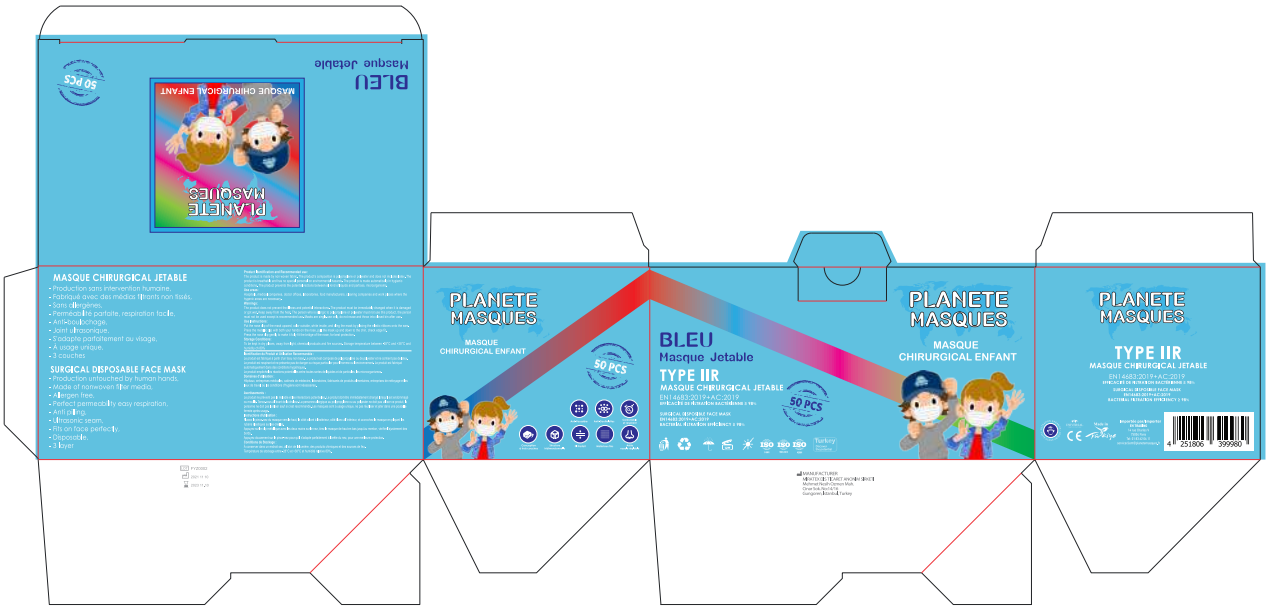
MASQUE MÉDICAL ENFANT TYPE IIR NORME EN14683 CERTIFIÉ CE Couleur BLEU

NORME EN14683 : 2019

CERTIFIÉ CE

PHOTO


BLEU
Masque Jetable
50 PCS
MASQUE CHIRURGICAL ENFANT
PLANETE MASQUES
MASQUE CHIRURGICAL JETABLE
SURGICAL DISPOSABLE FACE MASK
PLANETE MASQUES
MASQUE CHIRURGICAL ENFANT
BLEU
Masque Jetable
TYPE IIR
MASQUE CHIRURGICAL JETABLE
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Masque Jetable
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PLANETE MASQUES
MASQUE CHIRURGICAL ENFANT
50 PCS

DESCRIPTIF

- **Masque médical non tissé (70%) et tissu fondu (30%)**
- **3 couches de protection**
- **Taille 14,5cm x 9,5cm**
- **Fixation par boucles élastiquées**
- **Efficacité de filtration bactérienne >98 %**
- **Couleur bleue**

Conditionnement

- Carton de 3 600 masques
- 72 boites de 50 masques (1 sachet de 50 masques)
- Poids par carton 11,90 kg
- Dimension :
  Hauteur : 520 mm
  Largeur : 420 mm
  Longueur : 600 mm

Palette de 12 cartons (43 200 masques)
Hauteur 165 cm

Palette de 16 cartons (57 600 masques)
hauteur 220 cm

Palette de 20 cartons (72 000 masques)
Hauteur 270 cm

Certificat de conformité

UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-257

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 Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

TANKOÇ TEKSTİL ELEKTRİK MALZ. SANAYİ VE TİCARET LİMİTED ŞİRKETİ

at the following address

Mehmet Akif Mah. Şahinbey Cad. No: 51/A Çekmeköy ISTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: TANKOÇ
Model: TANKOÇ-01
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 11/09/2020 and valid until 10/09/2021 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.

