



# WARRANTY MED



- PRODUCT:** BLUE NITRILE GLOVES
- STANDARD :** Exam glove powder-free.
- FEATURE :** Disposable.  
It does not contain natural latex.  
Ideal for allergic bodies
- STERILE :** It is non-sterile and powder-free.
- MATERIAL :** Nitrile.
- COMPATIBILITY** It is also compatible with two hands.
- CERTIFICATE** CE
- COLOR** Medical Blue
- FEATURE :** Its soft structure and elastic structure provide superior grip.
- USAGE TIME** 5 years from the date of manufacture.
- PACKAGE** 100 pieces in carton box.
- SIZE** S / M / L / XL

**BOX** 20 PCS  
**BOX SIZE** 42\*26\*27  
**GROSS WEIGHT** 3,210 KG



# CERTIFICATE

International VEGAN Vegetarian Certificate

TÜRCERT Sertifikasyon Merkezi  
iş bu belge ile

## MB YATIRIM GRUP İÇ VE DIŞ TİCARETLİMİTED ŞİRKETİ

Koza Mah.1638.Sok.Çiğdem Sit. 1.Blok Apt.No:5 K/11 Esenyurt - İSTANBUL

Şirketinin;

EXAMINATION GLOVE ,  
MEDICAL PROTECTIVE APRON  
MEDICAL PROTECTIVE OVERALL  
PERSONAL PROTECTIVE MASK  
DISPOSABLE SURGICAL MASK

## VEGAN V-MARK VEGETARIAN



TÜRCERT tarafından gerçekleştirilen VEGAN V-MARK ürün/ürünler kontrolünde, 20210369 rapor numaralı denetim sonucuna göre, yukarıda bilgileri verilen imalatçının üretmiş olduğu ürünler, VEGAN V-MARK standardına uygun olduğu tespit edilmiştir. İmalatçı denetim esnasında görülen uygunluğu devam ettirdiği sürece, bu sertifika geçerlidir ve VEGAN logosunu ve etiketini kullanabilir.

Sertifika Kayıt No : 2021033006

Sertifika Yayın Tarihi : 30.03.2021

İlk belgelendirme tarihi : 30.03.2021

Sertifika Geçerlilik Tarihi : 30.03.2022



EAF-MS 007



Belgelendirme Bölümü Adına



Certificate Validity



see more..www.v-mark.org

This certificate is valid during the customer obeys the rules V-MARK™ procedures and agreements.



V-MARK

VEGETARIAN  
PRODUCT CERTIFICATE





# CERTIFICATE

TÜRCERT Certification Body  
with this document.

## MB YATIRIM GRUP İÇ VE DIŞ TİC.LTD.ŞTİ.

Koza Mah.1638.Sok. Çiğdem Sit. 1.blok Apt.No:5 K/11 Esenyurt / İstanbul

of the manufacturer

«MB-1200 EXAMINATION GLOVE »

effective medical devices quality management system  
and guarantees that you put in to apply.

MDQMS2020120201 with the nr. examination report;

## TS EN ISO 13485 : 2016

This certification has been completed according to TURCERT  
audit and certification procedures and is valid until surveillance  
audit 02.12.2021

Certificate Registration Nr : 2020120201

Date of Issue : 02.12.2020

Certificate Validity Date : 02.12.2021



51902430608 (MDQMS)

TÜRCERT

TÜRCERT TEKNİK KONTROL ve BELGELENDİRME ANONİM ŞİRKETİ  
Adres: Merkez Mah. Dr. Sadık Ahmet Cad. No:38/44 A Güngören - İstanbul - Turkey  
Tel: +90 212 702 40 00 www.turcert.com

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



Belge Geçerlilik Sorgulama



# CERTIFICATE

## ECO

### ECOLOGICAL PRODUCT CERTIFICATE

### Ekolojik Ürün Sertifikası

## MB YATIRIM GRUP İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ

Koza Mah.1638.Sok. Çiğdem Sit. 1.blok Apt.No:5 K/11 Esenyurt / İstanbul



Scope/Kapsam - Products/Ürünler:

MB-1200 EXAMINATION GLOVE

This is to certify that the Medical Textile Equipments and TÜRCERT ECOmark® Ecological Products Criteria Procedure of the above mentioned client meets the requirement of /Yukarda belirtilmiş olan kuruluş ECO İşareti kullanımı kriter gerekliliklerini karşılamıştır.

