HANDA GUARD®

HANDA GUARD is a subsidiary of Handa Tasarım Tekstil San. ve Tic.Ltd. Şti. based in İstanbul / TURKEY. The company produces all of its goods in-house and currently exports to many countries.

Basın Ekspres Yolu, Bahar Caddesi, Nurol Park Ofis, No:43 J Blok, Kat: 9, Ofis No:61,
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www.handaguard.com.tr

HANDA GUARD®

DISPOSABLE SURGICAL FACE MASKS WITH THE PATENTED EPS GUARD® BOX

HANDA GUARD®

We guard your health with 3-ply GUARD® surgical masks that have %98.6 bacterial filtration efficiency.

We guard your masks in airtight GUARD® BOX

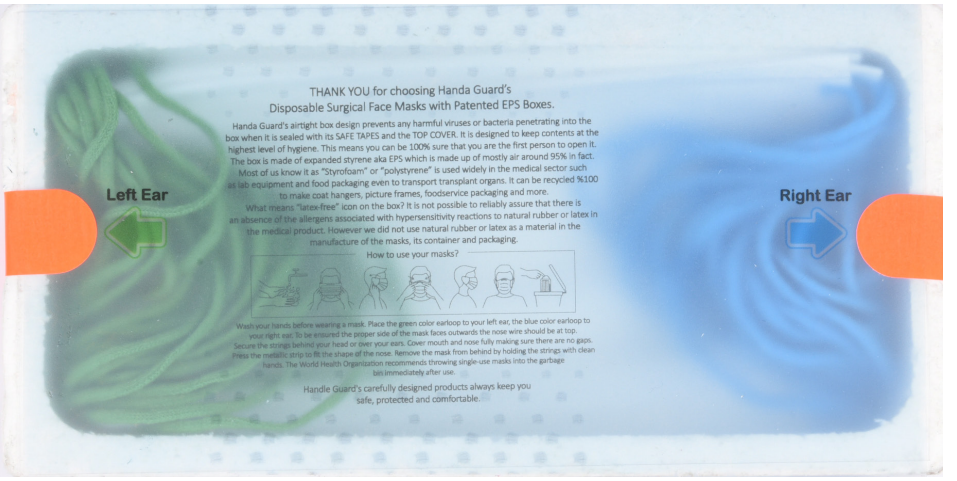
GUARD®BOX

We guard your masks in our patented tamper-proof EPS boxes.

Handa GUARD®'s airtight box design with its SAFE TAPES and the TOP COVER prevents penetration of harmful viruses or bacteria when it is sealed.

Safe Tape

Airtight Top Cover



GUARD®BOX is designed to keep contents at the highest level of hygiene. With its tamper-proof design, you can be %100 sure that you are the first person to open it.

GUARD®BOX is made of expanded polystyrene (EPS), 95% of which consists of air. Most of us know it as “Styrofoam”; it is used widely in the medical sector such as lab equipment, even to transport transplant organs. It is %100 recyclable.

Human organ transplant transport

%100 recyclable & eco-friendly

HOW TO OPEN YOUR GUARD® BOX?

