

DEPARTMENT of PERSONAL PROTECTIVE EQUIPMENT**LABORATORY of RESPIRATORY PROTECTIVE EQUIPMENT****TEST REPORT**

Order No.: 236/PB/2010/NO

Subject of the order: Tests of filtering half masks with exhalation valve and
without exhalation valveParty commissioning examination: MFA İŞ GÜVENLİĞİ MEDİKAL TEKSTİL
İMALAT TİC. LTD. ŞTİ.
Caydamar Mh. Ahmet Taner Kısali Cd.,
ZIGEM B Blok
67020 ZONGULDAK - TURKEY

Name and address of the client: -

Date of compilation of the test report: 14.05.2010

Main performer: Katarzyna Bociek

Verified by: 
KIEROWNIK
Pracowni Sprzętu Ochrony
Dłukładu Oddechowego
dr inż. Piotr Dętkowski

Approved by:

KIEROWNIK ZESPOŁU
Laboratoriów Badawczych i Wzorcujących

mgr inż. Kinga Makuła

AB 038

Copy No 4
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Test object:

Fourty eight filtering half masks: Z-067 FFP1 without exhalation valve, A-167 FFP1 without exhalation valve, Z-167 FFP1 without exhalation valve, A-167V FFP1 with exhalation valve, Z-267 FFP2 without exhalation valve, A-267 FFP2 without exhalation valve, Z-267V FFP2 with exhalation valve and A-267V FFP2 with exhalation valve were tested.

The filtering half masks were delivered by MFA İŞ GÜVENLİĞİ MEDİKAL TEKSTİL İMALAT TİC. LTD. ŞTİ., Caydamar Mh. Ahmet Taner Kisali Cd., ZIGEM B Blok, 67020 ZONGULDAK - TURKEY.

Samples registry number: NO1/8/2010 for: Z-067 FFP1 without exhalation valve,
A-167 FFP1 without exhalation valve,
Z-167 FFP1 with exhalation valve,
A-167V FFP1 with exhalation valve
NO1/9/2010 for: Z-267 FFP2 without exhalation valve,
A-267 FFP2 without exhalation valve,
Z-267V FFP2 with exhalation valve,
A-267V FFP2 with exhalation valve

Samples receiving date: 25.02.2010

Test report preparation date: 14.05.2010

Scope of tests:

- clogging according to EN 149:2001 + A1:2009 [p.8.10]

Note

This test report consists of ten (10) pages.

Estimation of conformity/nonconformity with the standard is out of the scope of accreditation.

This test report may not be copied fragmentarily, but only as the whole unless there is CIOP-PIB permission.

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks Z-067 FFP1 without exhalation valve

No. of sample	Penetration [%] after clogging		Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist	inhalation	exhalation		
	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $2,7 \text{ dm}^3 \text{ s}^{-1}$		
01 (A.R.)	5,2	-	122	160	For penetration FFP1 $\leq 20\%$ FFP2 $\leq 6\%$ FFP3 $\leq 1\%$ For breathing resistance FFP1 $\leq 300 \text{ Pa}$ FFP2 $\leq 400 \text{ Pa}$ FFP3 $\leq 500 \text{ Pa}$	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first protection class (FFP1)
02 (T.C.)	4,1	-	134	178		
03 (T.C.)	5,3	-	121	192		
04 (A.R.)	-	11	135	183		
05 (T.C.)	-	11	141	179		
06 (T.C.)	-	12	128	190		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks A-167 FFP1 without exhalation valve

No. of sample	Penetration [%] after clogging		Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist	inhalation	exhalation		
	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $2,7 \text{ dm}^3 \text{ s}^{-1}$		
07 (A.R.)	4,8	-	124	165	For penetration FFP1 $\leq 20\%$ FFP2 $\leq 6\%$ FFP3 $\leq 1\%$ For breathing resistance FFP1 $\leq 300 \text{ Pa}$ FFP2 $\leq 400 \text{ Pa}$ FFP3 $\leq 500 \text{ Pa}$	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first protection class (FFP1)
08 (T.C.)	5,0	-	116	150		
09 (T.C.)	5,1	-	122	158		
10 (A.R.)	-	11	130	180		
11 (T.C.)	-	10	135	177		
12 (T.C.)	-	12	131	181		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks Z-167 FFP1 with exhalation valve