**International ECO Label™ use approved.**

**ECO/2020120203/TR**

Certificate Number/Sertifika Numarası

**02.12.2020**

Date of Initial Registration

İlk Belgelendirme Kayıt Tarihi

**02.12.2020**

Date of Last Issue /Yayın Tarihi

**02.12.2021**

Date of Expiry/Geçerlilik Süresi Bitimi



TÜRCERT TEKNİK KONTROL ve BELGELENDİRME ANONİM ŞİRKETİ  
Adres: Merkez Mah. Geriçosman Cad. No:11 Güngören - İstanbul - Turkey  
Tel: +90 212 702 20 10 Fax:+90 212 909 21 10 www.ecomark.com.tr

Ecological Products Certification

ECOLOGICAL PRODUCTS CERTIFICATION





# CERTIFICATE

TÜRCERT Certification Body  
with this document.

## MB YATIRIM GRUP İÇ VE DIŞ TİC.LTD.ŞTİ.

Koza Mah.1638.Sok. Çiğdem Sit. 1.blok Apt.No:5 K/11 Esenyurt / İstanbul

of the manufacturer

« MB-1200 EXAMINATION GLOVE »

effective quality management system and  
guarentees that you put in to apply.

QMS2020120202 with the nr. examination report

## TS EN ISO 9001 : 2015

This certification has been completed according to TURCERT  
audit and certification procedures and is valid until surveillance  
audit **02.12.2021**

Certificate Registration Nr : 2020120202

Date of Issue : 02.12.2020

Certificate Validity Date : 02.12.2021



51902430124(QMS)

**TUR  
CERT**

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Belge Geçerlilik Sorgulama



**Report No:** 2020120103  
**Applicant:** MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.  
Koza mah. 1638. Sok. Çiğdem sit. 1. Blok apt. No:5 K/11 Esenyurt - İSTANBUL  
**Contact Person:** Melih BALKANLI  
**Contact Telephone:** -  
**Contact e-mail:** melihbalkanli@hotmail.com  
**Sample Accepted on:** 23.11.2020  
**Report Date:** 02.12.2020  
**Total number of pages:** 4 (Pg)

**Sample ID:** MB 1200 EXAMINATION GLOVE

TEST	METHOD	RESULT
Protective Gloves - General Requirements And Test Methods	EN 420	PASS



Seal



Customer Representative  
Hasan KUTLU



Laboratory Manager  
Hava SARIAYDIN



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**Environment**

The requirements and standards apply to equipment intended for use in

<b>X</b>	Residential (domestic) environment
<b>X</b>	Commercial and light-industrial environment
<b>X</b>	Industrial environment
<b>X</b>	Medical environment

### EN 420 Protective Gloves - General Requirements And Test Methods

This standard specifies the relevant test methods to be used for all protective gloves and the general requirements for design principles, glove assembly, resistance of the glove material to water penetration, harmlessness, comfort and performance as well as the labeling to be carried out by the manufacturer and the information to be provided by the manufacturer.

#### Test Results

Specimen	Test	Requirements	Result
MB 1200 EXAMINATION GLOVE	pH Test	The pH value for gloves must be greater than 3.5 and less than 9.5.	PASS
MB 1200 EXAMINATION GLOVE	Determination of the protein content	Protective gloves made of natural rubber must meet the requirements specified in EN 455-3 with regard to their extractable protein content. Protein content value must be <30 µg	PASS
MB 1200 EXAMINATION GLOVE	Length and Fit	See Table 2	PASS
MB 1200 EXAMINATION GLOVE	Dexterity	See Table 2	PASS LEVEL 5

Table 2

Glove Size	6	7	8	9	10	11
Minimum length (mm)	220	230	240	250	260	270

Performance Level	1	2	3	4	5
Diameter of Dexterity pin/mm	11.0	9.5	8.0	6.5	5.0



**IMAGE**



**\*\*\*END OF REPORT\*\*\***

# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

**Belge No / Certificate No** : 108-20-01-R01  
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /  
Certification Date / Certificate Validity Date** : 08.01.2021-31.12.2025  
**Belge Geçerlilik Tarihi / Document Validity Period** : 5 yıl / 5 years  
**Firma Unvanı ve Adresi /  
Company Name and Address** : MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.  
Koza Mah. 1638. Sk. Çiğdem Sit. 1. Blok Apt. No:5 K/11  
Esenyurt/ İSTANBUL  
**Ürün Adı /Modeller / Product Name / Models** : MB-1200  
**Direktifi / Directive** : 2016/425 REGULATION  
**Modülü/Kategori / Module / Category** : B MODÜLÜ/ KATEGORİ III  
MODULE B / CATEGORY III  
**Test Rapor No/ları / Test Report No** : MNA M-2020-00679  
**Ürün Tipi / Product Type:**  
- EN 420+A1 Koruyucu Eldivenler / Protective gloves  
- EN ISO 374-1 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler (Performans Seviyeleri: Tip C) / Protective Gloves Against Dangerous Chemicals And Micro-Organisms (Performance Level: Type C)  
- EN ISO 374-5 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler - Bölüm 5: Mikroorganizmal riskler için terimler ve performans kuralları / Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

**Ürünün Malzeme Bilgisi / Product Material Information:** MB-1200 model ürünleri sentetik nitril kullanılarak imal edilmiştir./ MB-1200 model products are manufactured using synthetic nitrile.

