ECOTEXTURA

DISPOSABLE CLEAR-PANEL FACE MASKS

TYPE IIR

THE ENVIRONMENTALLY-CONSCIOUS AND AFFORDABLE SUPPLIER OF PPE WORLDWIDE

PROPOSAL TO: THE NATIONAL HEALTH SERVICE (NHS)

NHS

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E: SALES@ECOTEXTURA.COM M: +44 7707 582928

EcoTextura Ltd

3-PLY CLEAR-PANEL FACE MASKS (TYPE IIR) PROPOSAL

ECOTEXTURA

EcoTextura is revolutionising the PPE and hygiene industry. We develop and produce our proprietary, sustainable medical personal protective equipment (PPE), whilst using our vast network of trusted OEMs to supply high-quality, existing PPE products.

Environmentally-conscious practices are at the centre of our operations; we will only employ manufacturing processes and materials which ensure reduced waste, water and energy usage, as well as offering more recycling waste management options. The majority of our manufacturing plants are located within Europe, and we look to offset carbon for all orders made.

Through reputable ties direct to manufacturers, we cut out the agents in between and deal directly to provide certified nitrile gloves, gowns, surgical masks, KN95 masks etc. We have been fulfilling multiple contracts across corporates, The NHS, educational establishments, local councils, care homes, NGO's and charities.

EcoTextura actively discourages price gouging, especially during such challenging times, and will only offer affordable, accessible and competitive pricing for all of our clients.

WHY CLEAR-PANEL FACE MASKS?

For those who are deaf and hard of hearing, lip-reading is heavily relied on as a form of communication. With the majority of the people now wearing masks, this has caused a huge problem for a significant proportion of the population, who are now struggling with daily interactions. Wearing clear-panel masks at in public places, not only keeps you protected (more effectively than a face-shield), but will allow effective lip-reading for those who are hard of hearing.

We want to help make mask wearing accessible and less stressful for deaf and hard of hearing patients, and those that take care of them.

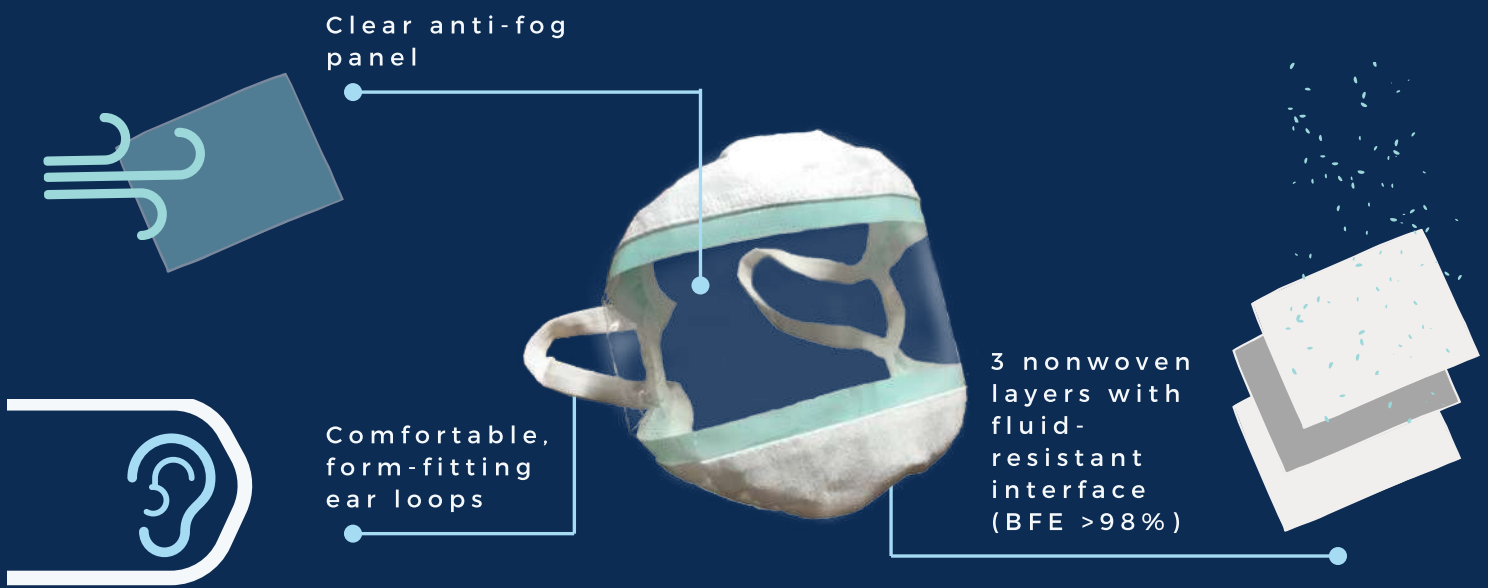
FUNCTIONAL BENEFITS OF THE ECOTEXTURA CLEAR-PANEL FACE MASK