No. of sample	Penetration [%] after clogging		Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist	inhalation	exhalation		
	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $2,7 \text{ dm}^3 \text{ s}^{-1}$		
13 (A.R.)	4,2	-	150	160	For penetration FFP1 $\leq 20\%$ FFP2 $\leq 6\%$ FFP3 $\leq 1\%$ For breathing resistance Inhalation FFP1 $\leq 400 \text{ Pa}$ FFP2 $\leq 500 \text{ Pa}$ FFP3 $\leq 700 \text{ Pa}$ Exhalation FFP1 $\leq 300 \text{ Pa}$ FFP2 $\leq 300 \text{ Pa}$ FFP3 $\leq 300 \text{ Pa}$	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first protection class (FFP1)
14 (T.C.)	4,7	-	155	165		
15 (T.C.)	4,3	-	142	178		
16 (A.R.)	-	12	135	139		
17 (T.C.)	-	12	148	162		
18 (T.C.)	-	11	140	171		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks A-167V FFP1 with exhalation valve

No. of sample	Penetration [%] after clogging		Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist	inhalation	exhalation		
	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $2,7 \text{ dm}^3 \text{ s}^{-1}$		
19 (A.R.)	4,4	-	143	159	For penetration FFP1 $\leq 20\%$ FFP2 $\leq 6\%$ FFP3 $\leq 1\%$ For breathing resistance Inhalation FFP1 $\leq 400 \text{ Pa}$ FFP2 $\leq 500 \text{ Pa}$ FFP3 $\leq 700 \text{ Pa}$ Exhalation FFP1 $\leq 300 \text{ Pa}$ FFP2 $\leq 300 \text{ Pa}$ FFP3 $\leq 300 \text{ Pa}$	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first protection class (FFP1)
20 (T.C.)	4,1	-	138	155		
21 (T.C.)	4,3	-	139	158		
22 (A.R.)	-	13	132	148		
23 (T.C.)	-	12	128	141		
24 (T.C.)	-	13	130	147		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks Z-267 FFP2 without exhalation valve

No. of sample	Penetration [%] after clogging		Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist	inhalation	exhalation		
	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $2,7 \text{ dm}^3 \text{ s}^{-1}$		
25 (A.R.)	1,4	-	210	250	For penetration FFP1 $\leq 20\%$ FFP2 $\leq 6\%$ FFP3 $\leq 1\%$ For breathing resistance FFP1 $\leq 300 \text{ Pa}$ FFP2 $\leq 400 \text{ Pa}$ FFP3 $\leq 500 \text{ Pa}$	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first and the second protection class (FFP1, FFP2)
26 (T.C.)	2,1	-	221	270		
27 (T.C.)	1,3	-	231	260		
28 (A.R.)	-	3,2	221	275		
29 (T.C.)	-	3,1	238	263		
30 (T.C.)	-	3,4	215	254		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks A-267 FFP2 without exhalation valve

No. of sample	Penetration [%] after clogging			Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist		inhalation	exhalation		
	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $2,7 \text{ dm}^3 \text{ s}^{-1}$		
31 (A.R.)	1,3	-	-	227	261	For penetration FFP1 \leq 20% FFP2 \leq 6% FFP3 \leq 1% For breathing resistance FFP1 \leq 300 Pa FFP2 \leq 400 Pa FFP3 \leq 500 Pa	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first and the second protection class (FFP1, FFP2)
32 (T.C.)	1,8	-	-	229	258		
33 (T.C.)	1,5	-	-	225	259		
34 (A.R.)	-	3,4	-	220	263		
35 (T.C.)	-	3,0	-	216	259		
36 (T.C.)	-	3,2	-	224	260		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks Z-267V FFP2 with exhalation valve