**Revizyon nedeni/ Reason for revision:** Ekler bölümüne kategori III ürünlerin açıklaması eklenmiştir./ The description of category III products has been added in the attachments.

**Volkan AKIN**  
08.01.2021  
Karar Verici / Approver

**Okan AKEL**  
08.01.2021  
Şirket Müdürü / General manager









**ATTACHMENTS (108-20-01-R01)**

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

**Model : MB-1200**

PPE SPECIFICATION	PERFORMANCE LEVELS
Dexterity	5
Material Resistance To Permeation By Chemicals	2 (Type C)
Phi-X174 Bacteriophage	Appropriate
Degradation (EN ISO 374-4:2019)	Acetone: 73,59%

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

MARKING			
<b>MANUFACTURER:</b> MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.			
<b>PPE TYPE:</b>			
<ul style="list-style-type: none"><li>- EN 420+ A1 Protective gloves</li><li>- EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms</li><li>- EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks</li></ul>			
<b>PRODUCT SIZE / MODEL:</b> MB-1200 (S, M, L, XL)			
<b>PICTOGRAM AND PERFORMANCE LEVELS:</b>			
	EN 420+A1	EN ISO 374-1/2016 Type C	EN ISO 374-5/2016
			
NB 2841		K	VIRUS

MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

## PRODUCT PICTURES



MB-1200 (S, M, L, XL)

## DOCUMENTS IN THE TECHNICAL FILE

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Review Reports
- Technical Report





**Report No:** 2020120104  
**Applicant:** **MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.**  
Koza mah. 1638. Sok. Çiğdem sit. 1. Blok apt. No:5 K/11 Esenyurt -  
İSTANBUL  
**Contact Person:** Melih BALKANLI  
**Contact Telephone:** -  
**Contact e-mail:** melihbalkanli@hotmail.com  
**Sample Accepted on:** 23.11.2020  
**Report Date:** 02.12.2020  
**Total number of pages:** 10 (Pg)

**Sample ID:** **MB 1200 EXAMINATION GLOVE**

	TEST	METHOD	Specimen	RESULT
*	Medical Gloves For Single Use Part 1: Requirments And Testing For Freedom From Holes	EN 455-1	MB 1200 EXAMINATION GLOVE	PASS
*	Medical Gloves For Single Use Part 2: Requirements And Testing For Physical Properties	EN 455-2	MB 1200 EXAMINATION GLOVE	PASS
*	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	EN 455-3	MB 1200 EXAMINATION GLOVE	PASS
	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	EN 455-4	MB 1200 EXAMINATION GLOVE	PASS



Seal

Customer Representative  
Hasan KUTLULaboratory Manager  
Hava SARIAYDIN

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**Environment**

The requirements and standards apply to equipment intended for use in

<b>X</b>	Residential (domestic) environment
<b>X</b>	Commercial and light-industrial environment
<b>X</b>	Industrial environment
<b>X</b>	Medical environment



**EN 455-1****Medical Gloves For Single Use Part 1: Requirments And Testing For Freedom From Holes****Scope;**

This part of this standard specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.

**Test Method;**

Fill vertically so that the glove fits in size and the pipe can hold any of the 1000 ml of water that can exceed the glove's natural filling volume.

Attach the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secure it by suitable means to obtain a watertight seal without damaging the glove.

Add 1 000 ml  $\pm$  50 ml of water at a temperature of (15 to 35) °C into the open end of the filling tube, allowing the water to pass freely into the glove.

NOTE Some of the water may remain in the filling tube depending on the glove being tested.

Immediately inspect the glove visually for water leakage. Allow the glove to hang and visually inspect the glove for water leakage again after a period of 2 min to 3 min.

If, because of distension of the glove, the water does not rise to within 40 mm of the cuff end, raise the glove after the second inspection by a suitable means until the water level reaches 40 mm from the cuff end. Inspect visually the previously untested portion of the glove after a further period of 2 min to 3 min. Disregard leakages within 40 mm of the cuff.