- **Our masks are 3-ply**; consisting of durable spunbond and microfilament nonwoven layers, including a fluid-resistant nonwoven interface
- 3 ply face masks are manufactured to EN14683 **Type IIR standards;** ideal for hospital settings, and have been tested to a **bacterial filtration efficiency (BFE) of >98%**
- Masks have elasticated ear loops and nose fit for **comfortable wear**
- **Masks are disposable** - when disposed of correctly, **can reduce the spread of infections**
- Clear-panel masks are **individually sealed** and packed in **sets of 25pcs**
- Our unique mask structure allows for **effortless lip-reading communication** without the mouth area touching the panel
- Masks are a **standard size** which can be worn by adults. Additionally, the ear-loop can be looped once more to fit smaller children or smaller faces
- Printing designs are **readily customisable** to your needs and do not compromise the structural integrity or performance of the masks. **Printed masks are reversible;** with one plain side and one printed side
- **Wholesale discounts available**

Parameters	Type I	Type II	Type IIR
Differential pressure	<40	<40	<60
Bacterial Filtration Efficiency	≥95	≥98	≥98
Bioburden	≤30	≤30	≤30
Splash test	n/a	n/a	Yes

Please see all supporting documents, internationally accredited EuroLab test results and certifications at the end of this proposal.

PROTECTION - COMFORT - IMPROVED COMMUNICATION



PRICING AND ORDER INFORMATION

Price (DDP Pricing):

DISPOSABLE FACE MASK TYPE	MASK QUANTITY (PCS)	PRICE/MASK	PACK QUANTITY (PACK OF 25 PCS)	PRICE/PACK	LEAD TIME	DELIVERY TIME
CLEAR-PANEL FACE MASK WHITE	100 - 5,000	£0.90	4 - 200	£22.50	In stock	1 day
IIR RATED	5,025 - 25,000	£0.85	201 - 1,000	£21.25	7-10 days	2-3 days
(ECOT01TRLR01)	25,025 - 50,000	£0.80	1,001 - 2,000	£20.00	14 days	2-3 days
	50,025 - 250,000	£0.75	2,001 - 5,000	£18.75	14 days	2-3 days
	250,025 - 500,000	£0.70	5,001 - 10,000	£17.50	14 days	2-3 days
	500,000+	£0.65	10,000+	£16.25	14 days	2-3 days
CLEAR-PANEL FACE MASK PRINTED	5000	£1.00	200	£27.50	In stock	1 day
IIR RATED	5,025 - 25,000	£0.95	201 - 1,000	£26.25	7-10 days	2-3 days
(ECOT01TRLR02)	25,025 - 50,000	£0.90	1,001 - 2,000	£25.00	14 days	2-3 days
	50,025 - 250,000	£0.85	2,001 - 5,000	£23.75	14 days	2-3 days
	250,025 - 500,000	£0.80	5,001 - 10,000	£22.50	14 days	2-3 days
	500,000+	£0.75	10,000+	£21.25	14 days	2-3 days

All masks are sold in packs of 25pcs

MOQ:

- **White Masks: 100 pcs face masks** (4 packs)
  Product code: ECOT01TRLR01

- **Printed Masks: 500 pcs face masks** (20 packs)
  Product code: ECOT01TRLR02

Mask size - Standard
Mask: 17.5 cm (W) x 21 cm (L)
Ear loop: 16 cm (loose), 32 cm (fully stretched)
(+/- 5% tolerance)

Packaging: Masks are individually wrapped, then sealed a film pack in sets of 25pcs, and packaged within a secure card box.

Ctn Dimensions (may vary on order size) (approx):
60 cm X 60 cm X 65 cm
Ctn Weight: 6.0 Kgs
Pcs / packet or box: 25 masks
Pcs / Carton: 1000 masks (40 packets)

Delivery: Free delivery on all orders

Please note that the quoted lead time is the maximum time expected. Lead times will be more accurately quoted once the order is placed.

