

# 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 : 15.12.2021  
Sertifika Geçerlilik Tarihi Date of validity : 14.12.2022  
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.

Onay Authorised   
Genel Müdür Executive Manager

15.12.2021



TÜRKAK BDS NO  
YS-8929-9DB5



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.

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](mailto:info@kascert.com) [www.kascert.com](http://www.kascert.com)

KAS CERT



# 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)

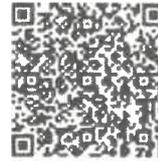
Sertifika İlk Yayın Tarihi Date of initial issue : 19.01.2018  
Sertifika Yayın Tarihi Date of issue : 17.01.2022  
Sertifika Geçerlilik Tarihi Date of validity : 18.01.2023  
Sertifika No Certificate No : KAS-190118-1235

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

Genel Müdür Executive Manager

17/01/2022



TURKAK BDS NO  
YS-90C1-1925



Kalite Yönetim Sistemi  
TS-EN-ISO 9001:2015  
AB-0071-YS

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.  
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Kurtuluş Cad. No: 27 K: 3 Bornova İzmir-Türkiye

info@kascert.com www.kascert.com

KAS CERT



# EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

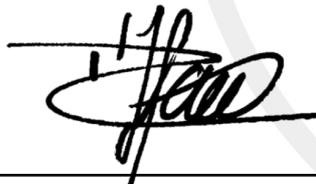
CE 758378

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):



Drs. Dave Hagenaaers, Managing Director

First Issued: 2022-01-11

Latest Issue: 2022-01-11

Effective Date: 2022-01-11

Expiry Date: 2027-01-11

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...making excellence a habit.™

# 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 option 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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A member of BSI Group of Companies.

# EU Type Examination Certificate

No. CE 758378

## Product Specification (continued)

**Description:** **C- Series - Vertical fold flat disposable face mask with clogging option 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 charcoal)  
C-267V-AC (mask with activated charcoal and exhalation valve fitted)

**FFP Class:** **FFP3 NR D**

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

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Effective Date: 2022-01-11

Expiry Date: 2027-01-11

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# EU Type Examination Certificate

No. CE 758378

## Product Specification (Continued)

**Description:** **F - Series – Conical Type disposable face mask with clogging option 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 charcoal)  
F-267V-AC (mask with activated charcoal and exhalation valve fitted)

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Latest Issue: 2022-01-11

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# EU Type Examination Certificate

No. CE 758378

## Product Specification (Continued)

**Description:** **P - Series - Vertical fold flat disposable face mask with clogging option 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 charcoal)

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

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

P-167V-AC-E (mask with activated charcoal 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 charcoal)

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

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

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

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

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# EU Type Examination Certificate

No. CE 758378

## Product Specification (Continued)

**Description:** **S - Series – Conical type disposable face mask with clogging option 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 charcoal)  
S-267V-AC (mask with activated charcoal and exhalation valve fitted)

**FFP Class:** **FFP3 NR D**

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

First Issued: 2022-01-11

Latest Issue: 2022-01-11

Effective Date: 2022-01-11

Expiry Date: 2027-01-11

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# EU Type Examination Certificate

