

# Alleiniger Maskenlieferant für Unilever



Unilever

## Commercial Terms Contract ("CTC") Product and Price Details – 3PM Version 2.0

Between:

Unilever Asia Private Limited, a company existing under the laws of Singapore and having its registered office at 20 Pasir Panjang Road #06-22 Mapletree Business City

Feng Chun Yuan Medical Equipment (Shenzhen) Co., Ltd a company registered in China at Room. 1304, technology innovation park, shajing dahong(xinqiao), Baoan district, Shenzhen

It is agreed that:

### 1. This CTC

- 1.1. This CTC may be used for purchases of Products by the above identified Unilever company and any of its affiliates ("Buyer") from the above identified supplier company and any of its affiliates (the "Supplier").
- 1.2. The terms of the Unilever Purchasing Agreement (UPA), as identified below, apply and are incorporated into this CTC by this reference. Terminology used in this CTC but not defined below will have the meaning set out in the UPA.

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Unilever

## Unilever Purchasing Agreement ("UPA") Third Party Manufacturing Version 2.0

As commenced and in effect as of Mar 1, 2019.

Between:

Unilever Asia Private Limited, a company existing under the laws of Singapore and having its registered office at 20 Pasir Panjang Road #06-22 Mapletree Business City

Feng Chun Yuan Medical Equipment(Shenzhen) Co.,Ltd, a company existing under the laws of China at Room. 1304, technology innovation park, shajing dahong(xinqiao), Baoan district, Shenzhen.

Background:

- A. The above identified Unilever Group company is a member of the Unilever Group ("Unilever" or "us" or "we").
- B. To support more efficient purchasing, this UPA will apply world-wide to any purchase by any member of the Unilever Group from the Supplier identified above or any of its affiliates ("Supplier" or "you").

It is agreed that:

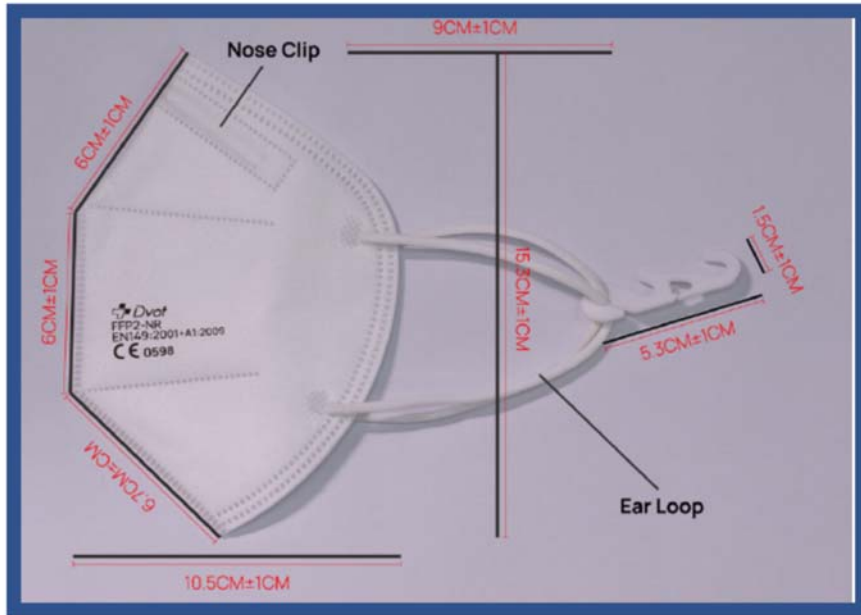


### 1. Documents comprising this contract

- 1.1. This UPA is an 'umbrella' set of terms and conditions for purchases by Unilever or its affiliates. It forms part of a set of contracting documents, as explained below.

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# FFP2 Mask Outlook



Single Pack in German



20 Packs / Inner box



48 Boxes / Carton



## QA Certificate

Certificate of conformity 合格证	
Product name 品名	PARTICLE FILTERING HALF MASK (FFP2 NR) 一次性防护口罩(FFP2 NR)
Executive standard 产品执行标准	EN 149:2001+AC:2009
Main Materials 主要原材料	45%Non-woven Fabric+25%Thermal Air Non-woven Fabric+30%Melt Blown Cloth 45%无纺布+25%热风棉+30%熔喷布
Quantity 数量	20PCS
Inspector 检验员	99
batch production 生产批号	11210101
Date of production 生产日期	2021/01/05
period of validity 有效期	2024/01/04
Production Enterprise 生产企业	Feng Chun Yuan Medical Equipment(Shenzhen)Co.,Ltd 峰春源医疗器械(深圳)有限公司
Production Address 生产地址	Room 15A, 15th floor, modern park, shajing street, shenzhen 深圳市宝安区新桥街道新玉路48号1304
Contact number 联系电话	+86 (755) 27900876

# Feng Chun Yuan Medical Equipment (ShenZhen) Co., Ltd

Room. 1304, Technology Innovation Park,  
Shajing Dahong(xinqiao),  
Baoan District,  
Shenzhen, China.

It is certified that the manufacturer's technical file and the PPE product detailed on  
page 2 have been assessed and found to be in accordance with

## Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 27 November 2020 until 27 November 2025  
1. Certified since 27 November 2020

Authorised by

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

SGS FIMKO OY, Notified Body 0598

Takomotie 8, FI-00380, Helsinki, Finland  
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Page 1 of 2



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extent of the law.



# Feng Chun Yuan Medical Equipment (ShenZhen) Co., Ltd

## Regulation (EU) 2016/425 Module B, EU type-examination

Issue 1

PPE Product

DVOT (logo) FCY-001A particle filtering half mask, consisting of a white five layer (polypropylene/ polypropylene/ polypropylene / polyester&polyethylene / polypropylene) disposable face mask, with nose clip, polyester /polyurethane ear loop and buckle.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment.