Certifications:
CE, EN 14683:2019+AC2019
ISO9001:2015
ISO11737-1

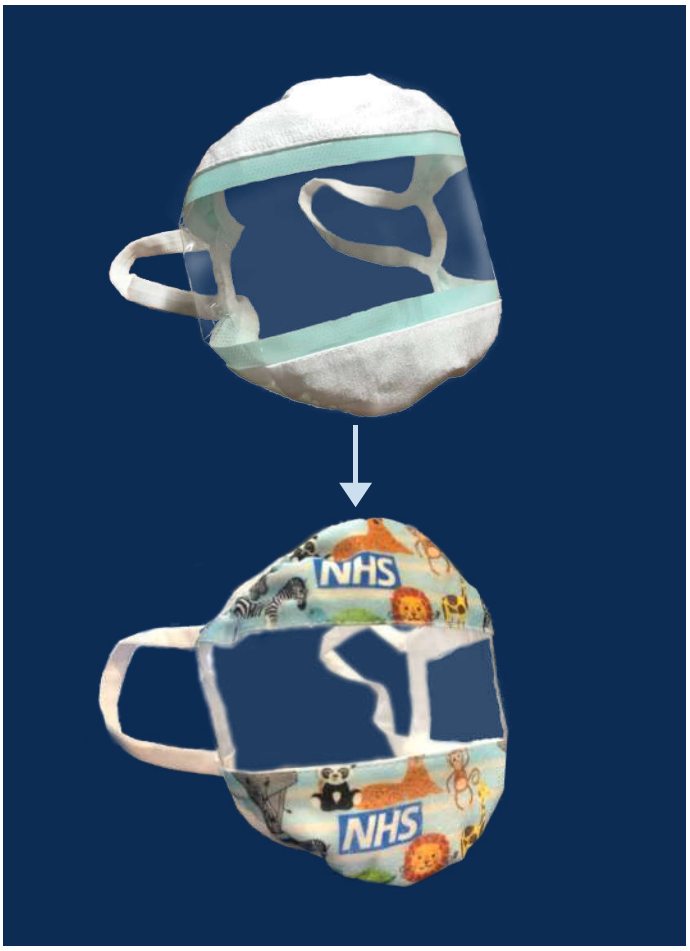
Country of origin:
Turkey

***Offer Validity:**
31st October 2020

PAYMENT TERMS

- TT Bank Transfer
- 100% in advance along with PO

To enquire please contact
sales@ecotextura.com



MASK IDEAS AND THEMES

Our printed lip-reading masks are reversible - it's up to you if you want to wear them the plain or printed side out!

What's great about our masks is that the designs are down to you! The possibilities are endless so please get in touch if you have any ideas.

Below, we have put together some example design themes for you to select from. Block colours and repeat patterns work well. Designs can be printed onto any non-woven masks.

You have free reign to select any design elements (subject to copyright and ownership), we can work with you immediately to digitise this into a repeated pattern that will be printed safely onto our high-quality non-woven mask fabric. (Therefore, please note that the positioning of the illustrations on each mask will vary)

Free samples can be requested, personalised design prototypes will require an MOQ - please get in touch for more information!

info@ecotextura.com

SPACE THEME

Take a trip to outer-space with our incredible space themed masks, covered in rockets, stars and planets!

DINOSAURS

Our fantastic dinosaur themed masks will come covered in dinosaurs, eggs, volcanoes and of course - the mighty T-Rex!

ANIMALS

Our brightly-coloured animal mask will feature all our favourite animals! In addition to this, we can offer the NHS logo to be printed onto any of the masks, free of charge.

SUPER HEROES

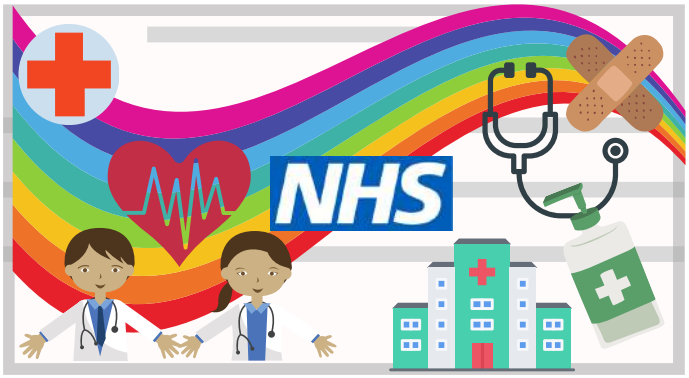
In 2020 we have seen many heroes rise! Our super hero mask comes complete with city skyline and various heroes and villians.