No. CE 758378

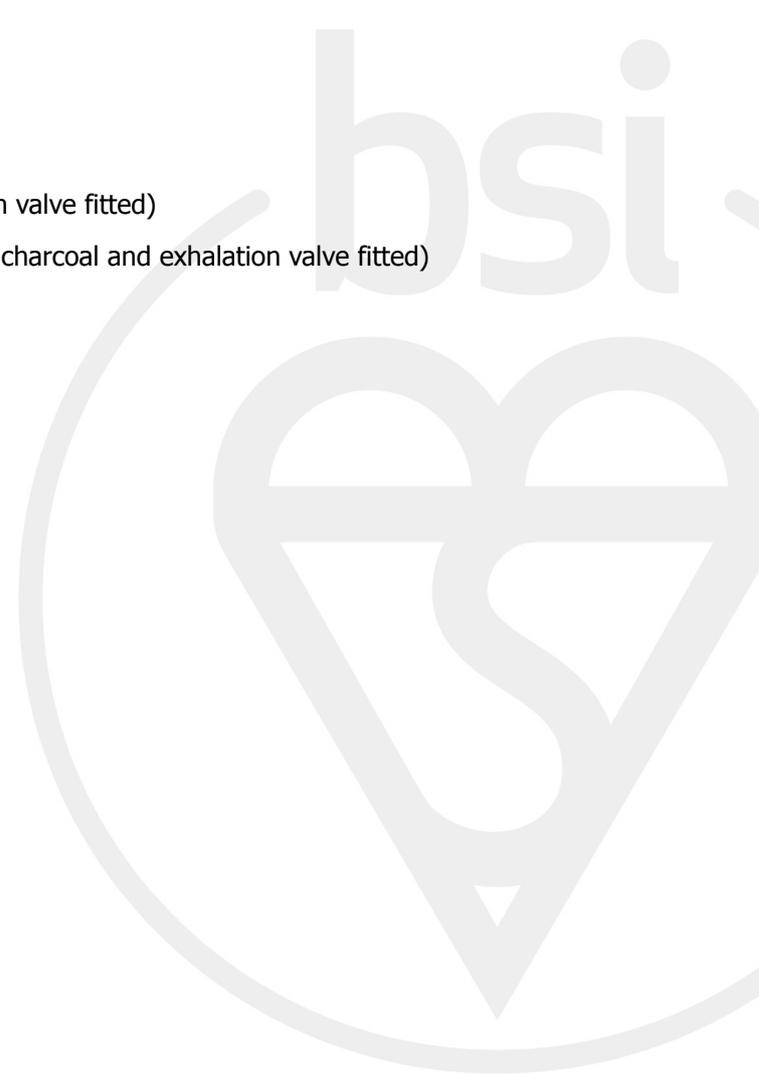
## Product Specification (Continued)

**Description:** **SR- Series – Conical type disposable face mask with clogging option 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 charcoal and exhalation valve fitted)



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Latest Issue: 2022-01-11

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# EU Type Examination Certificate

No. CE 758378

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

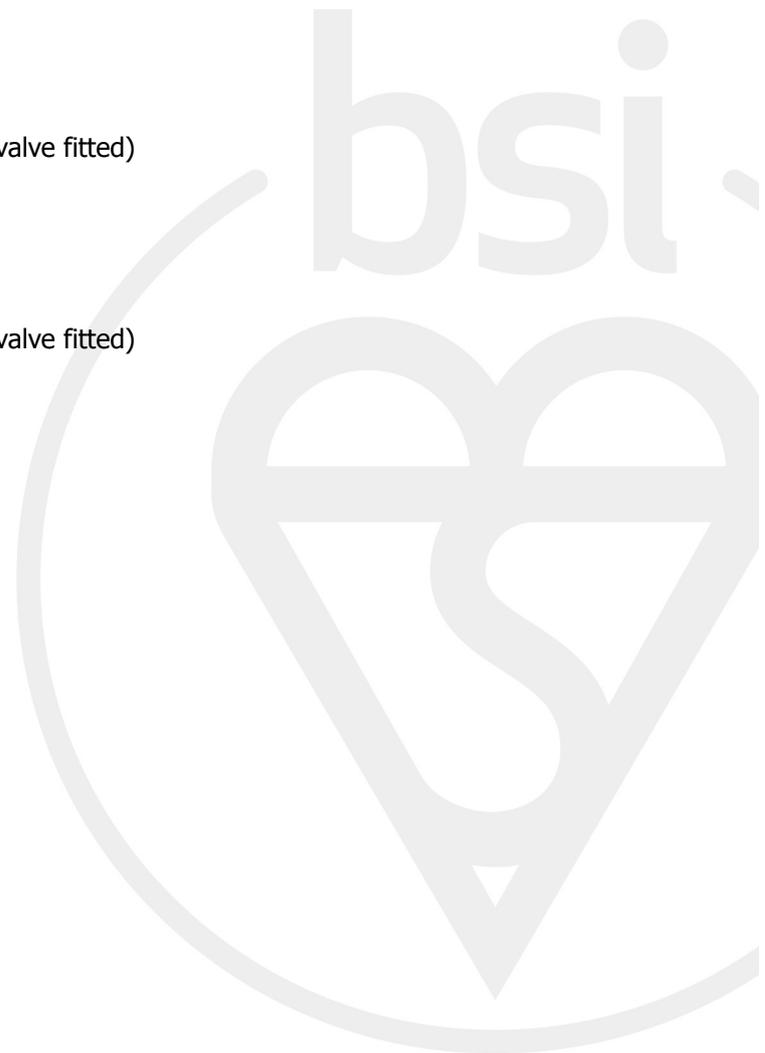
**Technical specification:** **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.  
Classification – Single shift - NR

