UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD-176

CANBEY TEKSTİL İNŞAAT VE ELEKTRONİK SANAYİ TİCARET LİMİTED ŞİRKETİ
İOSB Mahallesi Eski Turgut Özal Caddesi Altıntaç İş Merkezi B:308 Başakşehir İstanbul / TURKEY

The manufacturer's technical documentation (Dated 28.08.2021), manufacturing facilities and the product, identified below, found to meet the applicable requirements of Regulation (EU) 2017/745 for Class I devices, including the General Safety and Performance Requirements in Annex I of the regulation based on assessment results and evaluation of relevant test reports.

Identification of the Product
Brand Name: CANBEY, **Model:** 3448 **UDI-DI Number**: 86829523448YZ
Classification: Type IIR

Medical masks, as a medical device, manufactured from spunbound and meltblown fabrics, with ear loops and nose bridge. The mask is available in 1 size and have white, blue, green and black colour variants.

The following harmonised standards have been applied:

EN 14683+AC:2019, Medical face masks - Requirements and test methods.

This certification is based on the voluntary scheme for verification of obligations fulfilled by the manufacturer according to Class I product requirements defined in the medical device regulation EU 2017/745 to fix the CE mark on the product, identified above. The manufacturer shall also issue an appropriate EU Declaration of Conformity according to Medical Devices regulation (EU) 2017/745 Annex IV.

This certificate is initially issued on **08/07/2020**, will be valid until **15/12/2021**, without any change in the design and manufacturing process of the product.

İSTANBUL – 14.09.2021

CE

Verify the validity with the QR Code

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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
CANBEY TEKSTİL İNŞAAT VE ELEKTRONİK SANAYİ TİCARET LİMİTED ŞİRKETİ
Oruçreis Mahallesi Vadi Caddesi Giyimkent Sitesi B171 Blok Apt. No:176 Esenler
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

Branda Name: CANBEY **Model**: 3448
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 Çevre Endüstriyel Testing Laboratory Bavterial filtration efficiency
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Differential Pressure
- Results of laboratory tests Çevre Endüstriyel 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.

Abdullah CANBEY
General Manager
08/07/2020

CE

EU Declaration of Conformity

1. **Product model:** TYP IIR

2. **Name and address of the manufacturer or his authorised representative:**

CANBEY TEKSTİL İNŞ VE ELEKTRONİK SAN.TİC.LTD.ŞTİ
İOSB MH ESKİ TURGUT ÖZAL CD.ALTINTAÇ İŞ MERKEZİ NO:308 BAŞAKŞEHİR İSTANBUL
34490
0212 510 85 30
medikal@canbey.com

3. **This declaration of conformity is issued under the sole responsibility of the manufacturer.**

4. **Object of the declaration:**

Equipment: Spunbond and Meltblown
Brand name: CANBEY
Model/type: 3448
3 player 75- 80 gr

5. **The object of the declaration described above is in conformity with the relevant Union harmonization legislation:**

Fill in the directives and regulations that apply to the equipment, e.g.
Low Voltage Directive (LVD) 2014/35/EU,
Electromagnetic Compatibility Directive (EMC) 2014/30/EU,
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU,
Ecodesign Directive 2009/125/EC and
Commission Regulation (EU) No xx/xx regarding ecodesign reguirements for xxxx

6. **References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:**

LVD: Fill in one below the other the LVD standards that have been applied, e.g.
EN 60335-2:2012
EN 60335-2-7:2010

EMC: Fill in one below the other the EMC standards that have been applied, e.g.
EN 55014-1:2006 + A1:2009 + A2:2011
EN 55014-2:1997 + A1:2001 + A2:2008

RoHS: Fill in one below the other the RoHS standards that have been applied, e.g.
EN 50581:2012

xxx Fill in other possible standards and declarations

7. **Signed for and on behalf of:**

19.04.2021

CANBEY TEKSTİL İNŞ VE ELEKTRONİK SAN.TİC.LTD.ŞTİ

CANBEY TEKSTİL
İNŞAAT VE ELEKTRONİK SAN. TİC. LTD. ŞTİ.
İkitelli Org.Sa. Bölgesi Mah. Eski Turgut Özal Cad
No:6 Blok No:308 Altıntaç İş Merkezi
Başakşehir/İSTANBUL Tel:0212 510 85 30
Tel: 0212 510 38 61 Fax: 0212 458 58 20
İkitelli V.D. 199 028 4837 Tic.Sic.512491

MANAGER:ABDULLAH CANBEY

EU-försäkran om överensstämmelse

1. **Produktmodell: TYP IIR**

2. **Namn på och adress till tillverkaren eller dennes representant:**

CANBEY TEKSTİL İNŞ VE ELEKTRONİK SAN.TİC.LTD.ŞTİ
İOSB MH ESKİ TURGUT ÖZAL CD.ALTINTAÇ İŞ MERKEZİ NO:308 BAŞAKŞEHİR İSTANBUL
34490
0212 510 85 30
medikal@canbey.com