**TEST RESULTS**

	Test	Result	Overall Rating
Dimensions	15-35°C 1000 ml, 50ml Water	No Leakage	PASS
Test 2	15-35°C 1000 ml, 50ml Water	No Leakage	
Test 3	15-35°C 1000 ml, 50ml Water	No Leakage	

**Conclusion: There is no water leakage in the Glove, the test is successful.**

**EN 455-2****Medical Gloves For Single Use Part 2: Requirements And Testing For Physical Properties****Scope;**

This standard specifies requirements and gives test methods for physical properties for single use medical (is surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user.

**TEST RESULTS**

	Result	Overall Rating
Dimensions	$\geq 240$ mm (and $295 \pm 5$ mm for long) Extra-Small: 75 5 mm - Small: 80 10 mm - Medium: 95 10 mm Large: 110 10 mm - Extra-Large: $\geq 110$	<b>PASS</b>
Tensile Strength	$\geq 6,0$ Newton	
Breaking force after the tensile strength test	$\geq 6,0$ Newton	

**Conclusion: Meet EN 455-2 requirements Glove, the test is successful.**



## EN 455-3 Medical Gloves For Single Use - Part 3: Requirements And Testing For Biological Evaluation

### Scope:

This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.

### TEST METHODS

#### Endotoxins

The outside surface of a pair of gloves is extracted with 40 ml of endotoxin-free water (Water LAL, European Pharmacopoeia, for not less than 40 min and not more than 60 min at a temperature between 37 °C and 40 °C in a way to ensure that all surfaces come into contact with the extraction medium. The extract is centrifuged, if necessary, for 15 min at 2000 g to remove particles after which the liquid component is decanted and tested for endotoxin immediately afterwards.

#### Powder

This International Standard specifies methods for the determination of readily removable powder on the surface of gloves for medical use. Three methods are specified: method A for powdered gloves and methods B and C for powder-free gloves.

#### Procedure:

The surfaces of a glove are washed with water to remove the water-insoluble powder which is then determined by filtration followed by weighing.

#### Proteins, Leachable

This method is for the determination of the amount of aqueous extractable proteins in gloves for medical use made from natural rubber (NR). It has been validated during inter-laboratory round-robin tests. The lower quantification limit is approximately 10 µg protein per g of glove (i.e. 2 µg protein per ml of extract) depending on the glove weight.

**Procedure:**

Water soluble proteins are extracted into a buffer solution and then precipitated with acids in the presence of sodium deoxycholate to concentrate them and to separate them from water soluble substances which may interfere with the determination. The precipitated proteins are redissolved in alkali and quantified colorimetrically by a modified Lowry method. The assay is based on the reaction of proteins with copper and Folin reagent in an alkaline medium to give a characteristic blue colour. Spectrophotometric measurements are performed at a fixed wavelength in the range 600 nm to 750 nm.

**TEST RESULTS****Endotoxins**

Specimen	Endotoxin Requirement (EU)	Result
MB 1200 EXAMINATION GLOVE	<20	PASS

**Powder**

Specimen	Powder Value (mg)	Result
MB 1200 EXAMINATION GLOVE	<2 mg	PASS

**Proteins, Leachable**

Specimen	Protein value (µg)	Result
MB 1200 EXAMINATION GLOVE	<30 µg	PASS

## EN 455-4 Medical Gloves For Single Use - Part 4: Requirements And Testing For Shelf Life

### Determination

#### Scope:

This part of EN 455 specifies requirements for shelf life for medical gloves for single use. It also specifies the requirements for labelling and the disclosure of information relevant to the test methods used.

#### Real time shelf life determination

Gloves in consumer packages are conditioned at the temperature as defined by the manufacturer (e.g. 25 °C) for the intended shelf life period and then tested for compliance

Upon completion of the procedure, the shelf-life claim will be up to this time, not exceeding five years that the gloves are in compliance with the requirements of this European Standard.

#### Accelerated shelf life determination

Because of the errors and uncertainties inherent in the determination of shelf lives using accelerated ageing methods shelf life claims should be limited to a maximum of 3 years.

## TEST RESULTS

#### Real time shelf life determination

Test Item: Rapid Aging Test-Xenon-ark

Exposure Sample Description: Nitrile Examination Glove , Latex Examination Glove

Test Condition:

Exposure cycle

Irradiation:  $(0,50 \pm 0,2) \text{ W / (m}^2\text{-nm)}$ @340nm 1080 h

Filter: Daylight - UV-B / UV-A / UV-C - KSENON ARK

Exposure time: 1080 hours



Test	UVA Exposure Time	Gray Scale	Customer Requirement	Result
1	1080 h	5-5	-	PASS

**Observation ;**

Nitrile Examination Glove is resistant to Latex Examination Glove 1080 hours UV aging.

**UV AGING**

The molecular structure of the samples was examined by FTIR (Mattson) before and after this test.