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

FCY-001A, dated: 2020/11/16.

SGS Reference Number UK/CRS 242634.

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request.

Certificate CN20/42627

The management system of

# Feng Chun Yuan Medical Equipment (ShenZhen) Co., Ltd

Room. 1304, Technology Innovation Park,  
Shajing Dahong(xinqiao),  
Baoan District,  
Shenzhen, China.

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2016/425 Module C2

For the following activities

**Manufacture of DVOT (logo) FCY-001A particle filtering half mask.  
(Note: All products marked CE0598 must have a valid EU type-  
examination certificate issued under Module B or a valid EC type-  
examination certificate issued under Article 10 of Directive  
89/686/EEC.)**

This certificate is valid from 6 December 2020  
and remains valid subject to satisfactory surveillance audits.  
Issue 1. Certified since 6 December 2020

Authorised by



SGS FIMKO OY, Notified Body 0598

Takomotie 8, FI-00380 Helsinki, Finland  
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**FINAS**  
Finnish Accreditation Service  
S003 (EN ISO/IEC 17065)

Page 1 of 1





**Test Report**                      **SL52045300997801TX**                      **Date: November 10, 2020**                      **Page 1 of 10**  
 FENG CHUN YUAN MEDICAL EQUIPMENT(SHENZHEN)CO.,LTD  
 ROOM.1304, TECHNOLOGY INNOVATION PARK, SHAJING DAHONG(XINQIAO), BAOAN DISTRICT,  
 SHENZHEN, CHINA

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

Sample Description                      :    (A)Particle Filtering Half Mask

Sample Color                            :    (A)WHITE

Style No.                                 :    FCY-001A

Manufacturer                            :    FENG CHUN YUAN MEDICAL EQUIPMENT(SHENZHEN)CO.,LTD

Country of Destination                :    EUR

Test Performed                         :    Selected test(s) as requested by applicant

Sample Receiving Date                :    Oct 23, 2020

Testing Period                          :    Oct 23, 2020 - Nov 10, 2020

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).

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)

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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 imperfections	Pass



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**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
<p>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</p> <p>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</p>	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.	3.62	3.78	4.20	5.34	3.59	4.11
Luo	2	A.R.	4.19	6.08	5.97	4.49	4.73	5.09
Lu	3	A.R.	5.60	3.69	4.68	3.15	3.84	4.19
Wang	4	A.R.	3.15	3.89	3.80	2.30	2.54	3.14
Bao	5	A.R.	3.55	4.22	6.06	5.27	6.03	5.03
Ding	6	T.C.	2.78	4.35	4.16	3.12	3.83	3.65
Li	7	T.C.	5.09	5.32	5.17	5.56	5.27	5.28
Chen	8	T.C.	2.34	4.41	2.93	3.96	4.50	3.63
Song	9	T.C.	3.94	4.41	3.70	4.88	6.02	4.59
Ye	10	T.C.	6.17	5.32	3.72	5.83	5.06	5.22

**Facial Dimension(mm)**

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

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Ding	134	150	110	52
Liu	120	135	117	50
Ye	126	137	105	52

**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
Classification	Maximum penetration of test aerosol			
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min		
	% max.	% 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	As received	1	0.341
		2	0.345
		3	0.356
	Simulated wearing treatment	4	0.347
		5	0.385
		6	0.366
	Mechanical strength +Temperature conditioned	7	0.687
		8	0.653
		9	0.675
Paraffin oil test	As received	10	0.444
		11	0.416
		12	0.452
	Simulated wearing treatment	13	0.475
		14	0.453
		15	0.463
	Mechanical strength +Temperature conditioned	16	1.657
		17	1.093
		18	1.583

Flow conditioning: Single filter: 95.0 L/min



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**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)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature 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.	Detail refer to Appendix 3	Pass

**Appendix 3: Summarization of Test Data**

Flammability

Condition	Sample No.	Result
As received	1	NIL
	2	NIL
Temperature conditioned	3	NIL
	4	NIL

**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	0.4826
	2	0.4840
	3	0.4782
		Mean value: 0.48

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**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	

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**Clause 7.16 Breathing Resistance**

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

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 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**

Breathing resistance (mbar)

	Flow rate(l/min)	1					2					3					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
As received	Inhalation	30	0.5	0.4	0.4	0.4	0.5	0.5	0.4	0.5	0.5	0.4	0.5	0.5	0.5	0.4	0.5
		95	1.6	1.6	1.5	1.6	1.6	1.6	1.6	1.5	1.5	1.6	1.5	1.6	1.6	1.6	1.5
	Exhalation	160	2.3	2.4	2.4	2.5	2.3	2.3	2.5	2.5	2.5	2.3	2.4	2.3	2.4	2.4	2.4
Simulated wearing treatment	Inhalation	30	0.4	0.5	0.4	0.5	0.5	0.4	0.5	0.4	0.4	0.4	0.5	0.5	0.4	0.5	0.5
		95	1.5	1.6	1.6	1.6	1.5	1.6	1.6	1.6	1.5	1.5	1.6	1.5	1.5	1.6	1.6
	Exhalation	160	2.3	2.3	2.4	2.4	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.3	2.4	2.4	2.4
Temperature conditioned	Inhalation	30	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.4	0.5	0.4	0.4	0.4	0.4	0.4	0.5
		95	1.6	1.5	1.5	1.5	1.6	1.5	1.5	1.6	1.6	1.5	1.5	1.5	1.5	1.5	1.5
	Exhalation	160	2.4	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.3	2.3	2.3	2.3	2.4	2.3	2.3

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



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 Testing Center Technical Services (Shanghai) Co., Ltd. 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](mailto:sgs.china@sgs.com)

