常美医疗
Changmei Medtech

Particle Filtering Half Mask

(EN149:2001+A1:2009 FFP2 NR)

Jiangsu ChangMei Medtech Co., Ltd.

1.5 ISO13485 certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 088875 0008 Rev. 01

Holder of Certificate: **Jiangsu Changmei Medtech Co., Ltd.**
No. 27, Xinke West Road, Luoyang
213104 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of Dilation Balloon Catheter, Kyphoplasty Balloon Catheter, Disposable Polypectomy Snare, Kyphoplasty Tool Kit, Balloon Inflator, Disposable Endoscopic Hose-type Biopsy Forceps, Disposable Endoscopic Cytology Brush, Endoscopic Foreign Body Forceps, 3-stage Dilation Balloon Catheter, Guide Wire other than Intravascular, Disposable Endoscopic Stone Retrieval Basket, Bougie Dilator Sets, Wireguided Balloon Dilatation Catheter and Disposable Stone Extraction Balloon**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1889305

Valid from: 2019-03-30
Valid until: 2021-01-07

Date, 2019-03-30

Stefan Preiß

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 088875 0008 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Jiangsu Changmei Medtech Co., Ltd.
No. 27, Xinke West Road, Luoyang, 213104 Changzhou, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

Parameters:

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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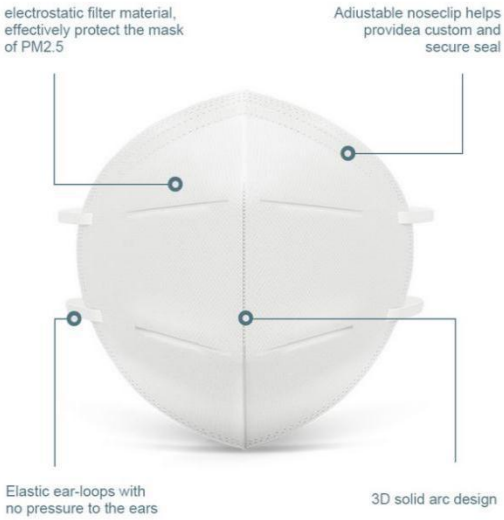
2. Product Introduction

2.1 Product structure

Particle filtering half mask consists of 4-layer non-woven fabrics, melt-blown fabrics,nose bridge and ear loop. The four layers are folded and composed by non-woven fabric and melt-blown.

Composition	Color	Raw material
Outer layer	White	Non-woven fabric
Filter layer: melt blown	White	Melt-blown non-woven fabric
Filter layer: melt blown	White	Melt-blown non-woven fabric
Inner layer	White	Non-woven fabric



2.2 Product size

2.2.1 Mask size 16.0cm*11.0cm

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200330-138-01-9B

Certificate holder:	**Jiangsu Changmei Medtech Co., Ltd.** No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China
Product:	**Particle Filtering Half Mask** Detailed product description listed in the Annex
Model(s):	DFM-01
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-05-01
Revision date:	2020-06-18
Expiry date:	2025-04-30

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE

Approved by Ireland Government
as a Notified Body
for CE Marking No.2834

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian - Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200330-138-FPC-B

Certificate holder:	**Jiangsu Changmei Medtech Co., Ltd.** No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China
The scope of the certification for:	**The manufacture of respiratory protective device** See annex for articles covered by this certificate
Validity from:	2020-05-01
To:	2021-04-30

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation.
The equipment covered by this certificate is listed in the accompanying schedule. This certificate is not complete and has no validity without the accompanying schedule and revision index.
The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE mentioned in the schedule which accompanies this certificate whilst this certificate remains valid.
This certificate and the accompanying schedule remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CE

Approved by Ireland Government
as a Notified Body
for CE Marking No.2834

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian - Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Schedule of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

Schedule to CCQS FPC Certificate No.: CE-PC-200330-138-FPC-B

Product reference and description		**Reference standard**
Particle Filtering Half Mask	Model: DFM-01	EN 149:2001+A1:2009

