

HAS GROUP



nefes
MASKE

ZAŠTITNE
MASKE



nifes
MASKE

**ZAŠTITNE
MASKE**

JEDNOKRATNE MASKE

- Ne iritiraju uši, mekane i uske gumice;
- Ultrasonično šivene;
- Ugodne za korištenje sa elastičnom gumom;
- 3 sloja nonwoven materijala uz dodatak žice za nos;
- Ne sadrže paraben;
- Ne sadrže najlon;
- Ne sadrže hlor;

- Ne sadrže latex;
- Ne izazivaju alergiju;
- Pakovanje 50/1.



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MASKE

**ZAŠTITNE
MASKE**

**FFP2
(NR MASKE)**



- Posjeduju CE i ISO certifikate;
- Meltblown platno sa visokim stepenom filtracije;
- Ultrasonično šivene;
- Ugodne za korištenje sa elastičnom gumom;
- 5 slojeva materijala uz dodatak žice za nos;
- Ne sadrže paraben;
- Ne sadrže najlon;
- Ne sadrže hlor;
- Ne sadrže latex;
- Ne izazivaju alergiju.



PAKOVANJE SADRŽI 10 KOMADA | SVAKA MASKA ZASEBNO PAKOVANJE

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MASKE

**ZAŠTITNE
MASKE**

**FFP3
(NR MASKE)**

- Posjeduju CE i ISO certifikate;
- Meltblown platno sa visokim stepenom filtracije;
- Ultrasonično šivene;
- Ugodne za korištenje sa elastičnom gumom;
- 5 slojeva materijala uz dodatak žice za nos;
- Ne sadrže paraben;
- Ne sadrže najlon;
- Ne sadrže hlor;
- Ne sadrže latex;
- Ne izazivaju alergiju.



PAKOVANJE SADRŽI 10 KOMADA | SVAKA MASKA ZASEBNO PAKOVANJE

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MASKE

**ZAŠTITNE
MASKE**

**FFP2 MASKE
(F95 TIP)**

- Posjeduju CE i ISO certifikate;
- Meltblown platno sa visokim stepenom filtracije;
- Ultrasonično šivene;
- Ugodne za korištenje sa elastičnom gumom;
- 4 sloja materijala uz dodatak žice za nos;
- Ne sadrže paraben;
- Ne sadrže najlon;
- Ne sadrže hlor;
- Ne sadrže latex;
- Ne izazivaju alergiju.



PAKOVANJE SADRŽI 10 KOMADA | SVAKA MASKA ZASEBNO PAKOVANJE

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MASKE**EU Declaration of Conformity**

This declaration of conformity has been prepared in accordance with the terms and requirements of the European Regulation (EU) 2016/425 on personal protective equipment.

Manufacturer:

Nokta Textile Products Industry and Trade Limited Company
Office:M. Nezir Özmen Mah. Zafer Cad. Kayalık Sok. No: 27 / A
34160 Merter-Istanbul / Turkey
Phone: +90 212 63 73755
Fax: +90 212 63 73755
Factory: Nefes Mask ,15 Temmuz Mh. Gülbahar Cad. 1498. Sok. No:24 Kat:2
34212 Güneşli-Istanbul/Turkey

We, the manufacturers, certify that the product listed below meets the requirements of the (EU) 2016/425 Personal Protective Equipment Directive.

Product: Breathing mask FFP3 NR without breathing valve, FFP2 NR, FFP3 with breathing valve.

Brand Name: N'FES, NEFES MASK
Model: N'FES 99, N'fes 95, N'fes 99 V.
Classification: FFP3 NR, FFP2

The manufacturer guarantees that all necessary measures have been taken to ensure that the manufacturing process and monitoring is in conformity with the type described in the EU type examination certificate of the PPE produced and with the applicable requirements of this regulation.

CE marking and EU declaration of conformity

3.1 The manufacturer has affixed the CE marking to each PPE that corresponds to the type described in the EU type examination report certificate and meets the applicable requirements of this regulation.

3.2 The manufacturer has issued a written EU Declaration of Conformity for each PPE model and will make it available to national authorities for ten years after the PPE is placed on the market. The EU declaration of conformity indicates for which PPE it has been issued.

A copy of the EU declaration of conformity will be provided to the responsible authorities on request.

Conformity according to Regulation (EU) 2016/425 and EN standard EN 149: 2001 + A1: 2009 has been verified by an officially notified testing body.

Universal Conformity Assessment Services and Trade Co.
Tatlısu Mah. Arif Ay sk. No: 16-3 Ümraniye-Istanbul / TURKEY
Ümraniye-Istanbul / TURKEY
Country: Turkey
Telephone: +90 216 455 80 80
Fax: +90 216 455 80 08
Email: info@universalcert.com
Website: www.universalcert.com
Notified Body number: 2163
Checked and provided.

nefes MASKE

As part of the 17 December 2020 exam, the "EU Type Examination Certificate" was awarded with the certificate number 2163-PPE-1810, Model name is N'fes 99.

As part of the 15 October 2020 exam, the "EU Type Examination Certificate" was awarded with the certificate number 2163-PPE-1572, Model name is N'fes 95.

As part of the 01 December 2020 exam, the "EU Type Examination Certificate" was awarded with the certificate number 2163-PPE-1728, Model name is N'fes 99 V.