**Clause 7.17 Clogging**

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

Test Requirement	Results	Comment																			
<p><u>Clause 7.17.2 Breathing resistance</u>  <u>Valved particle filtering half masks:</u>                      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.</p> <p><u>Valveless particle filtering half masks:</u>                      After clogging the inhalation and exhalation resistances shall not exceed:                      FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow</p>	Optional for single shift device only	N.A.																			
<p><u>Clause 7.17.3 Penetration of filter material</u>                      All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.</p> <table border="1"> <thead> <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>%</th> <th>%</th> </tr> </thead> <tbody> <tr> <td></td> <td>max.</td> <td>max.</td> </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> </tbody> </table>	Classification	Maximum penetration of test aerosol		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min	%	%		max.	max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	Optional for single shift device only	N.A.
Classification		Maximum penetration of test aerosol																			
		Sodium chloride test 95 l/min	Paraffin oil test 95 l/min																		
	%	%																			
	max.	max.																			
FFP1	20	20																			
FFP2	6	6																			
FFP3	1	1																			

**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	Comply	Pass

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%

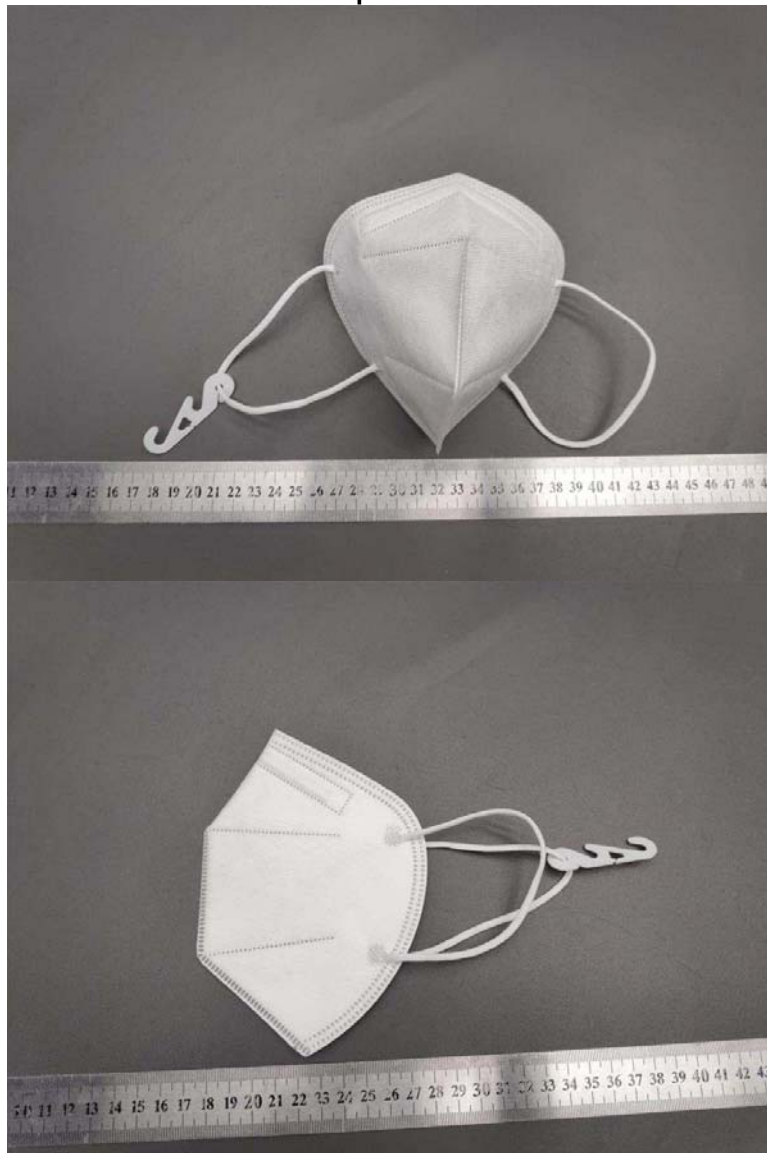


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### Sample Photo



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**Test Report No.:** 244313034a 001  
**Client:** FENG CHUN YUAN MEDICAL EQUIPMENT (SHENZHEN)CO., LTD  
**Contact Information:** ROOM. 1304, TECHNOLOGY INNOVATION PARK, SHAJING DAHONG (XINQIAO), BAOAN DISTRICT, SHENZHEN, CHINA  
 Contact Person: Qiyuan Ning

**Sample Description As Declared:**

No. Of Sample : 30 pcs  
 Product Description : Particle Filtering Half Mask  
 Product Type : Single shift use only  
 Material : Non-woven Fabric & Melt-blown& Thermal Air Non-woven Fabric  
 Colour : White  
 Lot No./Batch Code : 11210103  
 Buyer Name : -  
 Trademark : -  
 Type-identifying : FCY-001A  
 Claimed Classification : FFP2 NR  
 Manufacturer : FENG CHUN YUAN MEDICAL EQUIPMENT(SHENZHEN) CO., LTD/Qiyuan Ning/ROOM 1304, TECHNOLOGY INNOVATION PARK, SHAJING DAHONG(XINQIAO),BAOAN DISTRICT, SHENZHEN, CHINA  
 Country of Origin : China  
 Sales Destination (Country) : -  
 Test Type : Partial Test  
 Test Specification : EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing and Marking  
 Other Information : -

**Sample Obtaining Method:** Sending by customer  
**Delivery Condition:** Apparent good, samples tested as received  
**Sample Receiving date:** 2021-02-08  
**Testing Period:** 2021-02-08 to 2021-03-03  
**Place of Testing:** Textiles laboratory Shanghai

For and on behalf of  
 TÜV Rheinland (Shanghai) Co., Ltd.