Certificate Revision.	Revision date	Revision details
A	2020-05-01	Initial issue
B	2020-06-18	Extension from 3 months to 1 year

This schedule has no validity without the accompanying certificate.
This schedule and the accompanying certificate remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie

Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200330-138-01-9B

Applicable standards and specification:

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

Model reference	Product description
DFM-01	Folding filtering half mask without valve fitted with ear loops with head harness clip, internal metal nose clip Classification: FFP2 NR Test Report No.: 2020 (D) - 0145T

Certificate Revision	Revision date	Revision details
A	2020-05-01	Initial issue
B	2020-06-18	Extension of expiry date to 5 years

CCQS Ireland Certification

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie

3.2 EU Declaration of Conformity

常美医疗 Changmei Medtech 江苏常美医疗器械有限公司
Jiangsu Changmei Medtech Co., Ltd.

EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

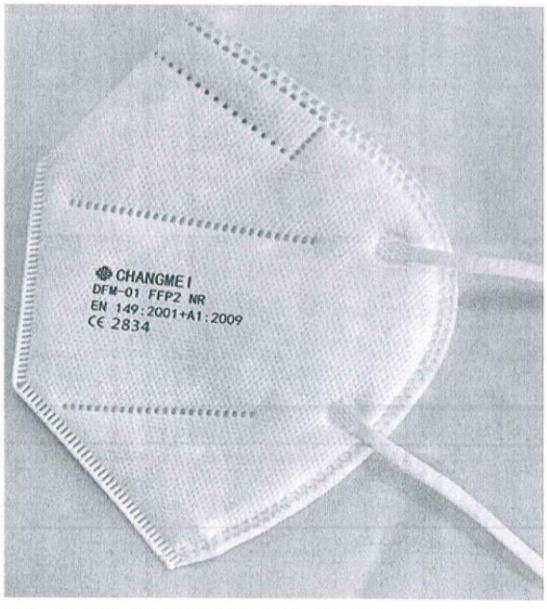
Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
Particle filtering half mask	DFM-01	FFP2 NR	

The Manufacturer 's name and address is as follows:

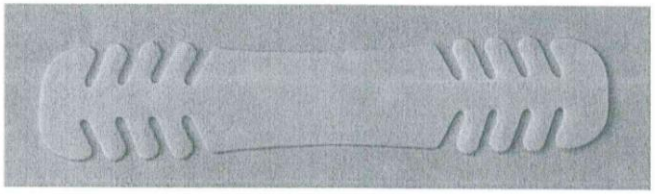
Name:	Jiangsu Changmei Medtech Co., Ltd.
Address:	No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China

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

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

DFM-01	White folder half mask without valve 1. The mask photo 

Jiangsu Changmei Medtech Co., Ltd.
No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China
Tel: +86 0519-88520118
Email sales@czmed.com

	2. The retaining clip photo 

The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

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

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

CCQS Certification Services Limited. (NB 2834) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number:

No.	EU Type Examination (Module B) Certificate Number
1	CE-PC-200330-138-01-9A

Product Category:

☐ This product is Category II.

☒ This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

☐ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

Signature: Date: 2020.05.01 Company stamp and/or legal signature:

Jiangsu Changmei Medtech Co., Ltd.
No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China
Tel: +86 0519-88520118
Email sales@czmed.com

3.3 Testing report for particle filtering half mask

National Quality Supervision and
Testing Center for Personal
Protective Equipment (Beijing)
No.55 Taoranting Street, Xicheng District,
Beijing, China.
Phone: +86 10 63519250 +86 10 6352077
+86 10 83530311
Fax: +86 10 63519250 +86 10 63520770

The Testing Center is accredited for compliance with ISO/IEC 17025.
The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.
CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT
Particulate respirator-half facepiece
EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Product:	**Particle filtering half mask**
Report No:	**2020 (D) - 0145**
Client:	**CCQS Certification Services Limited**
Model (s):	**DFM-01**
Date(s) of tests:	**2020.03.31-2020.04.15**

DESCRIPTION OF SAMPLES

General Information	**Classification**	**Main Components**
	FFP2 NR	White folding mask
Manufacturer	Jiangsu Changmei Medtech Co., Ltd.	
Manufacturer Address	No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China	

Signed: 陈倬为

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Issued: 2020.4.15

Conditions:

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

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

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

Test Results

7.3 Visual inspection **Not tested[1]**

The visual inspection shall include the marking and information supplied by the manufacturer.

Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.

7.4 Package **Pass[2]**

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.

Note2: In accordance with the requirement.

7.5 Material **Pass[3]**

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.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.6 Cleaning and disinfecting **N/A[4]**

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.

Note4: Single shift use only.

7.7 Practical performance **Pass[5]**

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

Note5: No imperfections.

7.8 Finish of parts **Pass[6]**

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

Note6: No sharp edges or burrs.

7.9.1 Total inward leakage **Pass[7]**

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than:
25% for FFP1, 11% for FFP2, 5% for FFP3

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than
22% for FFP1, 8% for FFP2, 2% for FFP3

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material **Pass[8]**

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

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%

FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.10 Compatibility with skin **Pass[9]**

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.

Note9: No irritation or any other adverse effect to health.

7.11 Flammability **Pass[10]**

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.

Note10: Test results are shown in Annex A Table 7.11.

7.12 Carbon dioxide content of the inhalation air **Pass[11]**

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

Note11: Test results are shown in Annex A Table 7.12.

7.13 Head harness **Pass[12]**

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

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision **Pass[13]**

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

Note13: Pass the practical performance tests.

7.15 Exhalation valve **N/A[14]**

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.

Note14: No exhalation valve.

7.16 Breathing resistance **Pass[15]**

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

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

7.17 Clogging **N/A[16]**

7.17.2 Breathing resistance

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

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

7.17.3 Penetration of filter material

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

Note16: Single shift use only.

7.18 Demountable parts **N/A[17]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand
Note17: No demountable parts.

9 Marking **Not tested**

9.1 Packaging

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

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.
9.1.2 Type-identifying marking.
9.1.3 Classification
The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.
9.1.4 The number and year of publication of this European Standard.
9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.
9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.
9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.
9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

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

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

9.2.2 Type-identifying marking.
9.2.3 The number and year of publication of this European Standard.
9.2.4 Classification
The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.
9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space
9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	7.19	7.25	7.34	7.27	7.13	7.2
Gong	2	A.R.	7.47	7.51	7.64	7.52	7.42	7.5
Yu	3	A.R.	7.34	7.48	7.53	7.44	7.31	7.4
Zhi	4	A.R.	7.21	7.32	7.46	7.21	7.17	7.3
Fang	5	A.R.	7.65	7.78	7.83	7.71	7.66	7.7
Hu	6	T.C.	7.56	7.62	7.71	7.68	7.52	7.6
Xu	7	T.C.	7.82	7.97	8.07	7.93	7.82	7.9
Deng	8	T.C.	8.74	8.85	8.93	8.81	8.87	8.8
Zhang	9	T.C.	7.31	7.47	7.53	7.43	7.38	7.4
Zhou	10	T.C.	8.43	8.53	8.67	8.52	8.47	8.5
50 out of the 50 individual exercise results ≤ 11 % 8 of the 10 individual arithmetic means ≤ 8 %						Pass		

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Zhou	110	121	110	53

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.298	Pass
		12	0.332	
		13	0.316	
	Simulated wearing treatment	14	0.326	
		15	0.431	
		16	0.345	
	Mechanical strength+ Temperature conditioned	17	0.432	
		18	0.416	
		19	0.391	
Paraffin oil test	As received	20	5.21	
		21	5.17	
		22	5.38	
	Simulated wearing treatment	23	5.73	
		24	5.45	
		25	5.66	
	Mechanical strength+ Temperature conditioned	26	5.72	
		27	5.86	
		28	5.75	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 2 s	Pass
	30	Burn for 2 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 2 s	