FUNKY PATTERNS

Go to town with our patterned masks - this can include retro patterns, cakes, animal print, and even cacti - you name it, we can probably make it!

PRINCESSES

Everyone should always feel like a royalty. Enjoy our princess mask, complete with tiaras, sparkles and of course - princesses from all the lands!



NHS DOCTORS AND NURSES

Our hospital themed mask can feature all the important elements of a hospital - complete with the NHS rainbow and logo!

STARS & EMOJIS

Another fantastic pattern idea - we can include any and all emojis and stars to cover our masks and help make mask-wearing fun & colourful!

NHS

Finally, our simple but elegant NHS logo mask.

The possibilities are endless with our masks so please get in touch if you have any ideas.

Free samples can be requested, design prototypes will require an MOQ - please get in touch for more information!

info@ecotextura.com

SPECIFICATION & CERTIFICATES

Further documents and product photos available upon request, please email: info@ecotextura.com

UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-153

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonization 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

DEVATEKS KONFEKSİYON SANAYİ TİC. LTD. ŞTİ.

at the following address

Kocasinan Merkez Mah. Sakıp Sabancı Cad. No: 14/3 Bahçelievler İstanbul/ TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: DEVMASKE
Model: DEV001
Classification: Type I

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 Çevre Endüstriyel Testing Laboratory BFE, Microbial Cleanliness, Differential Pressure

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 fulfills 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 17/06/2020 and valid until 16/06/2021 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 - 17/06/2020

CE

Sıtkı KAÇMAZ
UNIVERSAL CERTIFICATION
Genel Müdür

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 executed annually following the surveillance audits, updating the publication(s) without changing the certificate number.

UNIVERSALCERT.COM

EU DECLARATION OF CONFORMITY

MANUFACTURER
DEVATEKS KONFEKSİYON SANAYİ TİC. LTD. ŞTİ
Kocasinan Merkez Mah. Sakıp Sabancı Cad. No: 14/3 Bahçelievler İstanbul/ 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: DEVMASKE
Model: DEV001
Classification: Type I

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 BFE
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Differential 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.

CE

Filiz DEMİRHAN
General Manager
KAHRAMANMARAS 17/06/2020

Sample ID: FACE MASK
100 gr and 80 gr fabric medical face mask

TEST	METHOD	Specimen	RESULT	
Medical face masks - Requirements and test methods	EN 14683+AC 2019	Medical and surgical mask	PASS	
			100 gr	TYPE IIR
			80 gr	TYPE IIR

Seal

Customer Representative
Kenan KUTLU

Laboratory Manager
Fikret SARAYTEN

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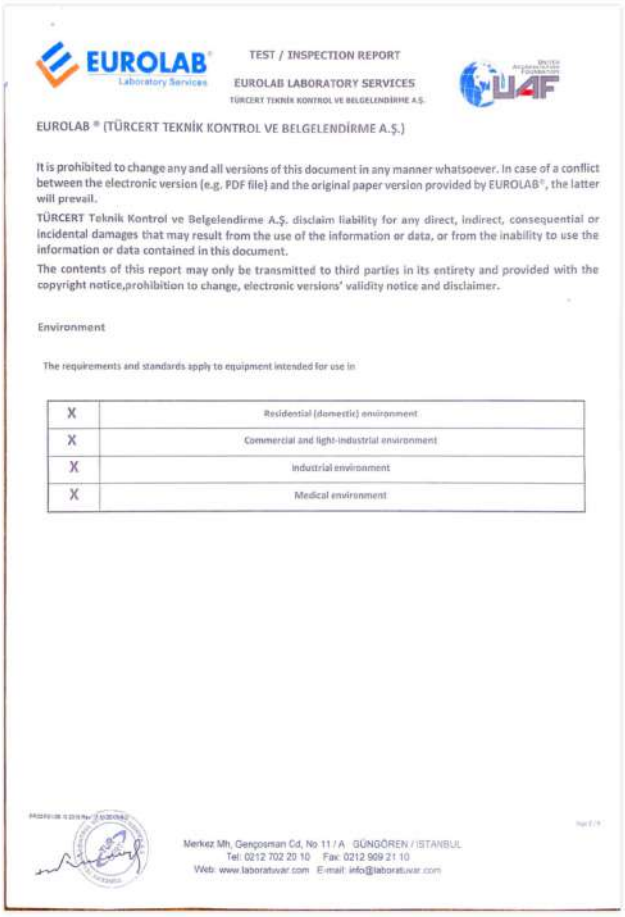

EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES
TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

EUROLAB ® (TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.)