1

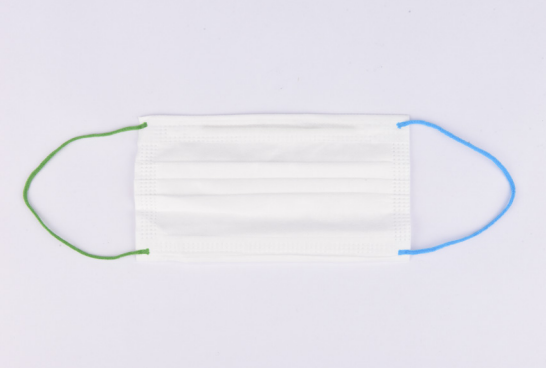
2

3

4

5

6

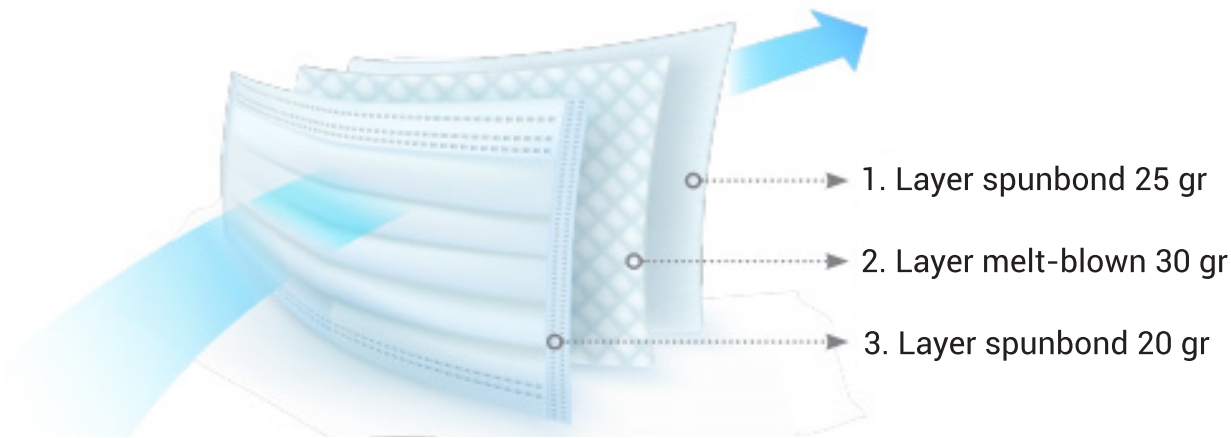


GUARD® MASK SPECIFICATIONS

- 3-PLY
- Melt-blown layer
- %98.6 Bacterial filtration efficiency
- Latex-free
- Non-woven
- Nose wire / Fog-Free
- Lint-free
- Earloop
- Ultrasonic

3-PLY

The design of Handa GUARD® surgical masks are three-ply. This three-ply material is made up of a melt-blown polypropylene, placed between spunbond non-woven fabric. The melt-blown material acts as the filter that stops microbes from entering or exiting the mask.



a. Visual Test
If you cut open your mask, you should see 3 distinct layers.

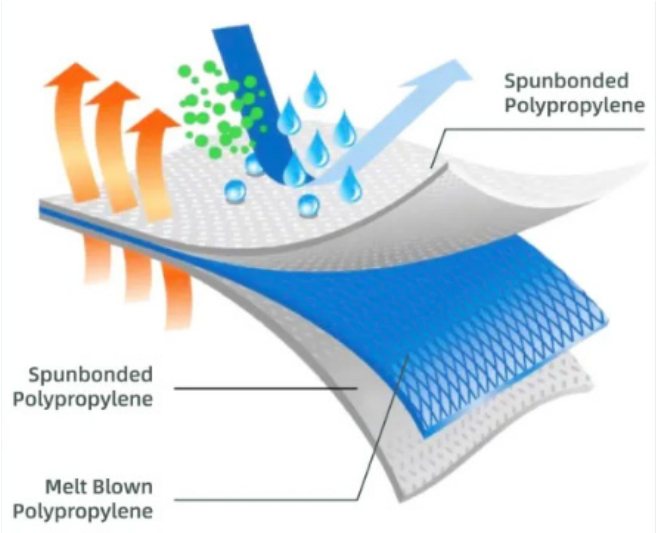
b. Non-flammability Test
The middle layer of a surgical mask is a melt-blown fabric, not made with paper; if you light it with a flame, it will not burn like paper. Instead, it melts without a flame.

c. Water-resistant Test
The outermost layer is designed to be waterproof. Pour some water onto the outer layer and you can see whether the mask repels water properly.

d. Electrostatic Adsorption Test
There is an electrostatic effect in the melt-blown layer. If you tear the melt-blown layer into strips, you will feel the electrostatic adsorption effect.

MELT-BLOWN LAYER

Meltblown fabric is a type of polypropylene spunbond nonwoven material used as the key filter material for all kinds of masks. The melt blown layers in GUARD® MASK, filter bacteria and viruses make your masks more breathable. GUARD® MASK breathing resistance is 27Pa/cm², bacterial filtration efficiency %98.6.



LATEX FREE

The total absence of the allergens associated with hypersensitivity reactions to natural rubber or latex in the medical product cannot be 100% guaranteed. However we did not use natural rubber or latex as a material in the manufacture of the masks, its container and packaging.

LINT-FREE

HANDA GUARD® surgical masks are lint-free.
Lint-free inner layer provides a cool and long-lasting soft feeling without fluff irritation.

NOSE WIRE / FOG-FREE

Embedded nose clip fits the nose bridge, prevents eyeglass fogging if placed properly.