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result		Assessment
As received	33	0.41%	Mean value 0.4%	Pass
	34	0.40%		
	35	0.41%		

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149-2001 Clause 8.9

			36					37					38				
As received	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4
		95 l/min	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5
	Exhalation	160 l/min	1.3	1.4	1.3	1.3	1.3	1.3	1.4	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
			39					40					41				
Simulated wearing treatment	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4
		95 l/min	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5
	Exhalation	160 l/min	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
			42					43					44				
Temperature conditioned	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4
		95 l/min	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5
	Exhalation	160 l/min	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.3	1.3	1.3
			45					46					47				
Flow conditioned	Flow rate		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.4
		95 l/min	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Exhalation	160 l/min	1.3	1.4	1.3	1.3	1.3	1.3	1.4	1.3	1.3	1.3	1.3	1.4	1.3	1.3	1.3
Assessment	Pass																

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

End of Annex A

ANNEX B PHOTOS OF SAMPLES

End of Annex B

3.4 Instructions for use

Particle Filtering Half Mask

Model: DFM-01 FFP2 NR

Following standard: EN 149:2001+A1:2009

Following Regulation (EU)2016/425

CE 2834

Use Instruction

1. Failure to follow all instructions and limitations could seriously reduce the effectiveness of this particle filtering half mask and could lead to illness, injury or death.
2. A properly selected particle filtering half mask is essential, before occupational use, the wearer must be trained by the employer in the correct use of the particle filtering half mask in accordance with applicable safety and health standards.
3. This particle filtering half mask does not supply the oxygen. Use only in adequately ventilated is as containing sufficient oxygen to support life.
4. Discard the particle filtering half mask and replace with a new one if excessive clogging of the particle filtering half mask cause breathing difficulty or the particle filtering half mask becomes damaged.
5. Leave the contaminated area if dizziness, irritation or other distress occurs.