2021-03-03 Carmen Yan / Department 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.  
 "Decision Rule" document announced in our website (<https://www.tuv.com/landingpage/en/qm-gcn/>) describes the statement of conformity and its rule of enforcement for test results are applicable throughout this test report.*

**Test Report No.: 244313034a 001**

Page 2 of 4

**Summary of Test Results:**

Clause	Item	Conclusion
7.3	Visual Inspection	N/R
7.4	Package	N/R
7.5	Material	N/R
7.6	Cleaning And Disinfection	N/R
7.7	Practical Performance	N/R
7.8	Finish Of Parts	N/R
7.9.1	Leakage	N/R
7.9.2	Penetration Of Filter Material	P
7.10	Compatibility With Skin	N/R
7.11	Flammability	N/R
7.12	Carbon Dioxide Content Of The Inhalation Air	N/R
7.13	Head Harness	N/R
7.14	Field Of Vision	N/R
7.15	Exhalation Valve(s)	N/R
7.16	Breathing Resistance	N/R
7.17	Clogging	N/R
7.18	Demountable Parts	N/R
9	Marking	N/R
10	Information To Be Supplied By The Manufacturer	N/R

Note: P = Pass F = Fail  
 # = No Comment - = Did Not Perform  
 NR = No Requirement N/A = Not Applicable

**Material List:**

Material No.	Material	Color	Location
M001	Whole Product	White	Particle Filtering Half Mask



**Test Report No.: 244313034a 001**

Page 3 of 4

**Clause 7.9.2: Penetration Of Filter Material**

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

Requirement : FFP2: ≤6%

M001			
Aerosol	Condition	Specimen No.	Penetration (%)
Sodium chloride Penetration	As received	1	0.236
	As received	2	0.234
	As received	3	0.240
	Simulated wearing treatment	4	0.253
	Simulated wearing treatment	5	0.229
	Simulated wearing treatment	6	0.214
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	7	0.167
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	8	0.184
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	9	0.189
Paraffin oil Penetration	As received	10	0.054
	As received	11	0.009
	As received	12	0.014
	Simulated wearing treatment	13	0.013
	Simulated wearing treatment	14	0.012
	Simulated wearing treatment	15	0.016
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	16	0.034
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	17	0.018
	Mechanical strength + Temperature conditioned @ Exposure test of 120mg	18	0.019
Conclusion	Pass		

Test Report No.: 244313034a 001

Page 4 of 4

Photo(s):



- 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 ("GTCS") 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, this GTCS 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 terms 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. If the client instructs TÜV Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland is, in its sole discretion, entitled to accept the order by giving written notice of such acceptance (including notice sent via electronic means) or by performing the requested services.

3.2 The contract term starts upon the coming into effect of the contract in accordance with article 3.1 and shall continue for the term agreed in the contract.

3.3 If the contract provides for an extension of the contract term, the contract term will be extended by the term provided for in the contract unless terminated in writing by either party with a six-week notice prior to the end of the contractual term.

## 4. Scope of services

4.1 The scope and type of the services to be provided by TÜV Rheinland shall be specified in the contractually agreed service scope of TÜV Rheinland by both parties, if no such separate service scope of TÜV Rheinland exists, then the written confirmation of order by TÜV Rheinland shall be decisive for the service to be provided.

4.2 The agreed services shall be performed in compliance with the regulations in force at the time the contract is entered into.

4.3 TÜV Rheinland is entitled to determine, in its sole discretion, the method and nature of the assessment unless otherwise agreed in writing or if mandatory provisions require a specific procedure to be followed.

4.4 On execution of the work there shall be no simultaneous assumption of any guarantee of the correctness (proper quality) and working order of either tested or examined parts nor of the installation as a whole and its upstream and/or downstream processes, organisations, use and application in accordance with regulations, nor of the systems on which the installation is based. In particular, TÜV Rheinland shall assume no responsibility for the construction, selection of materials and assembly of installations examined, nor for their use and application in accordance with regulations, unless these questions are expressly covered by the contract.

4.5 In the case of inspection work, TÜV Rheinland shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, unless otherwise expressly agreed in writing.

4.6 If mandatory legal regulations and standards or official requirements for the agreed service scope change after conclusion of the contract, with a written notice to the client, TÜV Rheinland shall be entitled to additional remuneration for resulting additional expenses.

4.7 The services to be provided by TÜV Rheinland under the contract are agreed exclusively with the client. A contract of third parties with the services of TÜV Rheinland, as well as making available of and justifying confidence in the work results (test reports, test results, expert reports, etc.) is not part of the agreed services. This also applies if the client passes on work results - in full or in extracts - to third parties in accordance with clause 11.4.

## 5. Performance periods/dates

5.1 The contractually agreed periods/dates of performance are based on estimates of the work involved which are prepared in line with the details provided by the client. They shall only be binding if being confirmed as binding by TÜV Rheinland in writing.

5.2 If binding periods of performance have been agreed, these periods shall not commence until the client has submitted all required documents to TÜV Rheinland.

5.3 Articles 5.1 and 5.2 also apply, even without express approval by the client, to all extensions of agreed periods/dates of performance not caused by TÜV Rheinland.

5.4 TÜV Rheinland is not responsible for a delay in performance, in particular if the client has not fulfilled his duties to cooperate in accordance with clause 6.1 or has not done so in time and, in particular, has not provided TÜV Rheinland with all documents and information required for the performance of the service as specified in the contract.

5.5 If the performance of TÜV Rheinland is delayed due to unforeseeable circumstances such as force majeure, strikes, business disruptions, governmental regulations, transport obstacles, etc., TÜV Rheinland is entitled to postpone performance for a reasonable period of time which corresponds at least to the duration of the hindrance plus any time period which may be required to resume performance.

## 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:

- it has required statutory qualifications;
- the product, service or management system to be certified complies with applicable laws and regulations; and
- 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 If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs actually incurred. If no price is agreed in writing, invoicing shall be made in accordance with the price list of TÜV Rheinland valid at the time of performance.