**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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Expiry Date: 2027-01-11

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# EU Type Examination Certificate

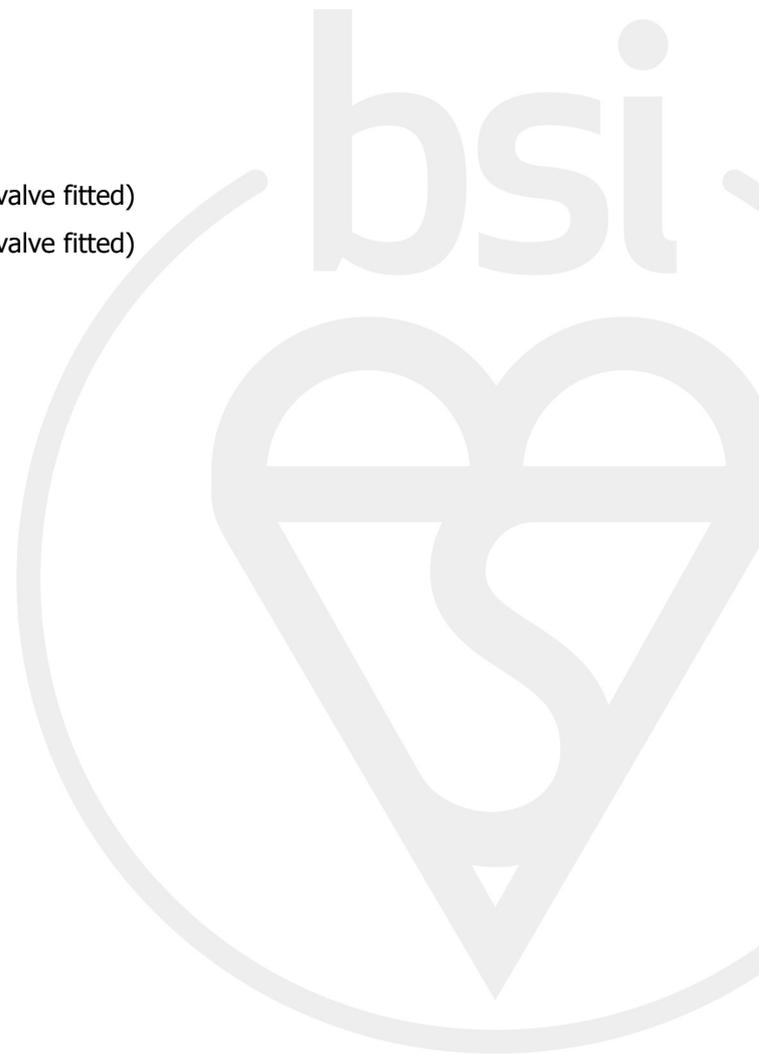
No. CE 758378

**Description:** **NFK- Series – Conical type disposable face mask with clogging option 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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# EU Type Examination Certificate

No. CE 758378

## 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

## Certificate Amendment Record

Issue date	Comments
January 2022	First issue.