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Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

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Requirements and test methods

This European Standard specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

General

All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.

Method for in-vitro determination of bacterial filtration efficiency (BFE)

Principle

A specimen of the mask material is clamped between a six-stage cascade 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.

Reagents and materials

General

Describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

Tryptic soy agar

Formula/liter:	
Enzymatic digest of casein	15 g
Enzymatic digest of soybean meal	5 g
Sodium chloride	5 g
Agar	15 g
Final pH	7,3 ± 0,2 at 25 °C

Tryptic soy broth

Formula/liter:	
Enzymatic digest of casein	17 g
Enzymatic digest of soybean meal	3 g
Sodium chloride	5 g
Dextrose	2,5 g
Final pH	7,3 ± 0,2 at 25 °C

Peptone Water

Formula/liter:	
Peptone	1 g
Sodium chloride	5 g
Final pH	7,3 ± 0,2 at 25 °C

Preparation of bacterial challenge

Staphylococcus aureus shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5 × 105 cfu/ml.

The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.6.3) and the dilution of the challenge suspension adjusted accordingly. The mean particle size in the bacterial challenge shall be maintained at (3,0 ± 0,3) µm (see B.6.9).

Procedure

Assemble the apparatus in accordance with the flow chart shown in Figure B.1.

Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,3 l/min. Deliver the bacterial challenge for 1 min. Maintain the airflow through the impactor for 2 min. Then remove the plates from the impactor. Ensure that each plate is numbered to indicate its position in the impactor.

Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.

Repeat this procedure for each test specimen.

After the last test specimen has been tested, perform a further positive control run.

Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

Incubate all the plates at (37 ± 2) °C for (48 ± 4) h.

For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the "positive hole" conversion table1) in accordance with the instructions of the cascade impactor manufacturer. For the two positive control runs, take the mean of the two totals. From the

positive control plates calculate the mean particle size of the bacterial challenge aerosol using the "positive hole" conversion table in accordance with the instructions of the cascade impactor manufacturer.

Calculation of bacterial filtration efficiency

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$$B = (C - T) / C \times 100$$

Where;

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.

Method for determination of breathability (differential pressure)

Principle

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure 1. Water-filled manometers (M1 and M2) are used to measure the differential pressure. A flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.

Key

1 air inlet	5 manometer M2
2 flow meter	6 valve
3 manometer M1	7 vacuum pump
4 filter material	

Figure 1 — Apparatus for measuring air resistance

Procedure

The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm2) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.
The pump is started and the flow of air adjusted to 8 l/min.
The manometers M1 and M2 are read and recorded.
The procedure described in steps 1 through 3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.

Calculation of differential pressure

For each test specimen calculate the differential pressure ΔP as follows:

$$\Delta P = (Xm1 - Xm2)/4,9$$

Where;

Xm1 is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;
Xm2 is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;
4,9 is the cm2 area of the test material;
ΔP is the differential pressure per cm2 of test material expressed in Pa.

Splash resistance

When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.

Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1).

To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below:

The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.

The total bioburden is expressed by addition of the TSA and SDA counts.

In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.

EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

TEST REQUIREMENTS

Test	Type I[a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

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EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

TEST RESULTS

EN 14683 Inspection

SAMPLE : 100 gr

Test	Type IIR	Result	Evaluation
Bacterial filtration efficiency (BFE), (%)	≥ 98	99,95	PASS
Differential pressure (Pa/cm2)	< 60	22	PASS
Splash resistance pressure (kPa)	≥ 16,0	20	PASS
Microbial cleanliness (cfu/g)	≤ 30	18	PASS

SAMPLE : 80 gr

Test	Type IIR	Result	Evaluation
Bacterial filtration efficiency (BFE), (%)	≥ 98	99,22	PASS
Differential pressure (Pa/cm2)	< 60	22	PASS
Splash resistance pressure (kPa)	≥ 16	18	PASS
Microbial cleanliness (cfu/g)	≤ 30	18	PASS