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

7.3 If the execution of an order extends over more than one month and the value of the contract or the agreed fixed price exceeds €2,500.00 or equivalent value in local currency, TÜV Rheinland may demand payments on account or in instalments.

## 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 In cases of default of payment, TÜV Rheinland shall be entitled to claim default interest at the applicable short term loan interest rate publicly announced by a reputable commercial bank in the country where TÜV Rheinland is located. At the same time, TÜV Rheinland reserves the right to claim further damages.

8.4 Should the client default in payment of the invoice despite being granted a reasonable grace period, TÜV Rheinland shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and refuse to continue performance of the contract.

8.5 The provisions set forth in article 8.4 shall also apply in cases involving returned cheques, cessation of payment, commencement of insolvency proceedings against the client's assets or cases in which the commencement of insolvency proceedings has been dismissed due to lack of assets.

8.6 Objections to the invoices of TÜV Rheinland shall be submitted in writing within two weeks of receipt of the invoice.

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

8.8 TÜV Rheinland shall be entitled to raise its fees at the beginning of a month if overheads and/or purchase costs have increased. In this case, TÜV Rheinland shall notify the client in writing of the rise in fees. This notification shall be issued one month prior to the date on which the rise in fees shall come into effect (period of notice of changes in fees). If the rise in fees remains under 5% per contractual year, the client shall not have the right to terminate the contract. If the rise in fees exceeds 5% per contractual year, the client shall be entitled to terminate the contract by the end of the period of notice of changes in fees. If the contract is not terminated, the changed fees shall be deemed to have been agreed upon by the time of the expiry of the notice period.

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

## 9. Acceptance of work

9.1 Any part of the work result ordered which is complete in itself may be presented by TÜV Rheinland for acceptance as an instalment. The client shall be obliged to accept it immediately.

9.2 If acceptance is required or contractually agreed in an individual case, this shall be deemed to have taken place two (2) weeks after completion and handover of the work, unless the client refuses acceptance within this period stating at least one fundamental breach of contract by TÜV Rheinland.

9.3 The client is not entitled to refuse acceptance due to insignificant breach of contract by TÜV Rheinland.

9.4 If acceptance is excluded according to the nature of the work performance of TÜV Rheinland, the completion of the work shall take its place.

9.5 If the client was unable to make use of the time windows provided for within the scope of a certification procedure for auditing/performance by TÜV Rheinland and the certificate is therefore to be withdrawn (e.g. performance of surveillance audits), TÜV Rheinland is entitled to immediately charge a lump-sum compensation of 10% of the order amount as compensation for expenses. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above lump sum.

9.6 Insofar as the client has undertaken in the contract to accept services, TÜV Rheinland shall also be entitled to charge lump-sum damages in the amount of 10% of the order amount as compensation for expenses if the service is not called within one year after the order has been placed. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above mentioned lump sum.

## 10. Confidentiality

10.1 For the purpose of these terms and conditions, "confidential information" means all information, documents, images, drawings, know-how, data, samples and project documentation which one party (the "disclosing party") hands over, transfers or otherwise discloses to the other party (the "receiving party"), and the confidential information created during performance of work by TÜV Rheinland, including product testing data, defects, comments on the technical standard and related reports. Confidential information also includes paper copies and electronic copies of such information. Confidential information is expressly not the data and know-how collected, compiled or otherwise obtained by TÜV Rheinland (non-personal) within the scope of the provision of services by TÜV Rheinland. TÜV Rheinland is entitled to store, use, further develop and pass on the data obtained in connection with the provision of services for the purposes of developing new services, improving services and analysing the provision of services.

10.2 The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it onto the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be appropriately informed in advance that confidential information is being disclosed and the confidentiality nature of the information within five working days of oral disclosure. Where the disclosing party fails to do so within the stipulated period, the receiving party shall not take any confidentiality obligations hereunder towards such information.

10.3 All confidential information which the disclosing party transmits or otherwise discloses to the receiving party and which is created during performance of work by TÜV Rheinland:

- may only be used by the receiving party for the purposes of performing the contract, unless expressly otherwise agreed in writing by the disclosing party;
- may not be copied, distributed, published or otherwise disclosed by the receiving party, unless this is necessary for fulfilling the purpose of the contract or TÜV Rheinland is required to pass on confidential information, inspection reports or documentation to the government authorities, judicial court, accreditation bodies or third parties that are involved in the performance of the contract;
- must be treated by the receiving party with the same level of confidentiality as the receiving party uses to protect its own confidential information, but never with a lesser level of confidentiality than that which is reasonably required.

10.4 The receiving party may disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform the services required for the contract. The receiving party undertakes to oblige these employees to observe the same level of secrecy as set forth in this confidentiality clause.

10.5 Information for which the receiving party can furnish proof that:

- is/was generally known at the time of disclosure or has become general knowledge without contribution to this confidentiality clause by the receiving party; or
- is/was disclosed to the receiving party by a third party entitled to disclose this information; or
- the receiving party already possessed this information prior to disclosure by the disclosing party;

10.6 If the receiving party developed it itself, irrespective of disclosure by the disclosing party, shall not be deemed to constitute "confidential information" as defined in this confidentiality clause.

10.6 All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or (ii) on request by the disclosing party, to destroy all confidential information, including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at any time if so requested by the disclosing party but at the latest and without special request after termination or expiry of the contract. This does not extend to including reports and certificates prepared for the client solely for the purpose of fulfilling the obligations under the contract, which shall remain with the client. However, TÜV Rheinland is entitled to make paper copies of such reports, certificates and confidential information that forms the basis for preparing these reports and certificates in order to evidence the correctness of its results and for general documentation purposes required by laws, regulations and the requirements of working procedures of TÜV Rheinland.