No. of sample	Penetration [%] after clogging		Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist	inhalation	exhalation		
	Flow rate 1,6 dm ³ s ⁻¹	Flow rate 1,6 dm ³ s ⁻¹	Flow rate 1,6 dm ³ s ⁻¹	Flow rate 2,7 dm ³ s ⁻¹		
37 (A.R.)	1,8	-	230	190	For penetration FFP1 ≤ 20% FFP2 ≤ 6% FFP3 ≤ 1% For breathing resistance Inhalation FFP1 ≤ 400 Pa FFP2 ≤ 500 Pa FFP3 ≤ 700 Pa Exhalation FFP1 ≤ 300 Pa FFP2 ≤ 300 Pa FFP3 ≤ 300 Pa	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first and the second protection class (FFP1, FFP2)
38 (T.C.)	1,7	-	241	187		
39 (T.C.)	1,3	-	252	193		
40 (A.R.)	-	4,0	248	183		
41 (T.C.)	-	3,2	236	175		
42 (T.C.)	-	3,0	240	192		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

TEST RESULTS OF CLOGGING according to EN 149:2001+A1:2009

Test object: filtering half masks A-267V FFP2 witht exhalation valve

No. of sample	Penetration [%] after clogging		Breathing resistance after clogging [Pa]		Requirements in accordance with EN 149:2001+A1:2009	Estimation of conformity / nonconformity with the standard
	NaCl	Paraffin oil mist	inhalation	exhalation		
	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $1,6 \text{ dm}^3 \text{ s}^{-1}$	Flow rate $2,7 \text{ dm}^3 \text{ s}^{-1}$		
43 (A.R.)	1,9	-	242	208	For penetration FFP1 \leq 20% FFP2 \leq 6% FFP3 \leq 1% For breathing resistance Inhalation FFP1 \leq 400 Pa FFP2 \leq 500 Pa FFP3 \leq 700 Pa Exhalation FFP1 \leq 300 Pa FFP2 \leq 300 Pa FFP3 \leq 300 Pa	Filtering half masks fulfill requirements of 7.17 EN 149:2001+A1:2009 for the first and tthe second protection class (FFP1, FFP2)
44 (T.C.)	2,0	-	238	201		
45 (T.C.)	1,8	-	242	210		
46 (A.R.)	-	3,8	244	205		
47 (T.C.)	-	3,5	239	197		
48 (T.C.)	-	3,7	243	205		

Given results relate to tested samples only.

A.R. – sample as received

T.C. – sample after temperature conditioning

END OF TEST REPORT

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Test Report 9642433.
MFA Is Guvenligi Medikal

Introduction.

This report has been prepared by Safwan Chowdhury and relates to the activity detailed below:

Job/Registration Details	Client Details
Job number: 9642433 Job type: Testing Samples Submitted Start Date: 16/10/2018 Test type: Type Sample ID: 10179889 Registration: CE 688360 Scheme: PPE CE Pt10 Protocol: PP123 Scheme Mgr: Nathan Shipley	MFA Is Guvenligi Medikal Tekstil Imalat Tic. San. ltd. Sti Caydamar Mah Ahmet Taner Kislali Cad Zigem No:9/A Zonguldak 67020 Turkey

The report has been approved for issue by T Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 19 November 2018

Objectives.

This is an independent Type Test evaluation to limited clauses of BS EN 149:2001 + A1:2009

- Clause 7.12 – Carbon dioxide content of inhalation air

Product Scope.

BS EN 149:2001+A1:2009 - Filtering half mask, respiratory protective device, to protect against particles.

Report Summary.

The samples were received on 09/10/2018 and the testing was started on 16/10/2018.

The samples submitted complied with the requirements of the limited test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 3	10179889	Valved filtering half mask – Model: A-267V

Description of Test Samples.

Sample Description
Horizontal fold flat valved filtering half mask – Model: A-267V, FFP2 NR D

Test Requirements.

BS EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles.

CLAUSE	REQUIREMENTS	ASSESSMENT
7	Requirements	
7.12	Carbon dioxide content of inhalation air	Pass

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories

Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.

Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.

Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.

Fail: Non-compliance. Product does not meet the requirements of this clause.

Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.

N/T: Not Tested

N/A: Not Applicable

AR: As Received

TC: Temperature Conditioned

SW: Simulated Wear

FT: Flow Tested

MS: Mechanical strength

MMDF: Manufactures Minimum Design Flow

MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

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Hertfordshire
HP2 4SQ



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Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

CLAUSE	REQUIREMENTS	ASSESSMENT
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7.12

Carbon dioxide content of inhalation air

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

Testing shall be done in accordance with 8.7.