In summary:

With this document, the manufacturer declares and warrants that the product listed here meets the European requirements according to Regulation 2016/425 and assumes full responsibility for it.

Responsible for this notification:

Manufacturer / Company: Nokta Tekstil Ürünleri Sanayi Ticaret Limited Sirketi

Surname, Name: SARUHAN, Okan Gürol

Position: General Manager

Publication Date: December 17, 2020

Istanbul, 17 December 2020

Okan Gürol Saruhan

NOKTA TEKSTİL ÜRÜNLERİ SAN. VE TİC. LTD. ŞTİ.
M. Nesir Ömer Saruhan Caddesi Kat: 3
Sakarya Bulvarı, Çarşı Çarşı Çarşı
Etiler V.D. 6310539400

CERTIFICATE

CERTIFICATE CERTIFICATE OF REGISTRATION

Bu sertifikaya aşağıdaki kuruluşa
This certificate has been awarded to the company

NOKTA TEKSTİL ÜRÜNLERİ TURİZM İNŞ.SAN.VE DIŞ TİC.LTD.ŞTİ.

**Merkez:Mehmet Nesih Özmen Mah. Zafer Cad.
Kayacık Sok.No:27/A Merter-GÜNGÖREN/İSTANBUL
Fabrika:15 Temmuz Mah. Gülbahar Cad. 1498
Sok. No:24 BAĞCILAR/İSTANBUL**

Uygulanmakta olan Kalite yönetim sisteminin
To certify that the implemented Quality
management system complies with

ISO 9001:2015

Standardına uygunluğunu belgelendirmek amacı ile
aşağıdaki kapsamda verilmiştir.
For the activities described below

**TEK KULLANIMLIK YÜZ KORUYUCU CERRAHİ MASKE.N95 KİŞİSEL
KORUYUCU EKİPMAN MASKESİ,TIBBİ ORTAMLAR İÇİN TEKSTİL ÜRÜNLERİ
ÜRETİMİ,TRİKO ÜRETİMİ VE SATIŞI,KUMAŞ,İPLİK VE TEKSTİL AKSESUAR ALIMI
VE SATIMI**

**DISPOSABLE FACE PROTECTIVE SURGICAL MASK.N95 PERSONAL PROTECTIVE
EQUIPMENT MASK, TEXTILE PRODUCTS PRODUCTION,KNITWEAR PRODUCTION
AND SALE FOR MEDICAL ENVIRONMENTS,PRODUCTION AND SALE OF
KNITWEAR,PURCHASE
AND SALE OF FABRIC,YARN AND TEXTILE ACCESSORIES**

Sertifika No. / Certificate No.:	202091460
İlk Belgelendirme Tarihi / Initial Certification Date:	04.09.2020
Sertifika Tarihi / Date of Certificate:	04.09.2020
Bitiş Tarihi / Expiry Date:	03.09.2021
Belgelendirme Periyodu / Certification Period:	3 Yıl / Years



[Signature]
Türcert A.Ş.

Belgelendirme Bölümü Adına
04.09.2020

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME ANONİM ŞİRKETİ

Merkez Mh, Gençosman Cd No11/A Güngören - İstanbul / Türkiye
Tel: + 90 212 702 40 00 Tel: + 90 312 500 00 10 web: www.turcert.com

Bu belge müşterinin TÜRCERT in kurallarına ve sözleşme şartlarına uydugu sürece geçerlidir.
This certificate is valid during the customer obeys the rules TÜRCERT procedures and agreements





UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1572

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Nokta Tekstil Ürünleri Sanayi Ticaret Limited Şirketi

15 Temmuz Mah. 1498. Sok. No:24 K:2-3 Bağcılar İstanbul TURKEY

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices -
Filtering Half Masks to Protect Against Particles -
Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: NFES

Model: N'FES 95

Filtering half mask

Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **15/10/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director



UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1810

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Nokta Tekstil Ürünleri Sanayi Ticaret Limited Şirketi

15 Temmuz Mah. 1498. Sok. No:24 K:2-3 Bağcılar / İstanbul TURKEY
are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices -
Filtering Half Masks to Protect Against Particles -
Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Single use particle filtering half mask for protection against solid and liquid aerosols, is a folding shape, 5 layered, without valve, ear straps.

Brand Name: NFES

Model: N'fes 99

Classification: FFP3 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2)** or **Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 17/12/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



ATTESTATION OF CONFORMITY

Certificate Nr: MDD-290

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Commission directive 2007/47/EEC amending Medical Devices Directive dated 05 September 2007,

the products manufactured by

NOKTA TEKSTİL ÜRÜNLERİ SANAYİ TİCARET LİMİTED ŞİRKETİ

at the following address

15Temmuz Mah. 1498. Sok. No:24 K:2-3 Bağcılar İSTANBUL/ TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: NFES

Model: NFES II

Type IIR

are tested according to the following initial type tests by the manufacturer

Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

For the assessment of conformity, the following documents were also applied to:
Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Bacterial Filtration Efficiency, Microbial Cleanliness, Differential Pressure and Splash Resistance Pressure tests.

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table 1) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 23/10/2020 and valid until 22/10/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

İSTANBUL – 23/10/2020



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager



Verify the validity with the QR Code

HAS GROUP

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