10.7 From the start of the contract and for a period of three years after termination or expiry of the contract, the receiving party shall maintain strict secrecy of all confidential information and shall not disclose this information to any third parties or use it for itself.

## 11. Copyrights and rights of use, publications

11.1 TÜV Rheinland shall retain all exclusive copyrights in the reports, expert reports/opinions, test reports/results, calculations, presentations etc. prepared by TÜV Rheinland, unless otherwise agreed by the parties in a separate agreement. As the owner of the copyrights, TÜV Rheinland is free to grant others the right to use the work results for individual or all types of use ("right of use").

11.2 The client receives a simple, unlimited, non-transferable, non-sublicensable right to use to the contents of the work results produced within the scope of the contract, unless otherwise agreed by the parties in a separate agreement. The client may only use such reports, expert reports/opinions, test reports/results, results calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose.

11.3 The transfer of right of use of the generated work results regulated in clause 11.2. of the GTCS is subject to full payment of the remuneration agreed in favour of TÜV Rheinland.

11.4 The client may use work results only complete and unshortened. The client may only pass on the work results in full unless TÜV Rheinland has given its prior written consent to the partial passing on of work results.

11.5 Any publication or duplication of the work results for advertising purposes or any further use of the work results beyond the scope regulated in clause 11.2 needs the prior written approval of TÜV Rheinland in each individual case.

11.6 TÜV Rheinland may revoke a once given approval according to clause 11.5 at any time without stating reasons. In this case, the client is obliged to stop the transfer of the work results immediately at his own expense and, as far as possible, to withdraw publications.

11.7 The consent of TÜV Rheinland to publication or duplication of the work results does not entitle the client to use the corporate logo, corporate design or test/certification mark of TÜV Rheinland.

## 12. Liability of TÜV Rheinland

12.1 Irrespective of the legal basis, to the fullest extent permitted by applicable law, in the event of a breach of contractual obligations or tort, the liability of TÜV Rheinland for all damages, losses and reimbursement of expenses caused by TÜV Rheinland, its legal representatives and/or employees shall be limited to: (i) in the case of a contract with a fixed overall fee, three times the overall fee for the entire contract; (ii) in the case of a contract for annually recurring services, the agreed annual fee; (iii) in the case of a contract expressly charged on a time and material basis, a maximum of 20,000 Euro or equivalent amount in local currency; and (iv) in the case of a framework agreement that provides for the possibility of placing individual

orders, three times of the fee for the individual order under which the damages or losses have occurred. Notwithstanding the above, in the event that the total and accumulated liability calculated according to the foregoing provisions exceeds 2.5 Million Euro or equivalent amount in local currency, the total and accumulated liability of TÜV Rheinland shall be only limited to and shall not exceed the said 2.5 Million Euro or equivalent amount in local currency.

12.2 The limitation of liability according to article 12.1 above shall not apply to damages and/or losses caused by malice, intent or gross negligence on the part of TÜV Rheinland or its vicarious agents. Such limitation shall not apply to damages for a person's death, physical injury or illness.

12.3 In cases involving a fundamental breach of contract, TÜV Rheinland will be liable even where minor negligence is involved. For this purpose, a "fundamental breach" is breach of a material contractual obligation, the performance of which permits the due performance of the contract. Any claim for damages for a fundamental breach of contract shall be limited to the amount of damages reasonably foreseen as a possible consequence of such breach of contract at the time of the breach (reasonably foreseeable damages), unless any of the circumstances described in article 12.2 applies.

12.4 TÜV Rheinland shall not be liable for the acts of the personnel made available by the client to support TÜV Rheinland in the performance of its services under the contract, unless such personnel made available is regarded as vicarious agent of TÜV Rheinland. If TÜV Rheinland is not liable for the acts of the personnel made available by the client under the foregoing provision, the client shall indemnify TÜV Rheinland against any claims made by third parties arising from or in connection with such personnel's acts.

12.5 Unless otherwise contractually agreed in writing, TÜV Rheinland shall only be liable under the contract to the client.

12.6 The limitation periods for claims for damages shall be based on statutory provisions.

12.7 None of the provisions of this article 12 changes the burden of proof to the disadvantage of the client.

## 13. Export control

13.1 When passing on the services provided by TÜV Rheinland or parts thereof to third parties in Greater China or other regions, the client must comply with the respectively applicable regulations of national and international export control law.

13.2 The performance of a contract with the client is subject to the proviso that there are no obstacles to performance due to national or international foreign trade legislations or embargos and/or sanctions. In the event of a violation, TÜV Rheinland shall be entitled to terminate the contract with immediate effect and the client shall compensate for the losses incurred thereof by TÜV Rheinland.

## 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 data controller 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@tdv.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 The risk and costs for freight and transport of documents or test material to and from TÜV Rheinland as well as the costs of necessary disposal measures shall be borne by the client.

15.2 Any destroyed and otherwise worthless test material will be disposed of by TÜV Rheinland for the client at the expense of the client, unless otherwise agreed.

15.3 Undamaged test material shall be stored by TÜV Rheinland for four (4) weeks after completion of the test. If a longer storage period is desired, TÜV Rheinland charges an appropriate storage fee.

15.4 After the expiry of the 4 weeks or any longer period agreed upon, the test material will be disposed of by TÜV Rheinland for the client for a fee in accordance with clause 15.2.

## 16. Termination of the contract

16.1 Notwithstanding clause 3.3 of the GTCS, TÜV Rheinland and the client are entitled to terminate the contract in its entirety or, in the case of services combined in one contract, each of the services of the contract individually and independently of the continuation of the remaining services with six (6) months' notice to the end of the contractually agreed term.