Table A: Carbon dioxide content of the inhalation air

Pass
See Table A

Sample No	Pre-test condition	Maximum Specified CO ₂ (%)	Actual CO ₂ (%)
1	AR	1.0	0.69
2	AR	1.0	0.69
3	AR	1.0	0.69

Product photographs.



Model: A-267V

*** End of Report ***

01.08.2022

DECLARATION LETTER

TO WHOM IT MAY CONCERN

Our FFP2 protection class half face respirators can be used for protection against tuberculosis spread. Below are the model we produce in FFP2 protection class and offer to you.

Model: A-267V

Protection Class: FFP2


MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.
Hayat Mahallesi Baruthane Caddesi No: 21/1
Elvanpazarcık Beldesi Merkez ZONGULDAK
Tel: 0.372 253 40 30 / 40 69 / 40 69
Mersis No: TR2013057600001
Ulaştırma Bakanlığı V.D. 620 130 5756

Fatih FURTUN
General Manager

EU Type Examination Certificate

This is to certify that:

MFA Is Guvenligi Medikal A.S.
Baruthane Cad. No:21/1
Elvanpazarcik Beldesi Hayat Mah.
Merkez/ ZONGULDAK
Zonguldak
67990
Turkey

Holds Certificate Number:

CE 758378

In respect of:

Filtering masks to EN 149:2001+A1:2009
Various models, see continuation sheet for details.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Denelise L'Ecluse, Managing Director Assurance - Continental Europe

First Issued: 2022-01-11
Latest Issue: 2023-01-17

Effective Date: 2023-01-17
Expiry Date: 2027-01-10

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EU Type Examination Certificate

No. CE 758378

Product Specification

Vertical Fold Flat Range with clogging

Description: **A- Series - Vertical fold flat disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification –Single shift NR

FFP Class: **FFP1 NR D**

Models:
A-167
A-167V (mask with exhalation valve fitted)
A-167V-E (mask with exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models:
A-267
A-267V (mask with exhalation valve fitted)

FFP Class: **FFP3 NR D**

Models:
A-367
A-367V (mask with exhalation valve fitted)

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Product Specification (continued)

Description: **C- Series - Vertical fold flat disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift NR

FFP Class: **FFP1 NR D**

Models:
C-067
C-067V (mask with exhalation valve fitted)
C-167
C-167V (mask with exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models:
C-267
C-267V (mask with exhalation valve fitted)
C-267-AC (mask with activated carbon)
C-267V-AC (mask with activated carbon and exhalation valve fitted)

FFP Class: **FFP3 NR D**

Model: C-367V (mask with exhalation valve fitted)

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Product Specification (Continued)

Description: F - Series – Conical Type disposable face mask with clogging Clause 7.17

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift NR

FFP Class: **FFP1 NR D**

Models: F-167
F-167V (mask with exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models: F-267
F-267V (mask with exhalation valve fitted)
F-267-AC (mask with activated carbon)
F-267V-AC (mask with activated carbon and exhalation valve fitted)

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Product Specification (Continued)

Description: **P - Series - Vertical fold flat disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.

Classification – Single shift NR

FFP Class: **FFP1 NR D**

Models:

P-167

P-167V (mask with exhalation valve fitted)

P-167-AC (mask with activated carbon)

P-167V-AC (mask with activated carbon and exhalation valve fitted)

P-167V-E (mask with exhalation valve fitted)

P-167V-AC-E (mask with activated carbon and exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models:

P-267

P-267V (mask with exhalation valve fitted)

P-267-AC (mask with activated carbon)

P-267V-AC (mask with activated carbon and exhalation valve fitted)

P-267V-E (mask with exhalation valve fitted)

P-267V-AC-E (mask with activated carbon and exhalation valve fitted)

FFP Class: **FFP3 NR D**

Models:

P-367

P-367-S (mask is smaller in size than the original model P-367)

P-367V (mask with exhalation valve fitted)

