INFORMACIÓN TÉCNICA DE PRODUCTO

LUHEPA INTERNACIONAL, SL.
Member of Uhealth Medical Group

Ref. 3600B—Mascarilla FFP2 NR, Sin Válvula.

CE 2834

Modelo Fabricante: 0117 FFP2 NR

INFORMACIÓN TÉCNICA:

Mascarilla de Protección FFP2NR, fabricada con 4 capas de tela no tejida y tela filtrante fundida, Sin Válvula y Gomas de Ajuste.

1ª Capa	2ª Capa	3ª Capa	4ª Capa
Tela No Tejida 50 g	Spunlace 50 g	Melt-Blown 50 g	Tela No Tejida 50 g

- Tira nasal moldeable fabricada en acero y PP.
- Dos gomas de ajuste a ambos pabellones auditivos, con Clip Salva Orejas incluido en cada sobre unitario
- Mascarilla y Gomas Libre de Látex, Grafeno y Fibra de Vidrio, no produce irritaciones en la piel.
- Las Mascarillas Ref. 3600B responde a las exigencias de la norma **EN 149:2001+A1:2009**
- Número de Ensayo (Test Report): **WLH0201-2021.**
- Las Mascarillas Ref. 3600B son conformes al **Reglamento UE 2016/425** relativo a los equipos de protección personal.

Clasificación:	Categoría EPI:	Certificado CE Nº:
FFP2 NR	Cat. III	CE-PC-200320-067-01-9D

INFORMACIÓN LOGÍSTICA:

Etiquetado conforme a la Norma EN 149:2001+A1:2009, como EPI Cat. III

Presentación:

- Sobres Higiénicos Individualizados
- Estuches Dispensadores de 50 unidades.
- Embalaje de 600 unidades

Medidas Cajas: 44x38,5x42 cm

Almacenar en el embalaje original en un lugar seco, limpio, temperaturas oscilantes entre 5º y 30º. No exponer a la luz solar

INSTRUCCIONES DE USO

Mascarilla Con una Vida útil de hasta 40 horas bajo unas condiciones optimas controladas en laboratorio, el fabricante recomienda un uso máximo de hasta 8 horas en condiciones normales. Producto marcado como NR (No Reutilizable), no debe usarse en más de un turno de trabajo.

Instrucciones para una correcta colocación:

1.-Lavarse las manos antes de manipular la mascarilla
2.-Toca únicamente la goma de la mascarilla
3.-Colocar la mascarilla sobre la nariz y boca
4.-Pasar las gomas por detrás de las orejas
5.-Ajustar adecuadamente la tira nasal de la nariz
6.– Evitar en todo momento tocar o manipular la mascarilla durante el uso

Calle Camino de la Torre, s/n—Nave 2 C.P.:45512 PORTILLO DE TOLEDO (Toledo) -Spain
Tlf: 925 67 8656—Mail: luisfran@luhepa.es—CIF: B01985480

EU Declaration of Conformity
Annex IX PPE Regulation (EU) 2016/425

1. This EU Declaration of conformity refers to the following products:
   Product name: Particle Filtering half mask
   Model: 0117
   Classification: FFP2 NR
   Batch No.: YYYYMMDD

2. The Manufacturer's name and address is as follows:
   Name: Uhealth Medical (Beijing) Protective Products Co., Ltd.
   Address: 1st Floor, Building 2, No.15, Jingsheng South Fourth Street, Tongzhou District, Beijing, China

3. This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.
4. Detailed description of the PPE to allow traceability/identification of the PPE.
   0117: White folding particle filtering half mask without valve.

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: **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:
CE-PC-200320-067-01-9D

Product Category:

- ■ 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).