ISTANBUL –11/09/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

EU DECLARATION OF CONFORMITY

MANUFACTURER
TANKOÇ TEKSTİL ELEKTRİK MALZ. SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Mehmet Akif Mah. Şahinbey Cad. No: 51/A Çekmeköy ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name: TANKOÇ
Model: TANKOÇ-01
Type IIR

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Bavterial filtration efficiency
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Differential Pressure
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

General Manager
11/09/2020

CE

CERTIFICATE OF COMPLIANCE

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

Related Directives :

MEDICAL DEVICES 93/42/EEC---------TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Class / Sınıf: CLASS 1 / SINIF 1, NON STERILE

Description of Product :
DISPOSABLE FACE MASK
TEK KULLANIMLIK YÜZ MASKESİ

Product Model: TYPE 2 R

Annex:
Annex 7 Declaration of conformity / EK 7 Uygunluk Beyanı

Regulations Applied acc. To Harmonized Standards:
EN 14683+AC:2019 - EN ISO 14971:2020 EN ISO 15223-1:2016

Trade Mark:

TANKOC TEKSTIL

Manufactured by

TANKOÇ TEKSTİL ELEKTRİK MALZEMELERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ
MEHMET AKİF MAH. ŞAHİNBEY CAD. NO: 51 / A ÇEKMEKÖY / İSTANBUL / TÜRKİYE

CE

Certificate No.: SISTUECE0620201281
Issue Date (Original): 19.06.2020
Issue Date(Latest): 31.08.2021
Expiry Date: 18.06.2022

This Certificate is issued under the following conditions:

1.It applies only to the above referenced models of the medical devices.
2.It does not imply that the SIS has performed any surveillance or control of their manufacture.
3.The manufacture is obligated to assure conformity of all in medical devices of the respective model to type assessed by the mean of this certificate.
4.The certificate remains valid until the manufacturing condition, the quality system or relevant legislation are changed .
5.After fulfilling of the relevant EU legislation requirements, the manufacture shall affix to each medical device, of the above referenced models, the CE-marketing according to this example:

Managing Director

SIS CERTIFICATIONS PVT. LTD.

Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Compliance is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid

Corporate office(SIS): Unit No. 514, 5th Floor, Vipul Business Park, Sohna Road, Sector-48, Gurgaon-122018, Haryana, India.
International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047.
Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91 99105 01396, + 91 96430 73391
The status of this certificate can be verified on "http://www.siscertifications.com/verify/"
Web:- http://www.siscertifications.co.in, www.siscertifications.com

Issue No.: **02**

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We Do Not Sell, We Certify!

Certificat ISO 9001 Usine

CERTIFICATE

TANKOÇ TEKSTİL ELEKTRİK MALZEMELERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MEHMET AKİF MAH. ŞAHİNBEY CAD. NO:51/A
ÇEKMEKÖY / İSTANBUL / TÜRKİYE

Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 9001:2015

The Quality Management System is applicable to:
Kalite Yönetim Sistemi:

PRODUCTION AND SALES OF DISPOSABLE FACE MASKS, PROTECTIVE OVERALLS AND PERSONAL MEDICAL PROTECTIVE PRODUCTS

TEK KULLANIMLIK YÜZ MASKESİ, KORUYUCU TULUM VE KİŞİSEL MEDİKAL KORUYUCU ÜRÜNLERİN ÜRETİMİ VE SATIŞI

Certificate Number: QMS-0101244
Belge Numarası: QMS-0101244

Initial Certification Date: 28.08.2021
İlk Belgelendirme Tarihi: 28.08.2021

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 27.08.2022
Belge Geçerlilik Tarihi: 27.08.2022

IQR Sertifikasyon Onayı

IAS ACCREDITED Management Systems Certification Body MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com

Rapport de Test

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TEST REPORT
DENEY RAPORU

TÜRKAK
AB-0583-T
20031655-ing
09-20

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM TİC. LMT. ŞTİ.
Address:	NECİP FAZIL BULVARI KEYAP SİTESİ E2 ÜMRANİYE/İSTANBUL
Buyer name:	TANKOÇ TEKSTİL ELEKTRİK MALZ. SANAYİ VE TİC. LTD..
Contact Person:	-
Order No:	-
Article No:	-
Name and identity of test item:	White non woven mask .
The date of receipt of test item:	01.09.2020
Re-submitted/re-confirmation date:	-
Date of test:	01.09.2020-10.09.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not specified.
Number of pages of the report:	5

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.
The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS	10.09.2020	Servin [illegible]SEVEN	Sevim A. RAZAK 10.09.2020

This report shall not be reproduced other than in full except with the permission of the laboratory.
Testing reports without signature and seal are not valid.