P-367V-S (mask is smaller in size than the original model P-367V)

P-367V-E (mask with exhalation valve fitted)

P-367V-AC (mask with activated carbon and exhalation valve fitted)

P-367V-AC-S (mask is smaller in size than the original model P-367V-AC)

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No. CE 758378

Product Specification (Continued)

Description: **S - Series – Conical type disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift NR

FFP Class: **FFP1 NR D**

Models: S-167
S-167V (mask with exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models: S-267
S-267V (mask with exhalation valve fitted)
S-267-AC (mask with activated carbon)
S-267V-AC (mask with activated carbon and exhalation valve fitted)

FFP Class: **FFP3 NR D**

Models: S-367V (mask with exhalation valve fitted)
S-367V-AC (mask with activated carbon and exhalation valve fitted)

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EU Type Examination Certificate

No. CE 758378

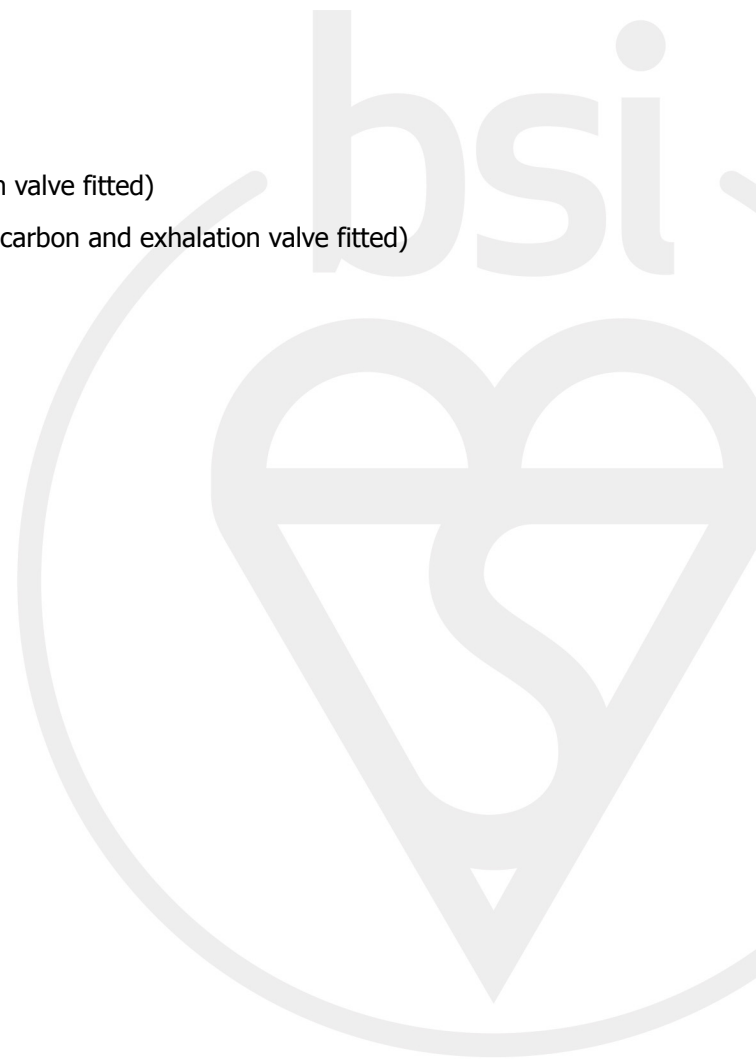
Product Specification (Continued)

Description: **SR- Series – Conical type disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Reusable R

FFP Class: **FFP2 R D**

Models: SR-S-267V (mask with exhalation valve fitted)
SR-S-267V-AC (mask with activated carbon and exhalation valve fitted)



First Issued: 2022-01-11

Latest Issue: 2023-01-17

Effective Date: 2023-01-17

Expiry Date: 2027-01-10

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No. CE 758378

Description: **Z- Series - Vertical fold flat disposable face mask with clogging Clause 7.17**