16.2 For good causes, TÜV Rheinland may consider giving a written notice to the client to terminate the contract which includes but not limited to the following:

- the client does not immediately notify TÜV Rheinland of changes in the conditions within the company which are relevant for certification or signs of such changes;
- the client misuses the certificate or certification mark or uses it in violation of the contract;
- in the event of several consecutive delays in payment (at least three times);
- a substantial deterioration of the financial circumstances of the client occurs and as a result the payment claims of TÜV Rheinland under the contract are considerably endangered and TÜV Rheinland cannot reasonably be expected to continue the contractual relationship.

16.3 In the event of termination with written notice by TÜV Rheinland for good cause, TÜV Rheinland shall be entitled to a lump-sum claim for damages against the client if the conditions of a claim for damages exist. In this case, the client shall pay 15% of the remuneration to be paid until the end of the fixed contract term as lump-sum compensation. The client reserves the right to prove that there is no damage or a considerably lower damage, TÜV Rheinland reserves the right to prove a considerably higher damage in individual cases.

16.4 TÜV Rheinland is also entitled to terminate the contract with written notice if the client has not been able to make use of the time windows for auditing /service provision provided by TÜV Rheinland within the scope of a certification procedure and the certificate therefore has to be withdrawn (for example during the performance of monitoring audits). Clause 16.3 applies accordingly.

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

17.1 All amendments and supplements must be in writing in order to be effective. This also applies to amendments and supplements to this clause 17.1.

17.2 Should one or several of the provisions under the contract and/or these terms and conditions be or become ineffective, the contracting parties shall replace the invalid provision with a legally valid provision that comes closest to the content of the invalid provision in legal and commercial terms.

17.3 Unless otherwise stipulated in the contract, the governing law of the contract and these terms and conditions shall be chosen following the rules as below:

a) If TÜV Rheinland in question is legally registered and existing in the People's Republic of China, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of the People's Republic of China.

b) If TÜV Rheinland in question is legally registered and existing in Taiwan, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Taiwan.

c) If TÜV Rheinland in question is legally registered and existing in Hong Kong, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Hong Kong.

17.4 Any dispute in connection with the contract and these terms and conditions or the execution thereof shall be settled friendly through negotiations.

Unless otherwise stipulated in the contract, if no settlement or no agreement in respect of the extension of the negotiation period can be reached within two months of the arising of the dispute, the dispute shall be submitted:

a) in the case of TÜV Rheinland in question being legally registered and existing in the People's Republic of China, to China International Economic and Trade Arbitration Commission (CIETAC) to be settled by arbitration under the Arbitration Rules of CIETAC in force when the arbitration is submitted. The arbitration shall take place in Beijing, Shanghai, Shenzhen or Chongqing as appropriately chosen by the claiming party.

b) in the case of TÜV Rheinland in question being legally registered and existing in Taiwan, to Chinese Arbitration Association Taipei Branch to be arbitrated in accordance with its then current Rules of Arbitration. The arbitration shall take place in Taipei.

c) in the case of TÜV Rheinland being legally registered and existing in Hong Kong, to Hong Kong International Arbitration Centre (HKIAC) to be settled by arbitration under the HKIAC Administered Arbitration Rules in force when the Notice of Arbitration is submitted in accordance with these rules. The arbitration shall take place in Hong Kong.

The decision of the relevant arbitration tribunal shall be final and binding on both parties. The arbitration fee shall be borne by the losing party.





# TEST REPORT

**Technical Report:** (6620)336-1189

December 7, 2020

Date Received: December 1, 2020

Page 1 of 12

Ning, Sue

**Feng Chun Yuan Medical Equipment (SHENZHEN) Co., Ltd**  
Room 1304, Technology Innovatin Park, Shajing Dahong(Xinqiao), Baoandistrict,  
Shanzhen,China

Sample Description: Sample(s) received is/are stated to be:  
Particle filtering half mask (FFP2-NR)

Color:	/	Style No(s):	FCY-001A
Order No.:	/	PO No.:	/
Model No.:	/	Batch No.:	/
Age Grade:	/	Product End Use:	/
Vendor:	/	Retest No.:	/
Manufacturer:	/	Supplier Reference:	/
Buyer:	/	Country of Origin:	/
Test Period:	December 1, 2020 to December 7, 2020	Country of Destination:	/
Fiber Content:	/		
Care Instruction:	/		

## SUMMARY OF TEST RESULTS

TEST REQUESTED	CONCLUSION	REMARK
Candidate List of Substances of Very High Concern for authorization published by European Chemicals Agency (ECHA) Regarding Regulation (EC) No. 1907/2006 concerning REACH	PASS	-

## REMARK

If there are questions or concerns on this report, please contact the following persons:

General enquiry

Mr. Fred Wu  
(021) 24081744  
fred-xh.wu@bureauveritas.com  
Ms. Molly Hu  
(021) 24081913  
molly.hu@bureauveritas.com