**BSI Internal Project  
No.**

2797:21:3541515

## 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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A member of BSI Group of Companies.

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 / Fax: No: 5465  
Mersis No: 02013057600001  
Ulaştırma Bakanlığı V.D. 620 130 5756

**Fatih FURTUN**  
General Manager



**MFA A-267 and A-267V**  
**DISPOSIBLE PARTICULATE RESPIRATORS**  
 Respiratory Mask for Protection Against  
 Low Level Hazardous Solid and Water Based Aerosols  
**Class: FFP2**

# TECHNICAL DATASHEET

## PRACTICAL PERFORMANCE RESULTS

## TRADITIONAL CHOICE IN RESPIRATORY PROTECTION

### Filter penetration

Model	Paraffin Penetration*	Limit
A-267 and A-267V	<b>% 0,197</b>	<b>&lt; %6</b>

\* Average of Test Results of Penetration for Paraffin Oil Mist (Flow Rate % 1.6 dm<sup>3</sup> s)

### Inhalation Resistance

Model	Inhalation Resistance*	Limit
A-267 and A-267V	<b>0,69 mbar</b>	<b>&lt; 2,4mbar</b>

\* Average of Test Results of Inhalation Resistance (Flow rate 1,6 dm<sup>3</sup> s)

### Exhalation Resistance

Model	Exhalation Resistance*	Limit
A-267	<b>1,272 mbar</b>	<b>&lt; 3mbar</b>
A-267V	<b>0,906 mbar</b>	<b>&lt; 3mbar</b>

\* Average of Test Results of Exhalation Resistance (Flow rate 2,7 dm<sup>3</sup> s)

### Applications

Product	EN 149:2001 +A1:2009 Classification	Maximum Workplace Exposure Limit (WEL)*
A-267	<b>FFP2 NR D</b>	<b>12</b>
A-267V	<b>FFP2 NR D</b>	<b>12</b>

\*Many countries apply Assigned Protection Factors (APFs) which reduce the maximum concentrations of particles in which these products can be used. See national regulations and EN 529:2005.

### Materials

Straps	: Latex Free TPE
Nose Clip	: Steel is planting with zinc
Filter	: Polypropylene
Layers	: Polypropylene
Valve	: Polypropylene
Valve Diaphragm	: TPE

### Approval

Our disposable particulate respirators has been tested and certificated by the BSI, Notified Body of the European Community (Number 0686). The filtering half masks produced true the relevant EU regulation EU 2016/425, standards from EN 149: 2001 + A1: 2009 FFP2 NR D and CE marked.

### Designations:

NR = Non Reusable (Single Shift Use Only)