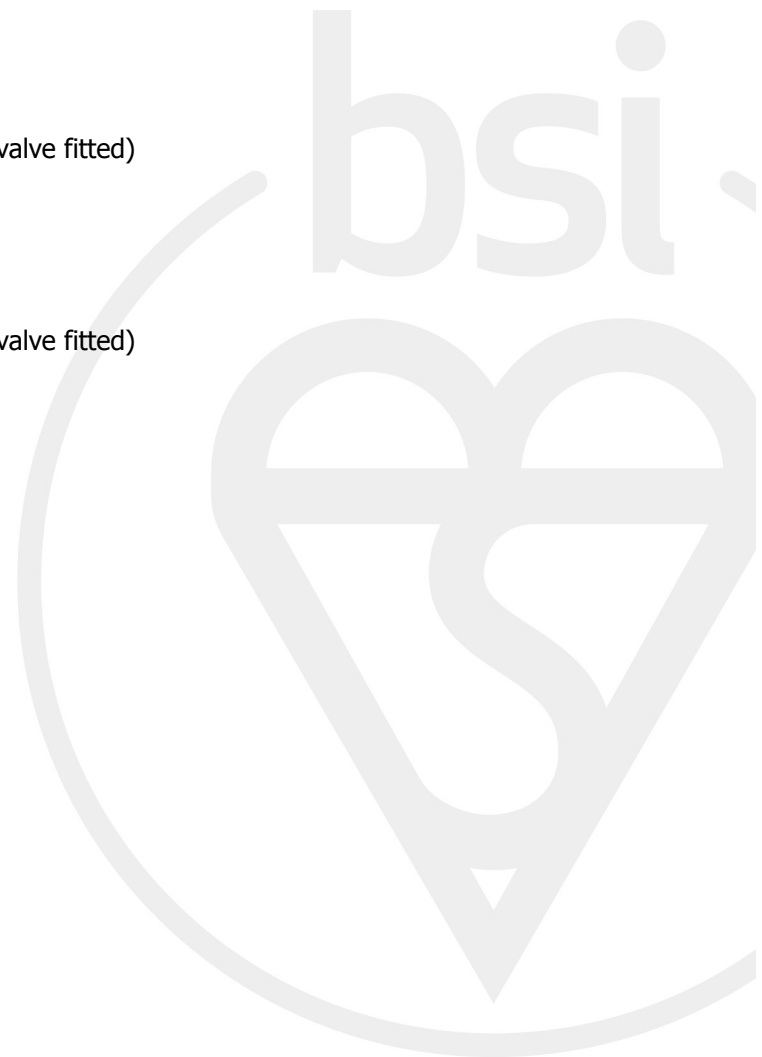
Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift - NR

FFP Class: **FFP1 NR D**

Models: Z-167
Z-167V (mask with exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models: Z-267
Z-267V (mask with exhalation valve fitted)



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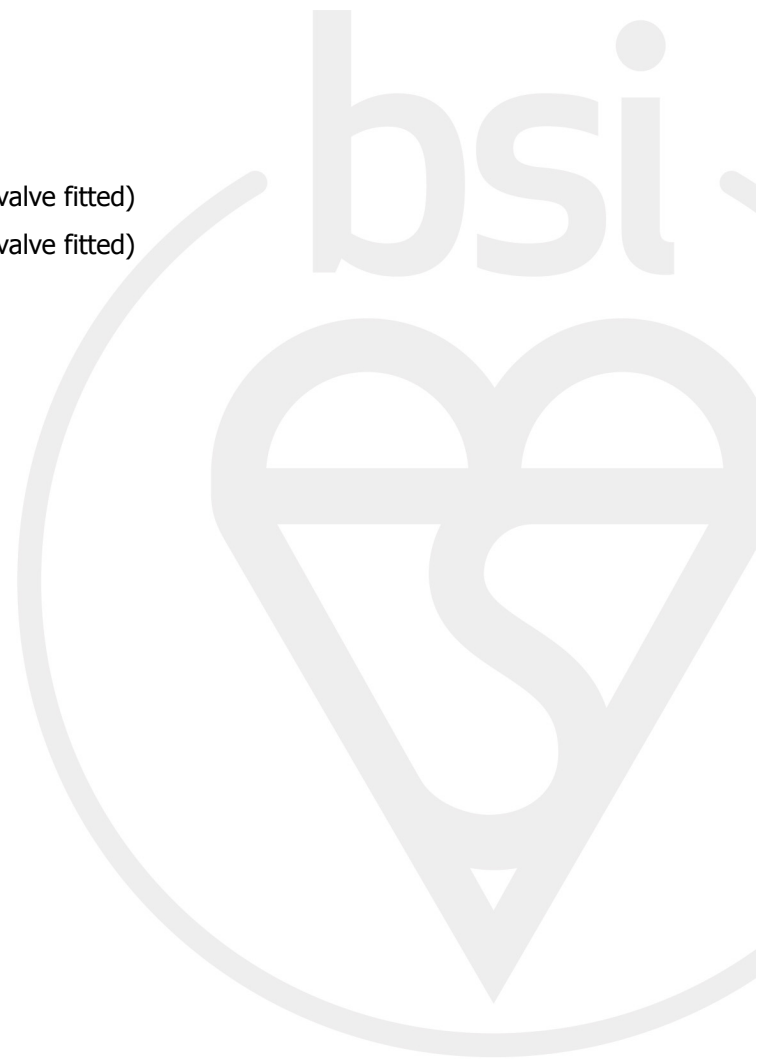
No. CE 758378