HANDA GUARD®

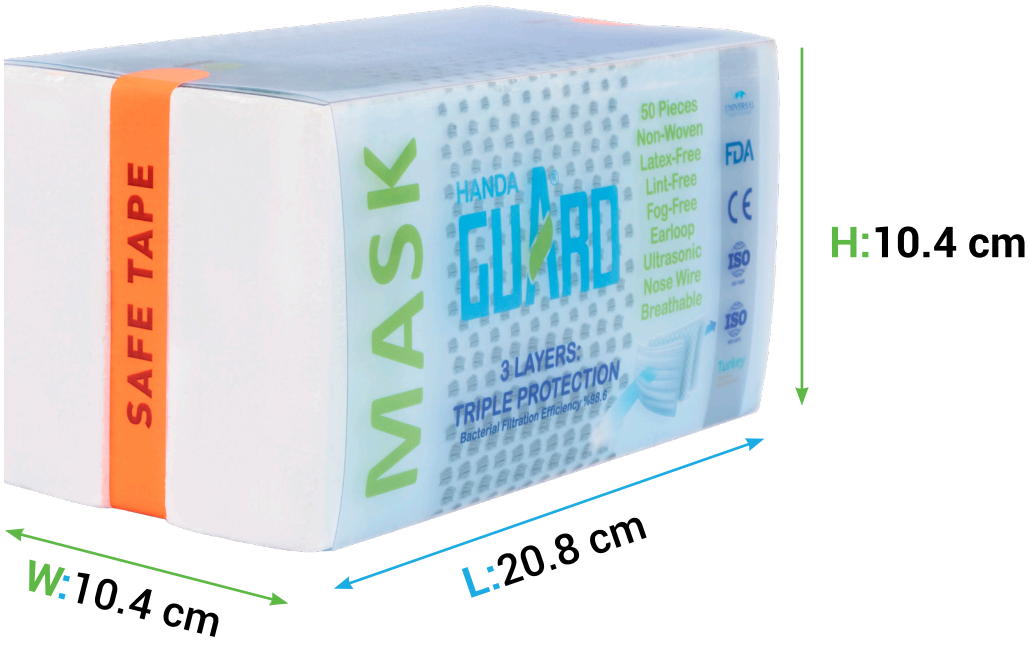
EAR LOOPS

Ultrasonically welded soft elastic ear loops provide a comfortable wearing experience, pose less press to ears and face, and minimize discomfort from long-time use.

Place the green earloop behind your left ear.

Place the blue earloop behind your right ear.

GUARD® BOX DIMENSIONS



LOGISTICS INFO

MASK BOX

Qnty	: 50 pcs
Dimensions	: W10.4 x L20.8 x H10.4 cm
Gross weight	: 240 g
Net weight	: 177 g

MASTER CARTON

Qnty	: 48 mask boxes (2400 masks)
Dimensions	: W63 x L43 x H43 cm
Gross weight	: 13 kg
Net weight	: 8.5 kg

PACKING OPTIONS :

1 full truck	: 730 master cartons (1.752.000 masks)
40' container	: 450 master cartons (1.080.000 masks)
40' HC container	: 594 master cartons (1.425.600 masks)

HANDA GUARD

UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-201

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

HANDA TASARIM TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

at the following address

15 Temmuz Mahallesi Bahar Cad. Nurol Park Sit. J Blok Apt. No:43/61 Bağcılar
ISTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name : HANDA GUARD
Model : HANDA-1
Type II
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

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 29/07/2020 and valid until 28/07/2021 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 –29/07/2020

CE

Suat 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 concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

CERTIFICATES

EU DECLARATION OF CONFORMITY

MANUFACTURER
HANDA TASARIM TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
15 Temmuz Mahallesi Bahar Cad. Nurol Park Sit. J Blok Apt. No:43/61 Bağcılar
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 : HANDA GUARD
Model : HANDA-1
Type II

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

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
29/07/2020

CE

HANDA GUARD

UNIVERSAL

UNIVERSAL CERTIFICATION

CERTIFICATE

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LİMİTED ŞİRKETİ,

HANDA TASARIM TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
15 Temmuz Mahallesi Bahar Caddesi Nurol Park Sitesi J Blok Apartmanı No:43/61Bağcılar İSTANBUL

has established and applies a Quality Management System for the activities below and it is certified according to UNIVERSAL CERTIFICATION procedures

" IMPORT, EXPORT, SALES AND MARKETING OF TEXTILE, FOOD, AUTOMOTIVE SUB-INDUSTRY, CAR COVER, MEDICAL MASK, MEDICAL APRON (STERILE AND NON STERILE), PROTECTIVE OVERALLS, DISINFECTANT, GALOSH, BONNET, GLOVE (STERILE AND NON STERILE)"
EA 29

BL.02569.20 numbered report prepared as a result of the audit carried out shows that the organization provided the requirements of

ISO 9001:2015

This certificate is valid until **29.06.2021**

Certificate Number: **20.02429**

First Date of Issue: **30.06.2020**, Recertification Date: -------, Date of Issue: **30.06.2020**