Signature: Date: 9th, June, 2021

Company stamp:

For and on behalf of
Uhealth Medical (Beijing) Protective Products Co., Ltd.
北京联合康力医疗防护用品有限公司

.....
Authorized Signature(s)

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-200320-067-FPC-C

Certificate holder:	**Uhealth Medical (Beijing) Protective Products Co., Ltd.** 1st Floor, Building 2, No.15, Jingsheng South Fourth Street, Tongzhou District, Beijing, China
Manufacturing location:	1st Floor, Building 2, No.15, Jingsheng South Fourth Street, Tongzhou District, Beijing, China
The scope of the certification for:	**The manufacture of respiratory protective device** See annex for articles covered by this certificate
Validity from:	2020-05-05
Revision date:	2021-06-21
To:	2023-05-04

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: verify@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-200320-067-FPC-C

Product reference and description		Reference standard
Particle Filtering Half Mask	Model: 0117	EN 149:2001+A1:2009

Certificate Revision	Revision date	Revision details
A	2020-05-05	Initial issue
B	2020-07-15	Certificate validity extended to one year
C	2021-06-21	Extension to certificate validity following Module C2 assessment and change the certificate holder's address

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 Ireland Certification

CE

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: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200320-067-01-9D

Certificate holder:	**Uhealth Medical (Beijing) Protective Products Co., Ltd.** 1st Floor, Building 2, No.15, Jingsheng South Fourth Street, Tongzhou District, Beijing, China
Product:	**Particle Filtering Half Mask** Detailed product description listed in the Annex
Model(s):	0117
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-05-05
Revision date:	2021-06-21
Expiry date:	2025-05-04

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: verify@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200320-067-01-9D

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
0117	Folding filtering half mask fitted with ear loops and head harness retaining clip, no valves, internal metal nose clip Mask body colour: White Classification: FFP2 NR Test report No.: 2020(F) - 0350

Certificate Revision	Revision date	Revision details
A	2020-05-05	Initial issue
B	2020-07-15	Certificate validity extended to one year
C	2020-08-31	Change the mask body design
D	2021-06-21	Extension to certificate validity following Module C2 assessment Editorial changes to certified listing to include colour description Change the certificate holder's address

CCQS Ireland Certification

CE

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: verify@ccqs.ie

Uhealth Medical (Beijing) Products Co., Ltd.

1 st Floor, Building 2, No.15, Jingsheng South Fourth Street,

Tongzhou District, Beijing, China

Technical Data Sheet

Model 0117 FFP2 NR—Ref. 3600B

	Components						
	Mask Body				Nose Clip	Head harness	Nose Foam
	1	2	3	4			
Material Type	Non-woven	Melt-Blown	Non-woven	Spunlace	PP+Iron Wire		N
Weight	50 gr	50 gr	25 grs	50 gr			
Grade		FFP2					
Dimension					5mm	5 mm	N

Packing Details

Package: 1 pc/Bag

50 pcs/dispenser box

600 pcs/carton

Website: www.uhealthbj.com Email:sales@uhealthbj.com Tel. 0086 10 8792 7887

Uhealth Medical (Beijing) Products Co., Ltd.

1 st Floor, Building 2, No.15, Jingsheng South Fourth Street,

Tongzhou District, Beijing, China

Model 0117 FFP2 NR

Ref. 3600B

Specifications:

Size	Nose Clip	Earloop	Color	Raw Material	PFE
Adul	8,2 cm	19 cm	White	50gr + 50gr + 50gr + 25 gr	>= 95%
Packing: 1pc/bag, 50 pcs/box, 12 box/cartón. Total 600 pcs per carton					

Certificates / Notify body:

CCQS certification services limited.

Block 1 Blanchardstown corporate park, Ballycoolin Road, Blanchardstown, Dublin 15, D15 AKK1, Ireland