Gen.f136-2/03

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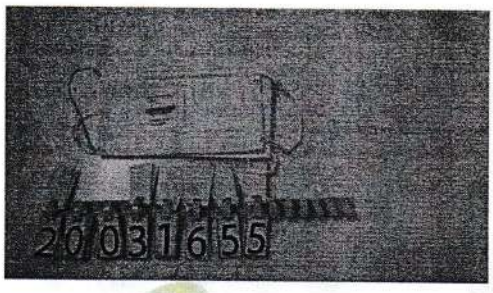
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20031655-ing
09-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	
Microbial Cleanliness(Bioburden)	P	
PHYSICAL PROPERTIES TESTS		
Breathability(Differential Pressure)	P	
Blood Splash	P	**TIP IIR**

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 14683:2019+AC :2019 Table/1 limit values.

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.



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EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20031655-ing
09-20

TEST RESULT
Medical face masks - Requirements and test methods EN 14683:2019+AC:2019 (TS EN 14683+AC:2019)

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)
A specimen of the mask material is clamped between a impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Flow Rate	28,3 L/min
Total Test Flow Time	2 minute
Sample Sizes	30 pieces mask
Test Alanı	4.9 cm^2 (5 replicas)
Test Condition	(21 ± 5) °C and (85 ± 5) % relative humidity, 4 hours
Test Microorganism	*Staphylococcus aureus* ATCC 6538
Bacterial concentration (cfu/ ml)	$5x10^5$ cfu/ ml
incubation conditions	24 hour, 35°C ± 2°C
Positive control sample average of number of Bacteria (C)	$1.93x10^3$ cfu/ ml
Mean particle size (MPS)	3.0µm

Gen.f136-2/03

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	37	%98.1	**Type I ≥95** **Type II ≥98**
2	36	%98.1	
3	39	%98.0	
4	30	%98.4	
5	34	%98.2	

cfu: Colony-forming unit
B= (C-T) / C x 100
%B: Bacterial Filtration Efficiency
C: is the mean of the total plate counts for the two positive control runs
T: is the total plate count for the test specimen

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20031655
09-20

TEST SONUÇLARI
BASINÇ FARKI (NEFES ALABİLİRLİK)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)

Test Kondüsyon koşulu ve süresi: (21 ± 5) °C ve (85 ± 5) % bağıl nem, 4 saat
2,5 cm çaplı 5 farklı deney numunesi alınır.
8 l/dk hava akışı uygulanır.
Fark Basınç Manometresi üzerinden okunan basınç farkı değeri Pa (Pascal) olarak kayıt edilir.

NUMUNE	BASINÇ PARKI SONUÇ	İSTENEN
1	25.7 Pa/cm^2	< 40 Pa/cm^2 Tip I ve Tip II maske
2	23.6 Pa/cm2	
3	26.6 Pa/cm2	
4	21.6 Pa/cm2	
5	22.0 Pa/cm2	
Ortalama Sonuç	23.9 Pa/cm2	

Gen.Fl36-1/03

MİKROBİYAL TEMİZLİK (BİYOYÜK)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019)
EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018

5 numune çalışılır. Numune tartılır ve test çözeltisi içerisine atılarak iyice çalkalanır (250 rpm de 5 dk) ve uygun besiyerlerine ekilir. Toplam aerobik bakteriler için 30±1°C'de 72 saat, küf ve maya için ise 20-25 °C'de 7 gün inkübasyon sonrası agarda oluşan mikroorganizmalar sayılır ve toplam sonuç verilir.Ortalama sonuç verilir.

	SONUÇ	İSTENEN
Mikrobiyal Temizlik (kob/gr)	18 kob/gr	≤30 kob/gr Tip I ve Tip II maske

**kob:Koloni oluşturan birim*

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20031655
09-20

TEST SONUÇLARI
KAN SIÇRAMA DİRENCİ

Test Metodu: EN 14683:2019+AC :2019 (Madde 5.2.4) (*) tıbbi yüz maskesinin sıvı sıçramalarına nüfuz etmesine karşı direnç

ISO 22609 :2004 Giysilerin enfekte edici ajanlara karşı koruma - Tıbbi yüz maskeleri - Sentetik kanın nüfuz etmesine karşı direnç için test yöntemi (sabit hacim, yatay olarak yansıtılmış)

Test Kondüsyon koşulu ve süresi: (21 ± 5) °C ve (85 ± 5) % bağıl nem, 4 saat
6 farklı deney numunesi alınır.

NUMUNE	SIÇRAMA DİRENCİ BASINCI (kPa)	SONUÇ	İSTENEN
1	>21.3 kPa	GEÇER	≥16 kPa Tip IIR maske
2	>21.3 kPa	GEÇER	
3	>21.3 kPa	GEÇER	
4	>21.3 kPa	GEÇER	
5	>21.3 kPa	GEÇER	
6	>21.3 kPa	GEÇER	
Ortalama Sonuç	>21.3 kPa	GEÇER	

Gen.f136-1/03