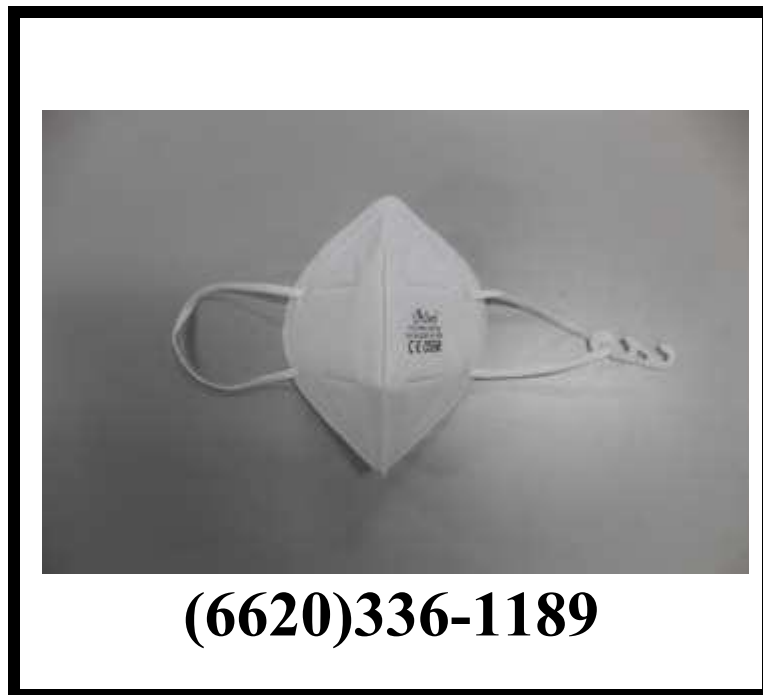
**BUREAU VERITAS**  
**CONSUMER PRODUCTS SERVICES DIVISION (SHANGHAI)**

PREPARED  
BY :

Mini

**Cherry Zhu**  
**Senior Technical Specialist**

**Photo of the Submitted Sample**



**SAMPLE DESCRIPTION ASSIGNED BY LABORATORY:**

<b>ITEM</b>	<b>ITEM DESCRIPTION</b>
S001	White mask
I001	White body with black printing
I002	white fiber
I003	white Melt-blown fabric
I004	white lining
I005	white ear rope
I006	White plastic(nose)
I007	white plastic buckle



Technical Report:

**(6620)336-1189**

December 7, 2020

Page 3 of 12

## TEST RESULT

### I.Candidate List of Substances of Very High Concern for authorization published by European Chemicals Agency (ECHA) Regarding Regulation (EC) No. 1907/2006 concerning REACH

Method: Analysis is based on GC, LC, IC, ICP and UV, with various detection techniques.

<b>Maximum Allowable Limit:</b>	<b>0.1% (Each of listed)</b>
---------------------------------	------------------------------

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001+I002+I003+I004+I005	87   Methoxy acetic acid	0.012	%	Pass

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I006+I007	ND	ND	%	PASS

Remark:

ND = Not detected

Conc. = Concentration

mg/kg = milligram per kilogram

% = percentage

1 mg/kg = 0.0001%

Detection Limit (%): See Appendix.

The detected SVHC and its value will be shown in above table, the else SVHC not shown in the table will be regarded as ND. When all SVHC for test are not detected, it will be shown ND.





# TEST REPORT

**Technical Report:** (6620)336-1169

December 4, 2020

Date Received: December 1, 2020

Page 1 of 5

Ning, Sue

**Feng Chun Yuan Medical Equipment (SHENZHEN) Co., Ltd**  
Room 1304, Technology Innovatin Park, Shajing Dahong(Xinqiao), Baoandistrict,  
Shanzhen,China

Sample Description:	Sample(s) received is/are stated to be:
	Particle filtering half mask (FFP2-NR)
Color: /	Style No(s): FCY-001A
Order No.: /	PO No.: /
Model No.: /	Batch No.: /
Age Grade: /	Product End Use: /
Vendor: /	Retest No.: /
Manufacturer: /	Supplier Reference: /
Buyer: /	Country of Origin: /
Test Period: December 1, 2020 to December 4, 2020	Country of Destination: /
Fiber Content: /	
Care Instruction: /	

## SUMMARY OF TEST RESULTS

TEST REQUESTED	CONCLUSION	REMARK
Formaldehyde Content	PASS	
Aromatic Amines Content from Azo Colorants	PASS	

## REMARK

If there are questions or concerns on this report, please contact the following persons:

General enquiry

Mr. Fred Wu  
(021) 24081744  
fred-xh.wu@bureauveritas.com  
Ms. Molly Hu  
(021) 24081913  
molly.hu@bureauveritas.com

**BUREAU VERITAS**  
**CONSUMER PRODUCTS SERVICES DIVISION (SHANGHAI)**

PREPARED  
BY :

Mini

Cherry Zhu  
Senior Technical Specialist



Technical Report:

**(6620)336-1169**

December 4, 2020

Page 2 of 5

**Photo of the Submitted Sample**



**SAMPLE DESCRIPTION ASSIGNED BY LABORATORY:**

<b>ITEM</b>	<b>ITEM DESCRIPTION</b>
S001	White mask
I001	White non-woven fabric (shell)
I002	White non-woven fabric (lining)
I003	White non-woven fabric (interlining)
I004	White melt-blown fabric (interlining)
I005	White rope







Technical Report:

(6620)336-1169

December 4, 2020

Page 4 of 5

## TEST RESULT

**Aromatic Amines Content from Azo Colorants - European Parliament and Council Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) with its Latest Amendment, Annex XVII, Entry 43, Points 1 and 2**

**Test Method I** : European Standard EN ISO 14362-1: 2017.

**Test Method II** : International Standard ISO 17234-1: 2015.

Test Item(s)	Result				Conclusion
	Test Method	Detected Analyte(s)	Conc.	Unit	
I001+I002+I003	I	ND	ND	mg/kg	PASS
I004+I005	I	ND	ND	mg/kg	PASS

Note / Key :

ND = Not detected

mg/kg = milligram(s) per kilogram = ppm = part(s) per million

% = percent

">" = Greater than

Conc. = Concentration

10 000 mg/kg = 1 %

Detection Limit ( mg/kg ) - Each of the listed aromatic amines : 5

Remark :

- The list of aromatic amines from azo colorants is summarized in table of Appendix.
- Quantitative and qualitative determinations of aromatic amines are carried out by gas chromatography with mass spectrometer (GC-MS) while qualitative confirmation is carried out by high performance liquid chromatography with diode array detector (HPLC-DAD).
- The colorant(s) of Test Item(s), that are able to form 4-aminoazobenzene, is (are) able to generate aniline and 1,4-phenylenediamine under the condition of Test Method I or II.

END