3. **Denna försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar.**

4. **Föremål för försäkran:**

Typ av utrysning: Spunbond and Meltblown
Varumärke: CANBEY
Typbeteckning: 3448
3 player 75-80gr

5. **Föremålet för försäkran ovan överensstämmer med den relevanta harmoniserade unionslagstiftningen:**

Fyll i de direktiv och förordningar som tillämpas på produkten, t.ex.
lågspänningsdirektivet (LVD) 2014/35/EU,
direktivet om elektromagnetisk kompatibilitet (EMC) 2014/30/EU,
direktivet om begränsning av användning av farliga ämnen (RoHS) 2011/65/EU,
direktivet om krav på ekodesign för energirelaterade produkter 2009/125/EG och
kommissionens förordning (EU) nr xx/xx vad gäller krav på ekodesign för xxx

6. **Hänvisningar till de relevanta harmoniserade standarder som använts eller hänvisningar till de andra tekniska specifikationer enligt vilka överensstämmelsen försäkras:**

LVD: Fyll i under varandra de LVD-standarder som använts, t.ex.
EN 60335-2:2012
EN 60335-2-7:2010

EMC: Fyll i under varandra de EMC-standarder som använts, t.ex.
EN 55014-1:2006 + A1:2009 + A2:2011
EN 55014-2:1997 + A1:2001 + A2:2008

RoHS: Fyll i under varandra de RoHS-standarder som använts, t.ex.
EN 50581:2012

xxx Fyll i eventuella övriga standarder och deklarationer

7. **Undertecknat för:**

19.04.2021
Tillverkare/Tillverkarens representant (välj det alternativ som du representerar)
CANBEY TEKSTİL İNŞ VE ELEKTRONİK SAN.TİC.LTD.ŞTİ

CANBEY TEKSTİL
İNŞAAT VE ELEKTRONİK SAN. TİC. LTD. ŞTİ.
İkitelli Org.San.Böl. Mah. Eski Turgut Özal Cad.
No:6 B Blok K:308 Altıntaç İş Merkezi
Başakşehir/İSTANBUL Tel:0212 510 85 30
Tel: 0212 516 38 61 Fax: 0212 458 58 20
İkitelli V.D. 199 028 4837 Tic.Sic.512491

MANAGER:ABDULLAH CANBEY

EU-vaatimustenmukaisuusvakuutus

Tuotteen tunnistenumero: TYP II R

1.

2. **Valmistajan tai sen valtuutetun edustajan nimi ja osoite:**
CANBEY TEKSTİL İNŞ VE ELEKTRONİK SAN. TİC. LTD. ŞTİ
İOSB MH ESKİ TURGUT ÖZAL CD. ALTINTAÇ İŞ MERKEZİ NO:308 BAŞAKŞEHİR İSTANBUL
34490
medikal@canbey.com

3. **Tämä vaatimustenmukaisuusvakuutus on annettu valmistajan yksinomaisella vastuulla.**

4. **Vakuutuksen kohde:**
Tuote: Spunbond and Meltblown
Tuotemerkki: Canbey
Malli/tyyppi: 3448
3 player 75-80 gr

5. **Edellä kuvattu vakuutuksen kohde on asiaa koskevan unionin yhdenmukaistamislainsäädännön vaatimusten mukainen:**
(LVD) 2014/35/EU,
(EMC) 2014/30/EU,
(RoHS) Directive 2011/65/EU,
Ecodesign Directive 2009/125/EC and

6. **Viittaus niihin asiaankuuluviin yhdenmukaistettuihin standardeihin, joita on käytetty, tai viittaus muihin teknisiin eritelmiin, joiden perusteella vaatimustenmukaisuusvakuutus on annettu:**

LVD: EN 60335-2:2012
EN 60335-2-7:2010

EMC: EN 55014-1:2006 + A1:2009 + A2:2011
EN 55014-2:1997 + A1:2001 + A2:2008

RoHS: EN 50581:2012

7. **[Tarvittaessa] Ilmoitettu laitos [yksilöinti] suoritti [toimenpiteen kuvaus] ja antoi todistuksen:**

19.04.2021
CANBEY TEKSTİL

CANBEY TEKSTİL
İNŞAAT VE ELEKTRONİK SAN. TİC. LTD. ŞTİ.
İkitelli Org.San.Bölgesi Mah. Eski Turgut Özal Cad
No:6 B Blok No:308 Altıntaç İş Merkezi
Başakşehir/İSTANBUL Tel:0212 510 85 30
Tel: 0212 516 88 61 Fax: 0212 458 58 20
İkitelli V.D./199 028 4837 Tic.Sic.512491

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

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
21025991 -ing
09-21

Customer name:	CANBEY TEKSTİL İNŞAAT ELEKTRONİK SAN.TİC.LTD.ŞTİ.
Address:	İKİTELLİ ORG.SAN.BÖLG.MAH. ESKİ TURGUT ÖZAL CAD. NO:6 B BLOK NO:308 ATLINTA. İŞ MERKEZİ
Buyer name:	-
Contact Person:	-
Order No:	-
Article No:	3448
Name and identity of test item:	White non woven mask (Claimed to be;200 Pieces Color:White)
The date of receipt of test item:	27.08.2021
Re-submitted/re-confirmation date:	-
Date of test:	27.08.2021-06.09.2021
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	-
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*
	06.09.2021	Servin YURTSEVEN	Sevim A. RAZAK 06.09.2021

