	A	0.5	1.8	2.7	
			B	0.5	1.8	2.7	
			C	0.5	1.8	2.7	
			D	0.5	1.9	2.8	
			E	0.6	1.8	2.7	
		46#	A	0.5	1.8	2.7	
			B	0.5	1.8	2.7	
			C	0.5	1.9	2.8	
			D	0.6	1.8	2.7	
			E	0.5	1.8	2.7	

Clause				Result			Assessment
				Inhalation		Exhalation	
				30 l/min	95 l/min	160 l/min	
		Temperature conditioned					
7.16	Breathing resistance	47#	A	0.5	1.8	2.7	Pass
			B	0.5	1.8	2.7	
			C	0.6	1.9	2.8	
			D	0.5	1.8	2.7	
			E	0.5	1.8	2.7	
		48#	A	0.5	1.8	2.7	
			B	0.5	1.8	2.7	
			C	0.5	1.8	2.7	
			D	0.6	1.9	2.8	
			E	0.5	1.8	2.7	
		49#	A	0.6	1.9	2.8	
			B	0.5	1.8	2.7	
			C	0.5	1.8	2.7	
			D	0.5	1.8	2.7	
			E	0.5	1.8	2.7	
7.16	Breathing resistance	A: facing directly ahead B: facing vertically upwards C: facing vertically downwards D: lying on the left side E: lying on the right side					
Remarks : M.S.: Mechanical strength; T.C.: Temperature conditioning; N/A: Not applicable							

Original Sample



======= End of Report =======

CE Certification

HANXIUTANG

UNIVERSAL CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-870

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

Anhui Hanxiutang Biotechnology Co., Ltd.
U13-31, Phase I Complex Building, Huxin Middle Road, Daguan District, Anqing City, Anhui 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: HANXIUTANG **Model:** HXT-01
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 **27/06/2020** 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 KACMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazil Bulvari Kayap Sitesi E2 Blok No:44/84 Yukari Dudulu Umraniye - ISTANBUL - TURKEY T:+90 216 455 80 80

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UNIVERSAL CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-870/01

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

Anhui Hanxiutang Biotechnology Co., Ltd
U13-31, Phase I Complex Building, Huxin Middle Road, Daguan District, Anqing City, Anhui 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
HANXIUTANG / HXT-01	FFP2 NR	2163-PPE-870	27.06.2020	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 **27/06/2020** and will be valid for one year, until **26/06/2021** 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

Suat KACMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazil Bulvari Kayap Sitesi E2 Blok No:44/84 Yukari Dudulu Umraniye - ISTANBUL - TURKEY T:+90 216 455 80 80

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UNIVERSAL CERTIFICATION

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 26.06.2020 / 2163-KKD-870

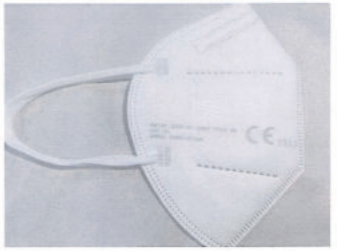
Manufacturer: Anhui Hanxiutang Biotechnology Co., Ltd.
Address: U13-31, Phase I Complex Building, Huxin Middle Road, Daguan District, Anqing City, Anhui Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Quality Supervision and Inspection Center for Special Safety Protection Products accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-7901 for the product identified below, dated 10.06.2020 with Serial Id STFWT202012466G based on EN 149: 2001 + A1: 2009 standard and the technical file dated 11 June, 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

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
Brand Name: HANXIUTANG **Model:** HXT-01



CE 2163

UNIVERSAL CERTIFICATION

UPR-385 12.12.2018 Rev:01

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CE Certification

HANXIUTANG

UNIVERSAL
CERTIFICATION

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 permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perceptions 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 effisiency.

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 address of 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 question:
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 markingsee 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 those 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

Materials: 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 effect to the health and safety of users.

Based on the test results, the masks did not collapse when subject to simulated wearing and temperature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.

Article 7.6

Cleaning and Disinfection: Particle filtering half masks is **not** designed to be re-useable. 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 exercises while they were wearing 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, necessity of fastenings and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fastening issues.