Description: **NFK- Series – Conical type disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift - NR

FFP Class: **FFP2 NR D**

Models:
NFK-200
NFK-201 (mask with exhalation valve fitted)
Q-267V (mask with exhalation valve fitted)



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No. CE 758378

Product Specification (Continued)

Description: **D - Series –Conical type disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift NR D

FFP Class: **FFP2 NR D**

Models:
D-267V-ECO (mask with exhalation valve fitted)
D-267V (mask with exhalation valve fitted)
D-267V-AC (mask with activated carbon and exhalation valve fitted)

FFP Class: **FFP3 NR D**

Models:
D-367V (mask with exhalation valve fitted)
D-367V-AC (mask with activated carbon and exhalation valve fitted)

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EU Type Examination Certificate

No. CE 758378

Product Specification (Continued)

Description: **PR- Series –Conical type disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Re-usable R D

FFP Class: **FFP2 R D**

Models: PR-5520 (mask with exhalation valve fitted)
PR-7720 (mask with activated carbon and exhalation valve fitted)

FFP Class: **FFP3 R D**

Models: PR-5530 (mask with exhalation valve fitted)
PR-7730 (mask with activated carbon and exhalation valve fitted)

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No. CE 758378

Product Specification (Continued)

Description: **DX- Series – Conical type disposable face mask with clogging Clause 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification –Single shift NR D

FFP Class: **FFP2 NR D**

Models: DX-267V (mask with exhalation valve fitted)
DX-267V-AC (mask with activated carbon and exhalation valve fitted)

FFP Class: **FFP3 NR D**

Models: DX-367V (mask with exhalation valve fitted)
DX-367V-AC (mask with activated carbon and exhalation valve fitted)

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Latest Issue: 2023-01-17

Effective Date: 2023-01-17
Expiry Date: 2027-01-10

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Certificate Administration Details

Technical File Reference: A - Series: Particle Filtering Half Masks TF1702
C - Series: Particle Filtering Half Masks TF1701
F - Series: Particle Filtering Half Masks TF1704
P - Series: Particle Filtering Half Masks TF1703
S - Series: Particle Filtering Half Masks TF1705
Z - Series: Particle Filtering Half Masks TF1706
NFK Series: Particle Filtering Half Masks TF1707
DX, D & PR - Series: Particle Filtering Half Masks TF1711, TF1709 & TF1710

Certificate Amendment Record

Issue date	Comments
January 2022	First issue.
January 2023	Addition of models for DX, D & PR Series

BSI Internal Project No.

2797:21:3541515
2797:22:3384420
&3542037

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 758381.

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Sertifika

Certificate



MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.