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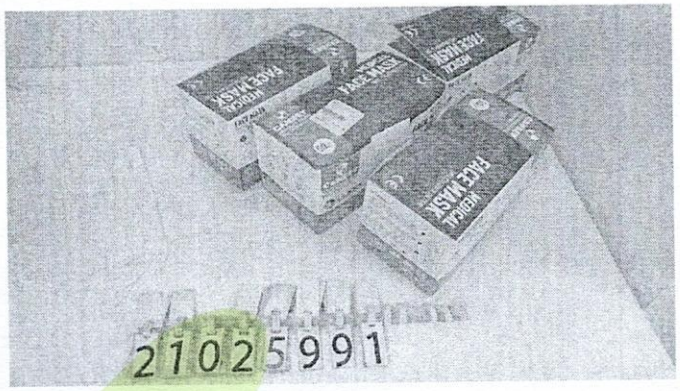
REQUIRED TESTS	EVALUATION	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	**TYPE IIR**
Microbial Cleanliness(Bioburden)	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	
Blood Splash Resistance	P	

P: Pass
F: Fail
R: Refer to retailer technologist

Test results evaluated according to EN 14683:2019+AC:2019 limit values

Gen.f136-2/03

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 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (*) in this report are not included in the accreditation schedule



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TEST RESULTS

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

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Method: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) Annex-B
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	5 Pieces
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)	**$3x10^3$ cfu/ ml**
Mean particle size (MPS)	**3.0 µm**

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	35	**%98.8**	**Type I ≥95**
2	34	**%98.9**	**Type II ≥98**
3	39	**%98.7**	
4	38	**%98.7**	
5	37	**%98.8**	

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

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09-21

TEST RESULTS

BREATHABILITY (Differential Pressure)

Test Method: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) Annex-C

Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs
Test area is 25 mm in diameter , 5 different sample was taken
Adjusted airflow is 8 l/min.The differential pressure is read directly using a differential pressure manometer .

SAMPLE	DIFFERENTIAL PRESSURE RESULT	REQUIREMENT
1	37.2 Pa/cm²	< 60 Pa/cm² Tip I ve Tip II maske
2	40.0 Pa/cm2	
3	28.5 Pa/cm2	
4	38.4 Pa/cm2	
5	39.6 Pa/cm2	
Average Result	38.7 Pa/cm2	

Gen.f136-2/03

MICROBIAL CLEANLINESS (Bioburden)

Test Method: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) Annex-D
EN ISO 11737-1:2018/Amd 1:2021 / TS EN ISO 11737-1 :2018/Amd 1:2021

5 sample were taken.The sample is weighted and put in extraction liquid after shaking well (250 rpm,5 min), inoculated on the suitable agar.
The plates are incubated for 3 days at 30 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.Total microoragnisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	2 cfu/g	≤30 cfu/g Type I and Type II mask

*cfu= Colony forming unit.

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21025991 -ing
09-21

TEST RESULTS

BLOOD SPLASH RESİSTANCE

Test Metod: EN 14683:2019+AC :2019 (Clause 5.2.4) the resistance of the medical face mask to penetration
ISO 22609 :2004 Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs
32 different samples were taken

	SPLASH RESISTANCE PRESSURE (kPa)	RESULTS	REQUIREMENT
1	>21.3 kPa	PASS	≥16 kPa Type IIR mask
2	>21.3 kPa	PASS	
3	>21.3 kPa	PASS	
4	>21.3 kPa	PASS	
5	>21.3 kPa	PASS	
6	>21.3 kPa	PASS	
7	>21.3 kPa	PASS	
8	>21.3 kPa	PASS	
9	>21.3 kPa	PASS	
10	>21.3 kPa	PASS	
11	>21.3 kPa	PASS	
12	>21.3 kPa	PASS	
13	>21.3 kPa	PASS	
14	>21.3 kPa	PASS	
15	>21.3 kPa	PASS	
16	>21.3 kPa	PASS	
17	>21.3 kPa	PASS	
18	>21.3 kPa	PASS	
19	>21.3 kPa	PASS	
20	>21.3 kPa	PASS	
21	>21.3 kPa	PASS	
22	>21.3 kPa	PASS	
23	>21.3 kPa	PASS	
24	>21.3 kPa	PASS	
25	>21.3 kPa	PASS	
26	>21.3 kPa	PASS	
27	>21.3 kPa	PASS	
28	>21.3 kPa	PASS	
29	>21.3 kPa	PASS	
30	>21.3 kPa	PASS	
31	>21.3 kPa	PASS	
32	>21.3 kPa	PASS	
Average Result	>21.3 kPa	PASS	

Gen.f136-2/03