D = Meets The Clogging Resistance Requirements

### Certificates

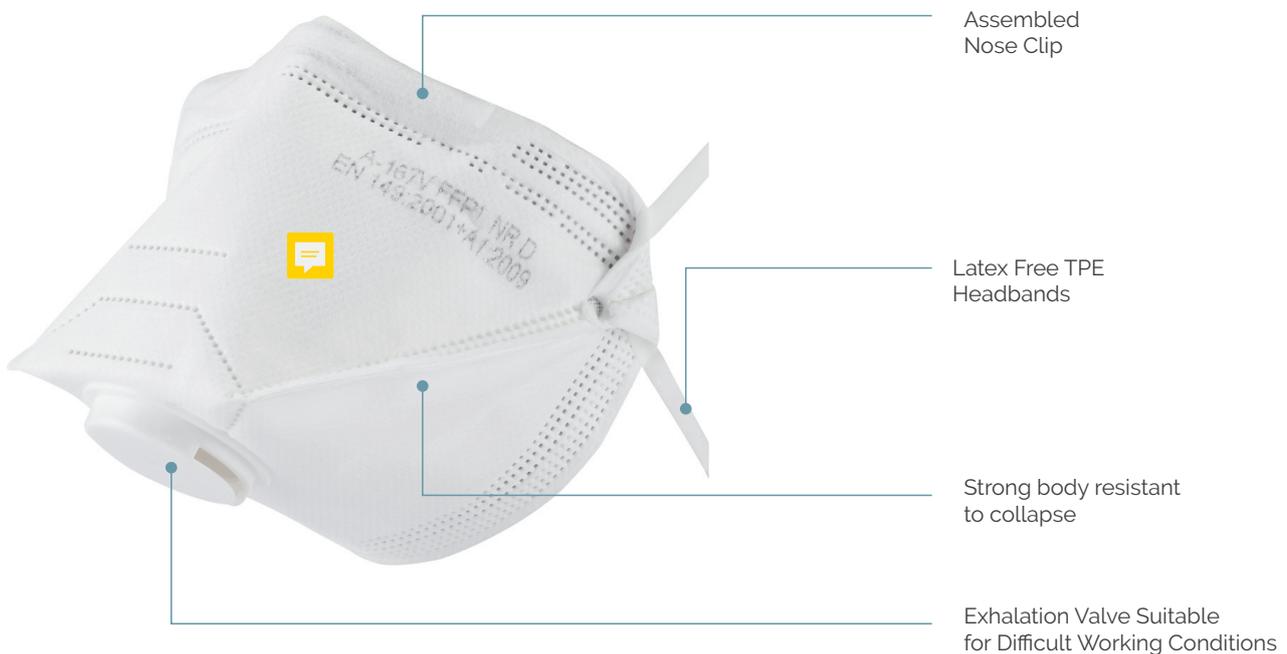
EN 149:2001+A1:2009 NR D  
 ISO 9001:2008 Quality Management System  
 ISO 13485:2003 Medical Devices Quality Management System

**MFA A-267 and A-267V**  
**DISPOSIBLE PARTICULATE RESPIRATORS**  
Respiratory Mask for Protection Against  
Low Level Hazardous Solid and Water Based Aerosols  
**Class: FFP2**



**TRADITIONAL CHOICE IN RESPIRATORY PROTECTION**

Our A-Series products offered by MFA to the market for the workers with a conventional design habit are user-friendly indeed. Thanks to its special filter technology, it filters above the standard and allow you to breathe fresh air filtering the airborne risks. Its special thermal bonding layer gives it a reinforced body that is resistant to deformation, perspiration-related problems and collapse.



Specially positioned nose clip does not pose any rupturing or dislocation risk or related injury risk. It maintains its features even after repeated usage.

Its special thermal bonding layer gives it a reinforced body that is resistant to deformation, perspiration-related problems and collapse.

Non-allergic, rupture-resistant, latex-free TPE headbands are used.

The set created in the inner mechanism of the exhalation valve prevents possible problems of moisture and dust accumulation. It works very efficiently thanks to its oval structure and the angle of seal. It provides coolness and comfort.

It is suitable for use with the other Personal Protective Equipment such as helmets, safety glasses and ear protection.

\* Passed dolomite dust test. It provides protection for minimum 8 hours

**WHAT IS DOLOMITE DUST TEST?**

This is an optional performance test defined in EN 149: 2001+A1:2009 standard. It demonstrates that the mask provides efficient protection for minimum 8 hours. The masks passing this test bear "D" marking (e.g. FFP2 D). Choose the masks with "D" marking while purchasing them and make sure that your mask can be used safely for minimum 8 hours.