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

TÜRKAK BDS NO YS-6053-337E

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

TÜRKAK Quality Management System TS EN ISO/IEC 17021 AB-0023-YS

The validity of this certificate is 3 years and depends on the success of the organization at the surveillance audit which will be held at least once a year. Certificate's status can be controlled from www.universalcert.com web site or verification of QR code.
UFR.870 Rev:0 Revizyon Tarihi:06.02.2020

CERTIFICATES

UNIVERSAL

UNIVERSAL
CERTIFICATION

CERTIFICATE

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LİMİTED ŞİRKETİ,

HANDA TASARIM TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
15 Temmuz Mahallesi Bahar Caddesi Nurol Park Sitesi J Blok Apartmanı No:43/61Bağcılar
İSTANBUL

has established and applies a medical devices Management System for the activities below and it is certified according to UNIVERSAL CERTIFICATION procedures

" IMPORT, EXPORT, SALES AND MARKETING OF MEDICAL MASK, MEDICAL APRON (STERILE AND NON STERILE), PROTECTIVE OVERALLS, GLOVE (STERILE AND NON STERILE)"
EA 29

BL.02569.20 numbered report prepared as a result of the audit carried out shows that the organization provided the requirements of

ISO 13485:2016

This certificate is valid until **29.06.2021**

Certificate Number: **20.02429-1**

First Date of Issue: **30.06.2020**, Recertification Date: -------, Date of Issue: **30.06.2020**

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

The validity of this certificate is 3 years and depends on the success of the organization at the surveillance audit which will be held at least once a year.
Certificate's status can be controlled from www.universalcert.com web site or verification of QR code.
UFR.870 Rev:0 Revizyon Tarihi:06.02.2020

HANDA GUARD®

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

TEST REPORT
DENEY RAPORU

20024271-ing
07-20

Customer name:	HANDA TASARIM TEKSTİL SAN. LTD. ŞTİ.
Address:	15 TEMMUZ MAH. BAHAR CAD. NUROL PARK OFİS J BLOK NO:43 K:9 NO:61 GÜNEŞLİ/İSTANBUL
Buyer name:	-
Contact Person:	SELİM ÖZCAN
Order No:	-
Article No:	-
Name and identity of test item:	White mask .
The date of receipt of test item:	14.07.2020
Re-submitted/re-confirmation date:	-
Date of test:	14.07.2020-23.07.2020
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

Gen.f136-2/03

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS	23.07.2020	Servin YURTSEVEN	Sevim A. RAZAK

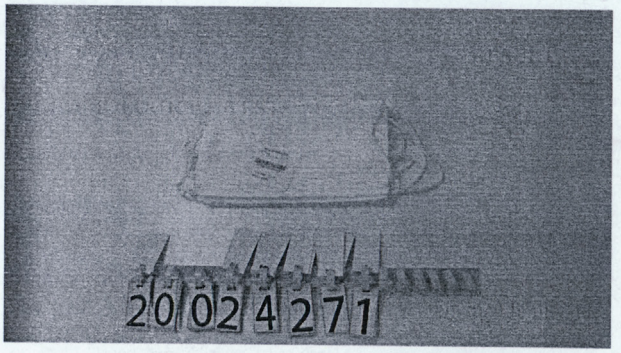
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20024271-ing
07-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	Type II
Microbial Cleanliness(Bioburden)	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to TSE K 599: 2020 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.



Gen.fl136-2/03

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20024271-ing
07-20

TEST RESULT

BREATHABILITY (Differential Pressure)

Test Metodu: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-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 .

Original		
SAMPLE	**DIFFERENTIAL PRESSURE RESULT**	**REQUIREMENT**
1	25.7 Pa/cm²	< 40 Pa/cm² Tip I ve Tip II maske
2	27.6 Pa/cm²	
3	29.8 Pa/cm²	
4	28.8 Pa/cm²	
5	23.1 Pa/cm²	
Average Result	27.0 Pa/cm²	

Gen.f136-2/03

HANDA GUARD

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20024271-ing
07-20

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) EK-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	20x20 cm^2
Test Area	49 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)	$2x10^3$ cfu/ ml
Mean particle size (MPS)	3.0 µm

Original

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	30	**%98.5**	**Type I ≥95**
2	34	**%98.3**	**Type II ≥98**
3	36	**%98.2**	
4	34	**%98.3**	
5	40	**%98.6**	

Gen.f136-2/03

HANDA GUARD

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20024271-ing
07-20

TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) EK-D (*)
EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018 (*)

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.

Original		
	RESULTS	**REQUIREMENT**
Microbial cleanliness (cfu/g)	8 kob/g	≤30 kob/g Tip I ve Tip II maske

***cfu= Colony forming unit.**

Gen.f136-2/03