Assessed Elements	Positive	Negative	Remarks/remarks in accordance with EN 149:2001 + A1:2009 and Result
7.3 Head harness comfort	8	0	Positive results are obtained from the test subjects No imperfections
7.3 Necessity of fastenings	8	0	
7.4 Field of vision	8	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 exercises 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.

It was reported that;

47 out of 50 exercise measurement results are smaller or equal to 11%.

9 out of 10 individual's arithmetic means is smaller or equal to 8%

According to the reported results, the product meets the limits for FFP1 and FFP2 classification.

Article 7.9.2

Penetration of filter material: Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 Litres/min (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	19	0,33		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.)	20	0,34		
(A.R.)	21	0,39	FFP1 ≤ 20 %	
(S.W.)	22	0,58		
(S.W.)	23	0,42	FFP2 ≤ 6 %	
(S.W.)	24	0,44		
(M.S. T.C.)	25	0,47	FFP3 ≤ 1 %	
(M.S. T.C.)	26	0,46		
(M.S. T.C.)	27	0,38		

Conditioning : (M.S.) Mechanical Strength — 95 Litres = *Lit dm³ /m²*

(T.C.) Temperature Conditioning

(A.R.) As Received, original

(S.W.) Simulated wearing treatment

CE Certification

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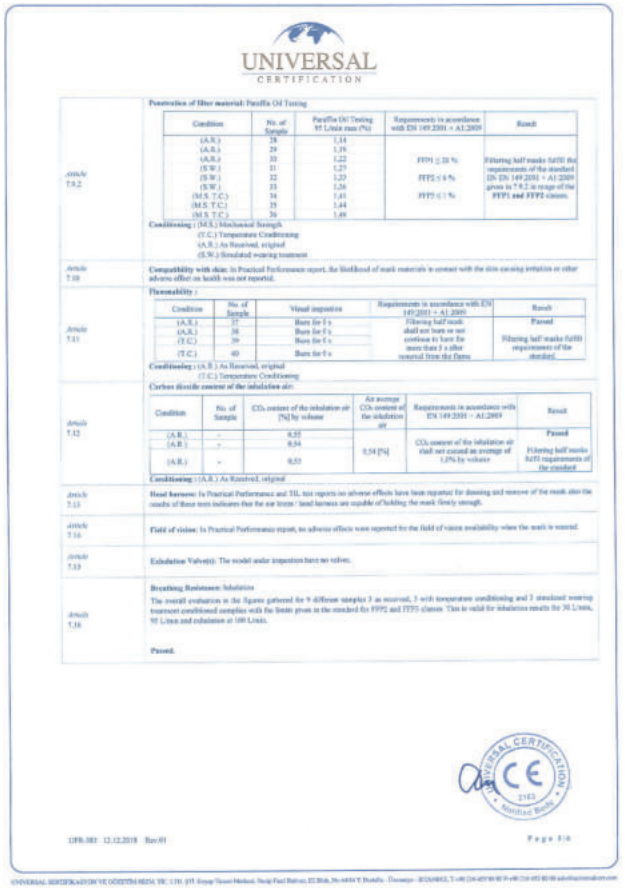

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Penetration of filter material: Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 Limit max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	28	1,14		
(A.R.)	29	1,19		
(A.R.)	30	1,22	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard (EN EN 149:2001 + A1:2009 given in * 8.2 in range of the **FFP1 and FFP2** classes.
(S.W.)	31	1,27		
(S.W.)	32	1,20	FFP2 ≤ 6 %	
(S.W.)	33	1,16		
(M.S. T.C.)	34	1,41	FFP3 ≤ 1 %	
(M.S. T.C.)	35	1,44		
(M.S. T.C.)	36	1,49		

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

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.

Flammability :

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	37	Burn for 0 s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed
(A.R.)	38	Burn for 0 s		
(T.C.)	39	Burn for 0 s		Filtering half masks fulfill requirements of the standard.
(T.C.)	40	Burn for 0 s		

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

Carbon dioxide content of the inhalation air:

Condition	No. of Sample	CO_2 content of the inhalation air [%] by volume	Air average CO_2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,55	0,54 [%]	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed
(A.R.)	-	0,54			
(A.R.)	-	0,53			Filtering half masks fulfil requirements of the standard

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

Head harness: In Practical Performance and 5IL test reports no adverse effects have been reported for donning and removal of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

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

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

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temperature conditioning and 3 simulated wearing treatment conditioned samples with the limits given in the standard for 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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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.)