## MFA A-267 and A-267V

### DISPOSIBLE PARTICULATE RESPIRATORS

Respiratory Mask for Protection Against  
Low Level Hazardous Solid and Water Based Aerosols  
**Class: FFP2**

## TECHNICAL DATASHEET

### Fitting Instructions

Before fitting the respirator, ensure hands are clean. With reverse side up and using the tab, separate top and



- Hold the respirator in hand with the nose-piece at your fingertips. Allow headbands to hang freely below hand.
- Cup the respirator firmly against your face with the nosepiece on the bridge of your nose.
- Stretch and pull the lower headband over the head and position below your ears. Stretch and pull the top headband on the back of your head above your ears
- Press soft nosepiece to conform snugly around the nose.
- To test fit for respirator without exhalation valve: cup both hands over the respirator and inhale sharply. A negative pressure should be felt inside respirator. If air flows around your nose, tighten the nosepiece. If air leaks around the edges, reposition the headband for better fit.

**IMPORTANT:** As with the use of any respiratory device, the wearer must first be trained in the proper use of the product. Change respirator immediately if breathing becomes difficult or respirator becomes damaged or distorted, or a proper face fit cannot be maintained. Careful observance of these instructions is an important step in safe respirator use.

### CONTROLS BEFORE USAGE

- Before use, read the instructions carefully
- Check the date of the end of shelf life
- Check the suitability of the mask to the area where used, looking at the signs on the mask.
- Check the head bandages of the mask.
- Check the nose clips of the mask.
- Check the mask if there is a damage or not before use.

### Fit Check

Cover the front of the respirator with both hands being careful not to disturb its fit.

(a) UNVALVED respirator - EXHALE sharply

(b) VALVED respirator - INHALE sharply.

If air leaks around the nose, re-adjust the nose clip to eliminate leakage. Repeat the above fit check.

If air leaks at the respirator edges, work the straps back along the sides of the head to eliminate leakage. Repeat the above fit check.

If you CANNOT achieve a proper fit DO NOT enter the hazardous area. See your supervisor.

Users should be fit tested in accordance with national requirements.



## MFA A-267 and A-267V

### DISPOSIBLE PARTICULATE RESPIRATORS

Respiratory Mask for Protection Against  
Low Level Hazardous Solid and Water Based Aerosols  
**Class: FFP2**

#### TECHNICAL DATASHEET

#### Warning and Use Limitations

1. Failure to follow all instructions and limitations on the use of this product could reduce the effectiveness of respirator and result in sickness or death.
2. A properly selected respirator is essential to protect your health. Before using this respirator, consult an Industrial Hygienist or Occupational Safety Professional to determine the suitability for your intended use.
3. This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this respirator when oxygen concentration is less than 19%.
4. Do not use when concentrations of contaminants are immediately dangerous to health or life.
5. Do not use explosive atmospheres.
6. Leave work area immediately and return to fresh air if (a) breathing becomes difficult, or (b) dizziness or other distress occurs.
7. Facial hairs or beards and certain facial characteristics may reduce the effectiveness of this respirator.
8. Never alter or modify this respirator in any way.
9. NR - Only for single use. No maintenance necessary. Discard the used respirator after single use.
10. Keep respirators in the display box away from direct sunlight until use.

#### MARKING:



#### STORAGE

- Must be kept in their original package.
- In the storage area, temperature must be between  $-20\text{ }^{\circ}\text{C} / +40\text{ }^{\circ}\text{C}$
- Moist must not be more than % 80.
- If kept under these conditions, shelf life is 5 years.

#### PACKAGING DETAILS

##### ECO PACKING

Model	Pcs in Box	Pcs in Carton	Carton Size	Carton Weight
A-267	120	960	55x55x35 cm	Ask MFA
A-267V	60	480	55x55x35 cm	Ask MFA

##### SPEC. PACKING

Model	Pcs in Box	Pcs in Carton	Carton Size	Carton Weight
A-267	90	720	55x55x35 cm	Ask MFA
A-267V	45	360	55x55x35 cm	Ask MFA

#### SYMBOLS AND PICTOGRAMS

 End of Shelf Life	 Storage Temperature Range	 Storage Maximum Relative Humidity
 Read User Information	 Caution	