Test Report: See Attachment WLH0201-2021

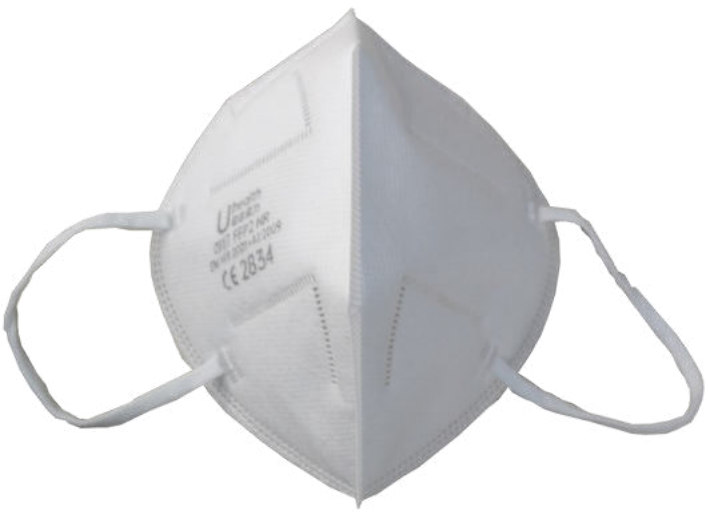
Standard: EN 149:2001+A1:2009

Certificate Module C2: See Attachment CE-PC-200320-067-FPC-C

Certificate Module B: See Attachment CE-PC-200320-067-01-9D

EU Declaration of Conformity Annex IX PPE Regulation (EU) 2016/425: see Attachment

Pictures:



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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

EN 149:2001+A1:2009
Filtering half masks to protect against particles

Report no:	**WLH0201-2021**
Product:	**Particle Filtering Half Mask**
Model(s):	**0117**
Main components:	**Mask body, without exhalation valve**
Date(s) of tests:	**13th May 2021～27th May 2021**

Client	**Manufacturer**
CCQS Certification Services Limited	**Uhealth Medical（Beijing) Protective Products Co., Ltd.**
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15, D15 AKK1, Ireland	5th Floor, Building 1, Courtyard No.11, Kechuang 14th Street, Economic and Technological Development Area, Beijing, China
Client order: /	Contact: /
Order(s) received: May, 2021	E-mail: /
	Phone: /

Conditions:

This report shall not be reproduced except in full, without the written approval of CASST.

The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the CASST.

Any objection should be submitted within 2 weeks from the date of receipt of the report, and it will not be accepted after the deadline.

Specimens will be disposed of 4 weeks from the date of this report, unless otherwise instructed.

Signed: **Issued:** 2021-05-28

张明明/Zhang Mingming, Authorized Signatory

中国安全生产科学研究院 检测检验专用章

中国安全生产科学研究院/China Academy of Safety Science and Technology
Address: No.17 Huixinxi Street, Chaoyang District, 100029, Beijing, China
Phone: +86 10 64892434 / 64941264
E-mail: ldfh@chinasafety.ac.cn
Sino-Japanese Cooperative Respiratory Protection Laboratory
Designated Testing Laboratory of the Certification of LA Mark in China

Summary of assessment*

Clause		Assessment
	Model:	**0117**
7.4	Packaging	NRq
7.5	Material	Pass
7.6	Cleaning and disinfecting	NAp
7.7	Practical performance	Pass
7.8	Finish of parts	Pass
7.9.1	Total inward leakage	Pass
7.9.2	Penetration of filter material: Sodium chloride	Pass
7.9.2	Penetration of filter material: Paraffin oil	Pass
7.10	Compatibility with skin	Pass
7.11	Flammability	Pass
7.12	Carbon dioxide content of the inhalation air	Pass
7.13	Head harness	Pass
7.14	Field of vision	Pass
7.15	Exhalation valve(s)	NAp
7.16	Breathing resistance	Pass
7.17	Clogging	NRq
7.18	Demountable parts	Pass
9	Marking	NRq
10	Information to be supplied by the manufacturer	NRq

Key

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

* Assessment relates only to those specimens which were tested and are the subject of this report.

Product characteristics

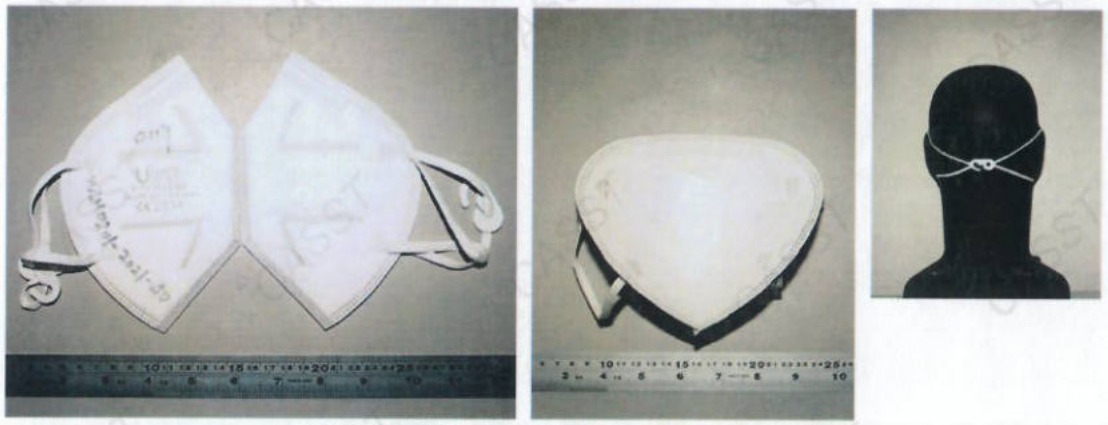
Property	Characteristic
Model	0117
Classification claimed	FFP2 NR
Exhalation valve(s)	None