Demountable Parts: There are no demountable parts on the product.

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.

Marking – Packaging: Necessary markings are available on the product package (box). The manufacturer and its trademark 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 end date 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 HXT-01. The mask image in the technical file carries information about the manufacturer / trademark (HANXIUTANG) 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. From the tested sample by the laboratory and design drawings do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model HXT-01 drawing exists in the technical file of the manufacturer, Annex 9 of technical file.

Information to be supplied by the manufacturer: In each of the smallest commercially available packaging of the product, implementation (installation instructions) given-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 commercially available package.

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

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Certification of White name list

HANXIUTANG

Product Introduction

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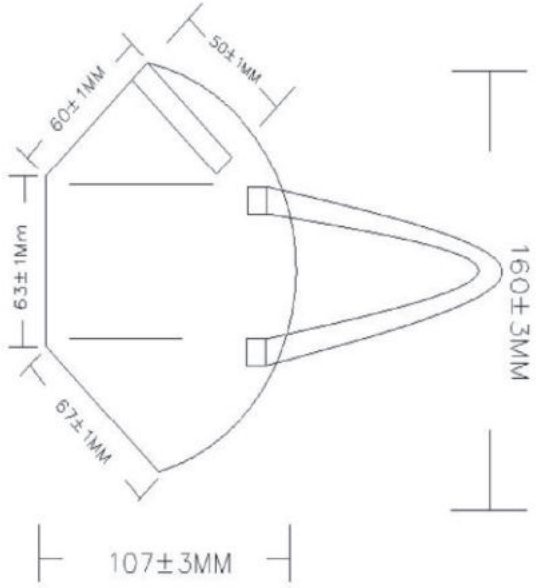
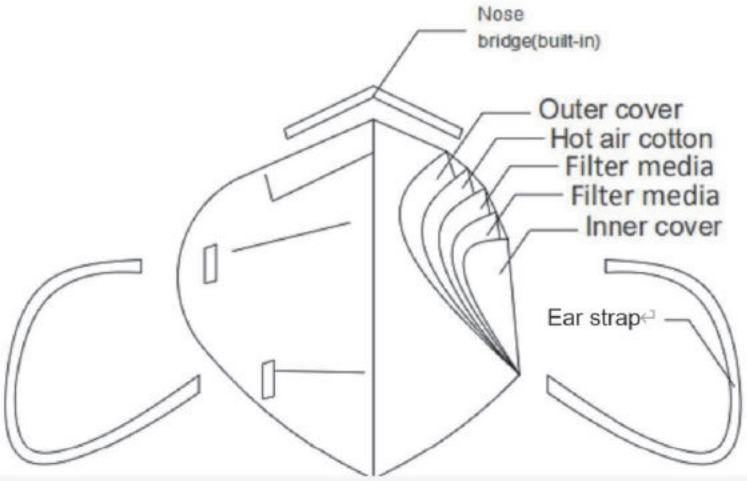


Manufacture	ANHUI HANXIUTANG BIOTECHNOLOGY CO.,LTD
Drawing name	HXT-A02
Figure number	20200302
Design	Tony Chen
Date	2020-03-02
Audit	Jerry Li
Date	2020-03-02