**Conclusion:** When adequate protection is not provided, radical formation, chain breakage and carbonyl formation did not occur in the structure of raw materials with the effect of UV, with the contribution of air oxygen.

During the test, normal daily conditions targeted at 25 ° C for 1080 hours were simulated and no color change and deterioration were observed.

Measurement Device	Rates	Date of Calibration
EUROLAB EL / UV IR VL Xenon	UVA-UVB (290 to 315 nm)	03.11.2019

In the test environment, the relative Humidity is 50% in the environment.

In the test environment, the air temperature is about 25 degrees centigrade.

**Accelerated shelf life determination**

Test Item: Rapid Aging Test-Xenon-ark

Exposure Sample Description: Nitrile Examination Glove , Latex Examination Glove

Test Condition:

Exposure cycle

Irradiation: (0,50 ± 0,2) W /(m<sup>2</sup>-nm)@340nm 720 h

Filter: Daylight - UV-B / UV-A / UV-C - KSENON ARK

Exposure time: 720 hours

Test	UVA Exposure Time	Gray Scale	Customer Requirement	Result
1	720 h	5-5	-	<b>PASS</b>

**Observation ;**

Nitrile Examination Glove is resistant to Latex Examination Glove 720 hours UV aging.

**UV AGING**

The molecular structure of the samples was examined by FTIR (Mattson) before and after this test.

**Conclusion:** When adequate protection is not provided, radical formation, chain breakage and carbonyl formation did not occur in the structure of raw materials with the effect of UV, with the contribution of air oxygen.

During the test, normal daily conditions targeted at 25 ° C for 720 hours were simulated and no color change and deterioration were observed.

Measurement Device	Rates	Date of Calibration
EUROLAB EL / UV IR VL Xenon	UVA-UVB (290 to 315 nm)	03.11.2019

**In the test environment, the relative Humidity is 50% in the environment.**

**In the test environment, the air temperature is about 25 degrees centigrade.**

IMAGE OF SAMPLE



\*\*\*END OF REPORT\*\*\*





Report No: 2020120101  
Applicant: MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.  
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Contact Person: Melih BALKANLI  
Contact Telephone: -  
E-Mail: melihbalkanli@hotmail.com  
Sample Accepted on: 23.11.2020  
Report Date: 02.12.2020  
Total number of pages: 7 (pg)

Sample ID: MB 1200 EXAMINATION GLOVE

TEST	METHOD	Specimen	RESULT
* Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage	ISO 16604	MB 1200 EXAMINATION GLOVE	PASS



Seal



Customer Representative  
Hasan KUTLU



Laboratory Manager  
Hava SARIAYDIN

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<b>X</b>	Commercial and light-industrial environment
<b>X</b>	Industrial environment
<b>X</b>	Medical environment

## ISO 16604 Clothing For Protection Against Contact With Blood And Body Fluids —Determination Of Resistance Of Protective Clothing Materials To Penetration By Blood-Borne Pathogens — Test Method Using Phi-X174 Bacteriophage

### Scope

This International Standard describes a laboratory test method for measuring the resistance of materials used in protective clothing to penetration by blood-borne pathogens. This test method uses a surrogate microbe under conditions of continuous liquid contact. Protective clothing “pass/fail” determinations are based on the detection of viral penetration at a specific hydrostatic pressure using the ISO 13994 test apparatus.

### General

A specimen is subjected to a nutrient broth containing a virus in a test apparatus as specified in ISO 13994 for a specified time and pressure sequence. Visual detection of penetration is supplemented with an assay procedure that will detect viable viruses which penetrate the material even when liquid penetration is not visible. Any evidence of viral penetration for a test specimen constitutes failure. This test method requires a working knowledge of basic microbiological techniques.

### Microorganisms and reagents

- Bacteriophage Phi-X174 (ATCC 13706-B1)
- Bacteria E. Coli*
- Purified water
- Nutrient broth
- Calcium chloride (CaCl<sub>2</sub>)
- Potassium chloride (KCl)
- Sodium hydroxide (NaOH)
- Surfactant
- Bacto-agar

### Preparation of test specimens

Test Conditioning	
Temperature (°C)	21 ± 5 ° C
Relative Humidity	% 60 ± 10
Time	24 h



**Procedure****-Bacteriophage nutrient broth (Phi-X)**

Bacto-tryptone (8,0 ± 0,1) g  
Potassium chloride (5,0 ± 0,06) g  
Calcium chloride (0,2 ± 0,003) g  
Purified water (1 000 ± 12,5) ml  
Surfactant (0,1 ± 0,001 25) ml

Adjust pH of the bacteriophage nutrient broth to (7,3 ± 1) using 2,5 mol/l sodium hydroxide.  
Dilute 1 volume of 0,1 % surfactant with 9 volumes of bacteriophage nutrient broth. To ensure adequate mixing, prior to sterilization, heat the bacteriophage nutrient broth while stirring in the surfactant. A final concentration of 0,01 % surfactant is recommended to adjust the surface tension to (0,042 ± 0,002) N/m. Sterilize the bacteriophage nutrient broth in the autoclave.