Submission details

Product	Quantity	Date received	Specimen No.
0117 Particle Filtering Half Mask	99	13th May 2021	WLH0201-2021 -01 to -99

Photographs of the products tested

Uhealth Medical（Beijing) Protective Products Co., Ltd.'s Model 0117 Particle Filtering Half Mask



CASSTspecimennumberWLH0201-2021-40

Procedures

Specimens were selected at random from the submission(s) detailed above.

Testing was performed in accordance with EN 149:2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received.

Result details

7.4 Packaging — NRq

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.

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.

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

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

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

Note1: In accordance with the requirement.
Specimens -14, -15, -16 were conditioned in accordance with 8.3.1，None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -01, -02, -03 were conditioned in accordance with 8.3.1 and 8.3.2，None of the specimens conditioned suffered collapse.

7.6 Cleaning and disinfecting — NAp[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.

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.

Note2: Single shift use only.

7.7 Practical performance — Pass[3]

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

Note3: No imperfections.

Specimen and subject details:

Specimen	Subject
-41	LCF
-42	YZF

7.8 Finish of parts — Pass[4]

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

Note4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 Total inward leakage (%) **Pass**[5]

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.

Note5: All of the 50 individual exercise results were not greater than 11%; All of the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Subject	Specimen	Cond	Walk	Head side/side	Head up/down	Talk	Walk	Mean
LCF	-41	AR	0.4	0.0	0.2	0.0	0.1	0.2
YZF	-42	AR	0.9	0.9	0.9	0.9	0.8	0.9
JLX	-43	AR	0.5	0.5	0.5	0.5	0.4	0.5
ZH	-44	AR	4.2	3.2	4.2	2.4	3.8	3.6
JXQ	-45	AR	3.3	3.4	4.5	2.6	4.0	3.6
MZH	-04	TC	3.1	4.4	5.7	1.5	0.8	3.1
ZWQ	-05	TC	3.2	2.4	3.2	1.8	2.9	2.7
TJ	-06	TC	4.9	6.8	8.8	2.5	1.4	4.9
ZMM	-07	TC	0.9	0.3	0.5	0.3	0.5	0.5
CH	-08	TC	3.7	6.7	5.1	1.9	1.0	3.7
Maximum permitted			11					8

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
ZWQ	128	150	128	58
YZF	113	151	106	48
JLX	119	152	109	59
ZH	102	152	113	55
JXQ	101	137	91	54
MZH	99	143	105	48
LCF	119	165	121	56
TJ	105	151	110	52
ZMM	114	157	119	50
CH	111	135	108	48

7.9.2 Penetration of filter material

Pass

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

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

Sodium chloride test results:（Pass）

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-26	A.R.	0.01	
-27		0.01	
-28		0.10	
-14	S.W.	0.02	
-15		0.12	
-16		0.06	
-20	M.S. + T.C.	0.18	0.19
-21		0.47	0.86
-22		0.04	0.06
Maximum permitted		6	

Paraffin oil test results:（Pass）

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
-29	A.R.	0.15	
-30		0.09	
-31		0.13	
-17	S.W.	0.37	
-18		0.19	
-19		0.19	
-23	M.S. + T.C.	0.07	0.93
-24		0.04	0.08
-25		0.15	0.60
Maximum permitted		6	

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: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 Flammability

Pass

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

Specimen	Condition	Results
-32	A.R.	burn for 0.5 s
-33		burn for 0.6 s
-09	T.C.	burn for 0.4 s
-10		burn for 0.4 s

7.12 Carbon dioxide content of the inhalation air

Pass

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).