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Product Introduction

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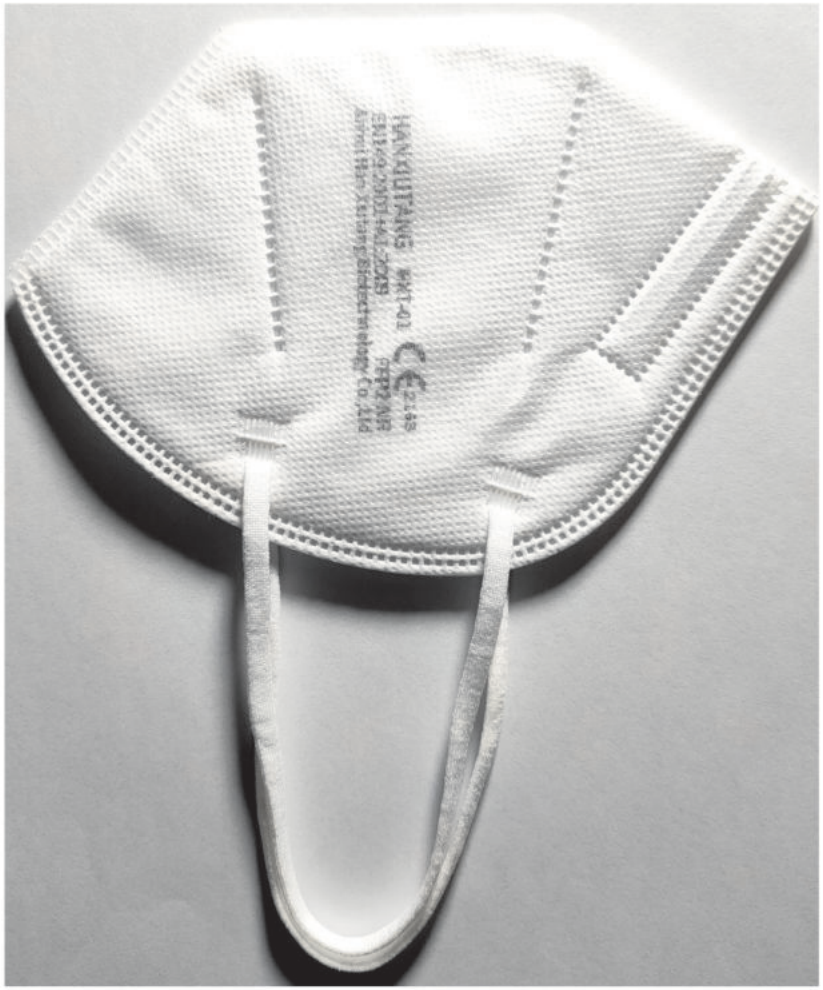
1 Open the mask.
2 The pro-muscle non woven side face the skin, and the nose band is above. Hang the straps on both ears and adjust to make the ears evenly stressed.
3 adjust the mask to cover the nose and mouth completely. Use both hands to adjust the nose band to fit the nose.
4 Smooth the mask on sides to sure the mask is properly fitted the face.

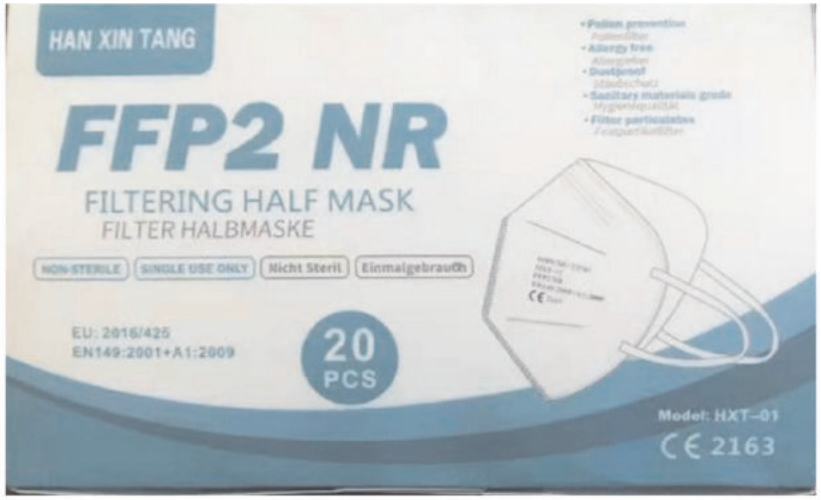
Product Display

HANXIUTANG



Product Display

HANXIUTANG



PACKAGING

HANXIUTANG

Products Name	Filtering half mask		Brand Name	HAN XIU TANG
Protection level	Q' ty	Q' ty/Ctn	Carton size	Weight
FFP2	20pcs	1000pcs	470*370*580mm	7kg

Factory Photos

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Factory Photos

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Factory Photos

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Factory Photos

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