**-Bottom agar (Phi-X)**

Prepare the bottom agar using the following:  
Bacto-agar (15,0 ± 0,19) g  
Nutrient broth (8,0 ± 0,1) g  
Potassium chloride (5,0 ± 0,06) g  
Purified water (5.3) (1 000 ± 12,5) ml  
Calcium chloride (1,0 ± 0,012 5) ml (to be added after autoclaving the bottom agar)

Prepare sterile calcium chloride by autoclaving a 1 mol/l solution of calcium chloride in purified water.  
Adjust pH of the bottom agar to (7,3 ± 1) using 2,5 mol/l sodium hydroxide.  
Sterilize the bottom agar in the autoclave.

**-Preparation of controls**

Use the following controls concurrently with the testing of each protective garment or protective garment material.  
a) Aerosol/airborne contamination controls: settle plates or other appropriate means to determine background aerosol/airborne counts for the Phi-X174 bacteriophage.  
Use the following controls at least one time per day:  
b) Negative test sample control: samples made of a heavy gauge monolithic film such as a medical packaging polyester film.  
c) Positive test sample control: samples made of a microfiltration medium with a pore size slightly larger, (0,050 ± 0,005) µm, than the mean diameter of the Phi-X174 bacteriophage, 0,027 µm.

**-Determination of material compatibility**

Conduct compatibility testing of protective clothing materials which are suspected of affecting the titre of the bacteriophage challenge suspension.

- Test three specimens representing each material to be tested.
- With the penetration cell placed horizontally on the lab bench, aseptically insert the sterile specimen in the penetration cell with the normal outside surface toward the cell reservoir.
- Torque the bolts in the penetration test cell to 13,6 N·m each.
- With the penetration cell remaining in the horizontal position on the lab bench, place a 2,0 µl aliquot of the Phi-X174 bacteriophage in the bacteriophage nutrient broth, containing a total of 900 PFU to 1 200 PFU, near the middle of each specimen.
- Prepare a control by adding a 2,0 µl aliquot of the Phi-X174 bacteriophage suspension directly to 5.0 ml of sterile bacteriophage nutrient broth.
- After 10 min, quantitatively assay as described in .
- Calculate the ratio of the control assay titre to the test material assay titre.
- Fix the titres of the Phi-X174 bacteriophage challenge suspension prepared , which is also used for the test exposure procedure , as being equal to the ratio calculated in h) multiplied by  $(2 \text{ to } 3) \times 10^8$  PFU/ml. If the calculated ratio is above 5.0 , the maximum titre for the bacteriophage challenge suspension shall be  $1 \times 10^9$  PFU/ml.

**Procedure for preparation of bacteriophage suspension**

Prepare the bacteriophage suspension using the following steps:

- Using an inoculating loop, inoculate 10 ml to 25 ml of bacteriophage nutrient broth in a 250 ml conical flask with *E. coli* C. Incubate the bacterial culture overnight at  $(36 \pm 1)^\circ\text{C}$  with shaking at  $(225 \pm 25)$  r/min.
- Prepare a 1:100 dilution of the overnight bacterial culture in 100 ml of fresh bacteriophage nutrient broth in a 1 l conical flask. Incubate the flask at  $(36 \pm 1)^\circ\text{C}$  with shaking at  $(225 \pm 25)$  r/min. Grow bacterial culture to a density of  $(3 \pm 1) \times 10^8$  CFU/ml (about 3 h). This cell density corresponds to a 0,3 to 0,5 absorbance reading (at 640 nm) as measured on a spectrophotometer.
- Inoculate the bacterial culture with 5 ml to 10 ml of the Phi-X174 bacteriophage stock having a titre of  $1,0 \times 10^9$  PFU/ml to  $1,0 \times 10^{10}$  PFU/ml. Ensure that the ratio of bacteriophage to bacteria cells is between 0,1 and 2,0.
- Incubate the inoculated bacterial culture at  $(36 \pm 1)^\circ\text{C}$  with vigorous shaking for 1 h to 5 h or until lysis is complete. Lysis is considered complete when the absorbance reading at 640 nm stops decreasing.
- Centrifuge the culture for 20 min at 10 000 g to remove large cell debris. Decant the supernatant into a clean tube.
- Filter bacteriophage-containing supernatant suspension through a 0,22 µm filter to purify the bacteriophage solution.
- Determine the titre of the bacteriophage stock and store at  $(5 \pm 3)^\circ\text{C}$ . The bacteriophage titre obtained is typically in the range of  $(5,0 \pm 2) \times 10^{10}$  PFU/ml.
- Prepare the bacteriophage challenge suspension by diluting the phage stock in the bacteriophage nutrient broth to the concentration required. Verify the final concentration of the phage using the assay procedure .