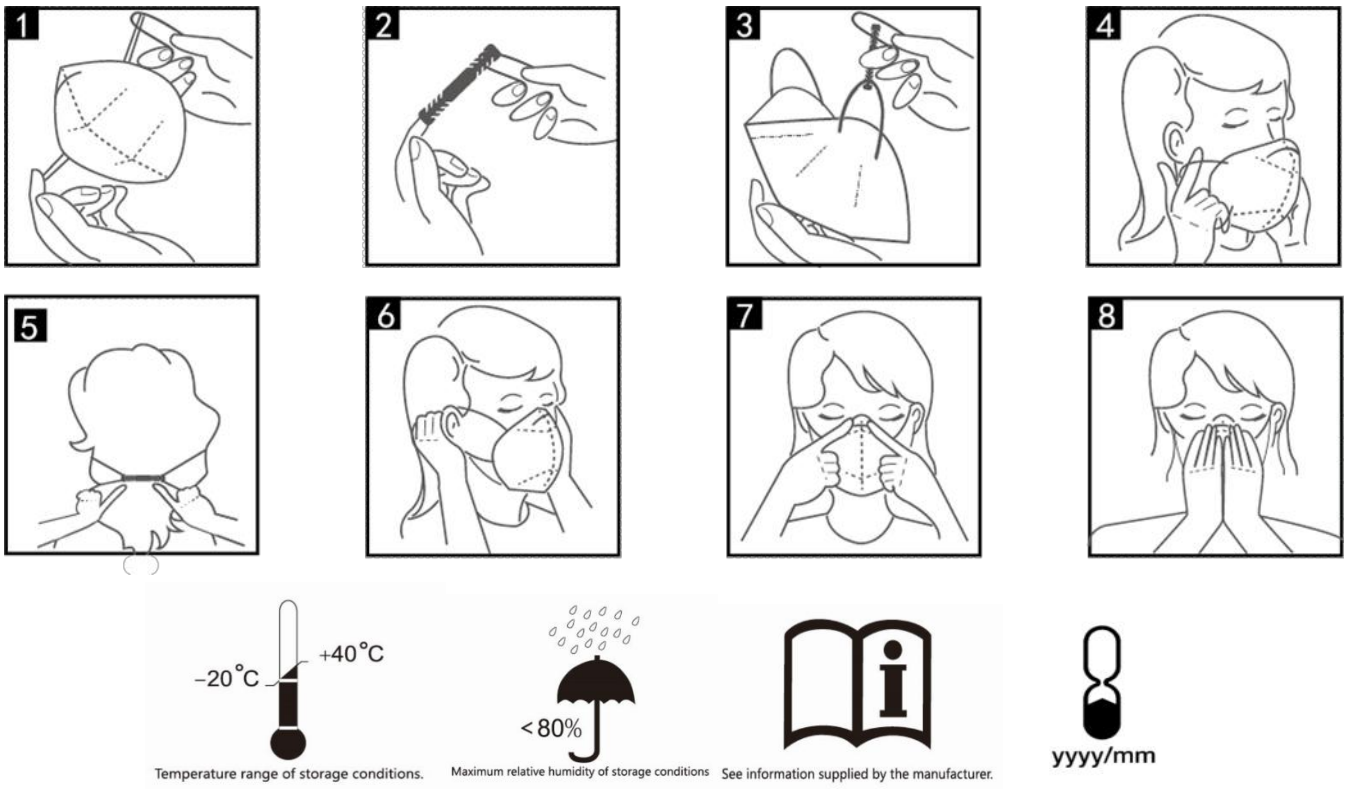
Use Limitation

1. Do not use the particle filtering half mask or enter or stay in a contaminated area under the following circumstance:
   a) Atmosphere contains less than 19.5% oxygen.
   b) If you smell or taste contaminant.
   c) For protection against gases or vapors.
   d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
   e) For sandblasting, paint-spray operations and asbestos.
   f) In underwater, fire and explosive atmospheres.
2. Do not modify or misuse the mask.
3. Do not use the particle filtering half mask with facial hair or any other conditions that may prevent a good face-seal, the requirements for leakage will be achieved.
4. Particle filtering half mask need to be inspected prior to each use to assure there are no holes in the breathing zone other than punctures around and staples and no damaged has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage.
5. This particle filtering half mask helps protect against certain particulate contaminants but does not eliminate exposure to the risk of contracting disease or infection. Misuse may result in sickness or death.
6. This particle filtering half mask marked “NR”, shall not be used for more than one shift.

Fitting Instruction

1. Open the particle filtering half mask, face to the inside of the mask, and hold the mask on each hand so that the nose clip is at the top.
2. Take out the retaining clip from the package and fasten one end of the retaining clip to one side of the mask.
3. Hold the particle filtering half mask in position over the nose and mouth, and fasten the other end of the retaining clip to the other side of the mask.
4. Adjust to a comfortable position and make the mask fit the face.
5. Bend the nose clip to make a tight seal around the nose.
6. Fit check
   a) To test the fit of the particle filtering half mask, cup both hands over the particle filtering half mask and inhale sharply. If air flow is felt in the nose area, re-adjust/tighten the nose clip.
   b) If flows is felt around the edges of the particle filtering half mask, re-position the mask harness to achieve a better fit.
7. Change the particle filtering half mask immediately if breathing becomes difficult or particle filtering half mask becomes damaged or distorted.
8. Change the particle filtering half mask if a proper face seal cannot be achieved.

9. Careful observances of these instructions is an important step in safe particle filtering half mask use.



Notified Body: CCQS Certification Services Limited
NB: 2834
Address: Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15, D15 AKK1, Ireland
Manufacturer: Jiangsu Changmei Medtech Co., Ltd.
Address: No.27, Xinke West Road, Luoyang, 213104 Changzhou City, Jiangsu Province, P. R. China

FFP2 NR

Inner package: 180*140mm, 5pcs in one bag.

2.2.2 Inner box size 225*135*120mm

2.2.3 Outer carton size 625*295*478mm

2.3 Product package

Item	Outer package	Inner box	N.W.	G.W.
Particle filtering half mask	400pcs/carton	20pcs/box	5.5kg	6.5kg