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EU DECLARATION OF CONFORMITY
AB UYGUNLUK BEYANI

Manufacturer name
Üretici adı
Manufacturer address
Üretici adresi

Product description / *Ürün tanımı*: **Single Use Medical Coverall** / *Tek Kullanımlık Tıbbi Tulum*

European directive(s) / *İlgili AT direktifleri*: **Medical Devices Regulation (EU) 2017/745** / *Tıbbi Cihazlar Direktifi (2017/745/AB)*

European standart(s) / *İlgili AT standartları*: **EN ISO 15223-1:2016**, **EN ISO 14971:2012**, **EN ISO 14155:2011**, **EN ISO 10993-1:2009**

Classification / *Sınıflandırma*: **Class I Other** / *Sınıf I Diğer (Steril ve ölçüm özelliği olmayan)*

This declaration of conformity is issued under the sole responsibility of the manufacturer.
Bu uygunluk deklarasyonu üreticinin kendi sorumluluğunda düzenlenmiştir.

The object of the declaration described above is in conformity with the relevant European Union harmonization legislation:
Yukarıda açıklanan deklarasyonun amacı, ilgili Avrupa Birliği uyum mevzuatı ile uygun olduğudur

Signed for and on behalf of the (

Signature
İmza

EU DECLARATION OF CONFORMITY
AB UYGUNLUK BEYANI

Manufacturer name
Üretici adı
Manufacturer address
Üretici adresi

Product description / *Ürün tanımı*: **Surgical Drapes and Gowns** / *Cerrahi Örtüler ve Önlükler*

European directive(s) / *İlgili AT direktifleri*: **Medical Devices Regulation (EU) 2017/745** / *Tıbbi Cihazlar Direktifi (2017/745/AB)*

European standart(s) / *İlgili AT standartları*: **EN 13795-1:2019**, **EN ISO 15223-1:2016**, **EN ISO 14971:2012**

Classification / *Sınıflandırma*: **Class I Other** / *Sınıf I Diğer (Steril ve ölçüm özelliği olmayan)*

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Signed for and on behalf of the (

Signature
İmza

Name, Function (İsim, Görevi): (
Place of issue (Yayınlanma yeri):
Date of issue (Yayınlanma tarihi): **30.03.2020**

SQR CERTIFICATION

Sertifika
CERTIFICATE

ISO 9001:2015

Kapsam/Scope

BAY VE BAYAN TEKSTİL ÜRÜNLERİNİN TASARIMI VE ÜRETİMİ İLE SAĞLIK ÜRÜNLERİ (MASKE, BONE, KEP, GALOŞ, KOLLUK, TULUM, ÖNLÜK VB.) ÜRETİMİ VE SATIŞI

DESIGN AND PRODUCTION OF MEN'S AND WOMEN'S TEXTILE PRODUCTS AND PRODUCTION AND SALES OF HEALTH PRODUCTS (MASK, BONNET, CAP, OVERSHOES, SLEEVE COVER, OVERALL, APRON ETC.)

Bu sertifika ile yukarıda adı geçen kuruluşun Kalite Yönetim Sistemi gerekliliklerini karşıladığı tevfik olunur.

This is to certify that the above mentioned Company meets the requirement of Quality Management System.

Belge NO / Certification Number	: MTS-17294
İlk Kayıt Tarihi / Date of Initial Reg.	: 31.3.2020
Basım Tarihi / Date of Certificate	: 31.3.2020
Geçerlilik Tarihi / Date of Expiry	: 30.3.2021
Yeniden Belgelendirme Tarihi / Date of Recertification	: 30.3.2023

Operasyon Müdürü / Operation Manager

SİGMACERT ULUSLARARASI BELGELENDİRME EĞİTİM VE TEST HİZMETLERİ LTD. ŞTİ.

Ostim Mahallesi 2239/1 Sokak No: 7/3
Tel: +90.312 385 08 85 Yenimahalle / ANKARA
belgelendirme@sigmacert.com.tr • www.sigmacert.com.tr

SQR CERTIFICATION

Sertifika
CERTIFICATE

GHP

Kapsam / Scope

BAY VE BAYAN TEKSTİL ÜRÜNLERİNİN TASARIMI VE ÜRETİMİ İLE SAĞLIK ÜRÜNLERİ (MASKE, BONE, KEP, GALOŞ, KOLLUK, TULUM, ÖNLÜK VB.) ÜRETİMİ VE SATIŞI

DESIGN AND PRODUCTION OF MEN'S AND WOMEN'S TEXTILE PRODUCTS AND PRODUCTION AND SALES OF HEALTH PRODUCTS (MASK, BONNET, CAP, OVERSHOES, SLEEVE COVER, OVERALL, APRON ETC.)