**Preparation of settle plates**

If elected, place settle pates in strategic locations during the aseptic test specimen insertion, filling, testing, draining, and assay operations, to help identify potential problems associated with aerosolized or airborne Phi-X174 bacteriophage. Prepare settle plates as follows.

- Dispense 2,5 ml of sterile molten top agar into sterile test tubes and hold the temperature of the top agar at  $(45 \pm 2)^\circ\text{C}$ . Prepare one test tube for each settle plate.



- b) Add 100 µl of an overnight culture of *E. coli* C. to each top agar tube.
- c) Vortex tubes well and pour contents over the surface of the bottom agar plates.
- d) Allow agar to solidify. Settle plates may be used immediately.
- e) After use, incubate settle plates with the assay plates for the test sample replicates and the positive and the negative controls.

### Exposure of material to bacteriophage challenge suspension

Expose each material specimen to the bacteriophage challenge suspension using the following steps.

- a) Carefully fill the chamber of the penetration cell through the top port with approximately 60 ml of Phi-X174 bacteriophage challenge suspension. If liquid appears to penetrate through the test specimen at anytime during the test, go straight to step h.
- b) Connect the air line to the penetration cell.
- c) Observe the viewing surface of the specimen at the end of each specified pressure and time interval for the appearance of liquid penetration or other evidence of wetness. If elected, record the time of visible liquid penetration.
- d) If there is no visible penetration, continue on to the next step of the time and pressure protocol.
- e) The pressure in the challenge side of the test cell shall be changed to the next level at a rate of  $(3,5 \pm 0,5)$  kPa/s.
- f) Hold the pressure constant at each specified level for the specified time.
- g) When returning to atmospheric pressure, turn off the pressure and open the cell valve to the vent position.
- h) At the end of the time period, open the drain valve and drain the penetration cell of bacteriophage challenge suspension.
- i) Dilute and assay the Phi-X174 bacteriophage challenge suspension collected from at least the last penetration cell of each set of replicates after the test to be sure that there has been no loss of bacteriophage virulence during the test.
- j) With the cell placed horizontally on the lab bench, remove the transparent cover.
- k) Immediately after removing the cover, slowly add 5,0 ml sterile nutrient broth with 0,01 % surfactant, onto the exposed surface of the specimen's normal inside surface. Gently swirl or rock the penetration cell for approximately 1 min to ensure contact of this assay fluid with the entire viewing surface of the test specimen. Remove the assay fluid, as soon as possible with a sterile pipette to a sterile vial. Some materials absorb the assay fluid, requiring a larger volume wash. If a larger volume is necessary, be sure to adjust the calculation of PFU/ml in the test report.
- l) Assay immediately as specified. A longer period may lapse between collection of the assay fluid and the actual assay if stability of the bacteriophage in the assay fluid can be demonstrated.
- m) Disassemble the apparatus and clean the penetration cell. Disinfect the air lines periodically to prevent contamination. Clean the penetration cell by rinsing with a 10 % bleach solution, and subsequently autoclaving it at  $(122 \pm 1)$  °C and  $(214 \pm 7)$  kPa absolute for 15 min.
- n) Test the remaining specimens.



**Procedure for quantification of assay fluid**

Quantify the number of bacteriophage in the assay fluid using the following procedure:

- Dispense 2,5 ml of sterile molten top agar into sterile test tubes and hold top agar at (45 ± 2) °C.
- Prepare duplicate plates for each assay collected for each replicate and control.
- Prepare inoculate tubes by adding 0,5 ml of the assay medium fluid from each specimen to a top agar tube immediately after removing the tube from the heat.
- Add 100 µl of an overnight culture of E. coli C to each of the inoculate tubes.
- Vortex tubes well and pour over the surface of the bottom agar plates.
- Allow agar to solidify and incubate at (36 ± 1) °C until plaques are clearly visible, usually for at least 6 h.
- Observe for the of plaques and interpret result .
- If quantification is needed, and the total number of plaques is too great to count, prepare a series of 1:10 dilutions in bacteriophage nutrient broth of the assay fluid and assay for bacteriophages as in steps a) to g).