ELVANPAZARCIK BELDESİ HAYAT MAH. BARUTHANE CAD. NO:21/1 MERKEZ
ZONGULDAK - TÜRKİYE

kuruluşu KAS Sertifikasyon tarafından değerlendirilmiş ve

has been assessed by KAS Certification and confirmed to comply with the requirements of

ISO 9001:2015

Kalite Yönetim Sistemi

Quality Management System

standardının gerekliliklerini aşağıdaki faaliyet kapsamında karşıladığı tespit edilmiştir:

standard for following scope:

Koruyucu amaçlı solunum ekipmanları ve gaz maskelerinin imalatı (tedavi edici olanlar hariç)
Manufacture of respiratory protective equipment and gas mask purpose (except of therapeutic)

Sertifika İlk Yayın Tarihi *Date of initial issue* : 19.01.2018

Sertifika Yayın Tarihi *Date of issue* : 16.01.2023

Sertifika Geçerlilik Tarihi *Date of validity* : 18.01.2024

Sertifika No *Certificate No* : KAS-190118-1235

Sertifika geçerlilik süresi her yıl yapılan gözetim tetkiki sonucu başarılı ise 1 yıl uzatılır.

If annual surveillance audit result is successful, certificate validity is extended for 1 year.

Onay *Authorised*

UĞUR EKİCİ

Genel Müdür *Executive Manager*

16/01/2023



TÜRKAK BDS NO
YS-4640-0A7A



Belgelendirmenin yenilenebilmesi için 3 yıllık sertifika çevriminin dolduğu tarih olan 18/01/2024 tarihinden önce müşteri 'yeniden belgelendirme' tetkikini başarılı olarak tamamlamış olmalıdır.
In order to renew the certification, recertification audit shall be successfully completed by 18/01/2024, before 3 years of certification cycle is expired.

Bu belgenin doğruluğunu <https://www.kascert.com/belgesor/> adresinden veya mobil cihazlarınıza yükleyeceğiniz karekod okuyucu programı ile yukarıdaki karekodu okutarak yapabilirsiniz.
You can verify the accuracy of this document at <https://www.kascert.com/belgesor/> or by reading the above QR code with the QR code reader program you will install on your mobile devices.

KAS Uluslararası Sertifikasyon Göz. Tek. Kont. Hiz. Ltd. Şti.
Kurtuluş Cad. No: 27 K: 3 Bornova İzmir-Türkiye

info@kascert.com www.kascert.com

KAS CERT



Sertifika

Certificate



MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.

ELVANPAZARCIK BELDESİ, HAYAT MAHALLESİ, BARUTHANE CAD. NO:21/1,
MERKEZ, ZONGULDAK

kuruluşu KAS Sertifikasyon tarafından değerlendirilmiş ve

has been assessed by KAS Certification and confirmed to comply with the requirements of

ISO 13485:2016

Tıbbi Cihazlar için Kalite Yönetim Sistemleri – Mevzut Amaçları Bakımından Şartlar

Medical Devices – Quality Management Systems – Requirements of Regulatory Purposes

standardının gerekliliklerini aşağıdaki faaliyet kapsamında karşıladığı tespit edilmiştir:
standard for following scope:

TOZ MASKESİ, GAZ MASKESİ VE FİLTRELERİ ÜRETİMİ
MANUFACTURE OF RESPIRATORS / GAS MASKS AND FILTERS

Sertifika İlk Yayın Tarihi *Date of initial issue* : 15.12.2021
Sertifika Yayın Tarihi *Date of issue* : 15.12.2022
Sertifika Geçerlilik Tarihi *Date of validity* : 14.12.2023
Sertifika No *Certificate No* : KAS-151221-45165

Sertifika geçerlilik süresi her yıl yapılan gözetim tetkiki sonucu başarılı ise 1 yıl uzatılır.
If annual surveillance audit result is successful, certificate validity is extended for 1 year.

Genel Müdür *Executive Manager*

UĞUR EKİCİ

Onay *Authorised*

15.12.2022



TÜRKAK BDS NO
YS-3B4A-A561



Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021-1
AB-0071-YS

Belgelendirmenin yenilenebilmesi için 3 yıllık sertifika çevriminin dolduğu tarih olan 15.12.2024 tarihinden önce müşteri 'yeniden belgelendirme' tetkikini başarılı olarak tamamlamış olmalıdır.
In order to renew the certification, recertification audit shall be successfully completed by 15.12.2024, before 3 years of certification cycle is expired.

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