This is to certify that the above mentioned Company meets the requirement of Good Hygiene Practices.

Belge NO / Certification Number	: MTS-17294
İlk Kayıt Tarihi / Date of Initial Reg.	: 06.03.2020
Basım Tarihi / Date of Certificate	: 06.03.2020
Geçerlilik Tarihi / Date of Expiry	: 05.03.2021
Yeniden Belgelendirme Tarihi / Date of Recertification	: 05.03.2023

Operasyon Müdürü / Operation Manager

SİGMACERT ULUSLARARASI BELGELENDİRME EĞİTİM VE TEST HİZMETLERİ LTD. ŞTİ.

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UKS ULUSLARARASI KALİTE SİSTEMLERİ VE BELGELENDİRME LTD. ŞTİ.

Bu Belge ile

Firmasının

ISO 13485:2016

şartlarına uygun bir Medikal Tıbbi Cihazlar Kalite Yönetim Sistemine aşağıda belirtilen kapsam dahilinde sahip olduğunu onaylar

Bay Ve Bayan Tekstil Ürünlerinin Tasarımı Ve Üretimi İle Sağlık Ürünleri (Maske, Bone, Kep, Galoş, Kolluk, Tulum, Önlük Vb.) Üretimi Ve Satışı

Kategori/Alt Kategori	: ---
Belge No	:MDQ-0024
Belge İlk Yayın Tarihi	:30 Mart 2020
Kesir Tarihi	:30 Mart 2020
Belge Yayın Tarihi	:30 Mart 2020
Geçerlilik Tarihi	:29 Mart 2021

CAS ACCREDITED CAS-MS-0011

Genel Müdür

www.uksbelgelendirme.com.tr

İSTANBUL SANAYİ ODASI

TÜRKİYE ODALAR VE BORSALAR BİRLİĞİ

KAPASİTE RAPORU

İSTANBUL SANAYİ ODASI

Geçerlilik Süresi Sonu 29.04.2021

Rapor Tarihi :25.04.2019
Rapor No :2019/2155

Firma Ünvanı	:
Tescilli Markaları	:
Vergi Dairesi/No	:Anadolu Kur.V.D.Bşk. / 3030025566
İşyeri SGK No	:2141308081013572035423-81
MERSİS No	:
Sanayi Sicil No	:543362
Oda Sicil No	:25652
Ticaret Sicil No	:16648
Faaliyet Kodu (NACE)	:14.13.04

Üretimin Yapıldığı Yer

Merkez

Üretim Konuları: Dokuma ve örme kumaştan mamul hazır giyim ürünleri

Üretim Tesisinin Durumu		Sermaye Kaynaklar Durumu (TL)		Personel Durumu	
Kirası		Makine ve Teçhizat Değeri	3.386.206	Mühendis	1
Arsası (m2)	-	Tescilli Sermayesi	10.000.000	Teknisyen	-
Toplam Kapalı Sahası (m2)	800			Usta	7
Bina İnşaat Tipi	B.ARME			İşçi	4
				İdari Pers.	20
				Taşeron	288
				Toplam	320

İbrahim GÜNEŞ
Uzman Yardımcısı

T.C.

14 -05- 2019

Üretim Faaliyetine Başlama Tarihi : 08.02.1995

Yabancı Sermaye		Gayri Maddi Hak			
Ülkesi	Oranı (%)	Patent	Know How	Lisans	Ülkesi

Seyitlikahr :

Yukarıda ünvanı yazılı işletmenin, işyerinde mevcut makine ve teçhizatının yürürlükteki yönteri ve kriterlere göre teorik olarak hesaplanan azami üretim kapasitesi ile fiiletim kapasitesini kapsayan bu kapasite raporu 25.04.2019 günü tanzim edilmiştir.

RAPORTÖR	1.EKSPER	2.EKSPER
Esin BALTACI Uzman	Mehmet BEŞPARMAK Tekstil Mühendisi	-