Specimen	CO_2 (%)
-32	0.28
-33	0.31
-34	0.32
Maximum permitted	1.0

7.13 Head harness

Pass[7]

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.

Note7: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. Head harness (ear straps with auxiliary hook) can be donned and removed easily, adjustable or self-adjusting, and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

7.14 Field of vision

Pass[8]

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

Note8: Specimens -41 and -42 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 Exhalation valve

NAp

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

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

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

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

7.16 Breathing resistance

Pass[9]

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min×2.0 l/stroke)
FFP1	0.6	2.1	3.0
FFP2	**0.7**	**2.4**	**3.0**
FFP3	1.0	3.0	3.0

Note9: FFP2 Filtering face mask. Test results are detailed below.

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)				
		At 30 l/min	At 95 l/min	Breathing machine (25 cycles/min×2.0 l/stroke)				
				A	B	C	D	E
-35	A.R.	0.37	1.02	2.19	2.14	2.24	2.18	2.15
-36		0.38	1.05	2.21	2.28	2.22	2.26	2.23
-37		0.39	1.07	2.27	2.29	2.21	2.25	2.24
-11	T.C.	0.34	0.97	2.08	2.13	2.06	2.11	2.07
-12		0.34	0.98	2.12	2.16	2.09	2.08	2.11
-13		0.35	1.00	2.11	2.17	2.16	2.14	2.11
-17	S.W.	0.35	1.00	2.17	2.15	2.21	2.20	2.16
-18		0.37	1.01	2.18	2.24	2.15	2.21	2.19
-19		0.37	1.04	2.24	2..21	2.27	2.25	2.29
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		0.7	2.4	3.0				

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

7.17 Clogging

NRq[10]

7.17.1 Breathing resistance

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed,

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar, at 95 l/min continuous flow;

The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Valveless particle filtering half masks:

After clogging the inhalation and exhalation resistances shall not exceed,

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar, at 95 l/min continuous flow.

7.17.2 Penetration of filter material

All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.

Note10: Single shift use only.

7.18 Demountable parts **Pass**[11]

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

Note11: Auxiliary hook are fitted with the ear straps, in accordance with the requirement.

9 Marking **NRq**

9.1 Packaging

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

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

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:

"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or

"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."

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

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

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

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

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

9.2 Particle filtering half mask

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

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

9.2.2 Type-identifying marking.

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

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:

"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or

"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."

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

Examples FFP3 NR D, FFP2 R D"

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

10 Information to be supplied by the manufacturer NRq

10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.

10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on:

application/limitations; the meaning of any colour coding; checks prior to use; donning, fitting; use;maintenance (e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.

10.5 Warning shall be given against problems likely to be encountered, for example:

- fit of particle filtering half mask (check prior to use);
- it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
- air quality (contaminants, oxygen deficiency);
- use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift."

Estimates of the uncertainty of measurement

Clause	Test	Uncertainty
7.4	Packaging	Not applicable
7.5	Material	Not applicable
7.6	Cleaning and disinfecting	Not applicable
7.7	Practical performance	See Note 1
7.8	Finish of parts	Not applicable
7.9.1	Total inward leakage	±4.4%
7.9.2	Penetration of filter material: Sodium chloride	±2.7%
7.9.2	Penetration of filter material: Paraffin oil	±3.2%
7.10	Compatibility with skin	Not applicable
7.11	Flammability	See Note 1
7.12	Carbon dioxide content of the inhalation air	±8.0%
7.13	Head harness	Not applicable
7.14	Field of vision	See Note 1
7.15	Exhalation valve(s)	See Note 1
7.16	Breathing resistance	±5.7%
7.17	Clogging	/
7.18	Demountable parts	Not applicable

Note 1 The acceptance criterion for this test is a straightforward "Pass/Fail", rather than a numerical value. Consequently, as there is no value to be reported, uncertainty has not been reported either.

Note 2 The uncertainty value is based on a standard uncertainty multiplied by a coverage factor k = 2, which provides for a confidence level of approximately 95%. Values expressed as a percentage (%) are relative.

Note 3 It should be noted that the above values have not been taken into account when making assessment to the pass/fail criteria.

End of Test Report.