**Test Results**

Tested Specimen Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Observation	Result
1-5	3.50 X 10 <sup>8</sup>	3.10 x 10 <sup>8</sup>	<1	Not Observed Improperly	PASS
Negative Control	3.50 X 10 <sup>8</sup>	3.10 x 10 <sup>8</sup>	<1	Not Observed Improperly	Acceptable
Positive Control	3.50 X 10 <sup>8</sup>	3.10 x 10 <sup>8</sup>	TNTC <sup>b</sup>	Yes	Acceptable

<sup>a</sup> A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.

<sup>b</sup> TNTC = PFUs were too numerous to count.

**Comment:** This test method has been applied to evaluate the barrier performance of protective materials intended to protect against bloodborne pathogen hazards. It has been tested for viral penetration using test materials. Viral penetration method complies with ISO 16604. All test method met acceptance criteria and passed successfully.

\*\*\*END OF REPORT\*\*\*



Report No: 2020120719  
Applicant: **MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.**  
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Sample Accepted on : 30.11.2020  
Report Date: 07.12.2020  
Total number of pages: 7 (pg)

Sample ID : **MB EXAMINATION 1200 GLOVE**

	TEST	METHOD	Specimen	RESULT
*	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	EN 2859-1	MB EXAMINATION 1200 GLOVE	PASS



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Customer Representative  
Hasan KUTLULaboratory Manager  
Hava Sarıaydın

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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





**EN 2859-1 Sampling Procedures For Inspection By Attributes – Part 1: Sampling Schemes Indexed By Acceptance Quality Limit (AQL) For Lot-By-Lot Inspection****Scope**

The purpose of this standard is to use the economic and psychological pressure that arises from the rejection of an inspection lot to get a supplier to maintain an average quality level of the process that is at least as good as the specified acceptable quality limit. The customer's upper risk limit ensures that the occasional bad inspection lot is accepted.

**General**

AQL is an industry standard. It is a statistical sampling process for evaluating quality. According to the International Standards Organization (ISO) (2859-1), AQL is "the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling". Process average is the typical percentage gloves in the lots/batches sampled of defective.

**Procedure**

AQL is a pass/fail where a predetermined sample size of a manufactured lot is tested following the sampling plan and protocols established by the various international standards or more stringent standards set by manufacturers to ensure stricter and higher quality is delivered to the customer.

The sampling plan is an inspection procedure of a sample size that is used to determine acceptance or rejection criteria from an inspection batch or lot.

First the manufacturer will need to know the size of the lot being manufactured; this is the amount of gloves produced without any conditions changing in a single run. Based on the lot size, the standards will determine the sampling size, which is the number of gloves inspection, which randomly selected to be tested. The gloves tested, according with Statistical Quality Control, have all been through 'identical' processing and are truly representative of the total lot or batch. In this test, the gloves are filled with 1000 ml of water, bound or sealed at the cuff and hung upside down for two minutes and checked for leaks under sustained pressure. This is the recognised test method for global glove standards.

Requirements	
Glove Type	AQL
Examination gloves	1.5-2.5

The lower the AQL, the lower the chance of finding a defect in the batch of gloves and the higher the quality of the product.

Specimen	Characteristics	Requirements	Acceptable Quality Level (AQL)	Result																				
MB 1200 EXAMINATION GLOVE	Dimentions	<table border="1"> <thead> <tr> <th>Description</th> <th>Size</th> <th>Standard</th> </tr> </thead> <tbody> <tr> <td>Length (mm)</td> <td>All Sizes</td> <td>Min 240</td> </tr> <tr> <td rowspan="5">Palm width (mm)</td> <td>Xs</td> <td>76 ± 3</td> </tr> <tr> <td>S</td> <td>84 ± 3</td> </tr> <tr> <td>M</td> <td>94 ± 3</td> </tr> <tr> <td>L</td> <td>105 ± 3</td> </tr> <tr> <td>Xl</td> <td>113 ± 3</td> </tr> <tr> <td>Thickness (mm)</td> <td>All Sizes</td> <td>Finger: 0.05 ± 0.05 (Typical value: 0.11-0.14)  Palm: 0.05 ± 0.05 (Typical value: 0.10-0.12)</td> </tr> </tbody> </table> <p>(See table 1)</p>	Description	Size	Standard	Length (mm)	All Sizes	Min 240	Palm width (mm)	Xs	76 ± 3	S	84 ± 3	M	94 ± 3	L	105 ± 3	Xl	113 ± 3	Thickness (mm)	All Sizes	Finger: 0.05 ± 0.05 (Typical value: 0.11-0.14)  Palm: 0.05 ± 0.05 (Typical value: 0.10-0.12)	1.5	PASS
		Description	Size	Standard																				
		Length (mm)	All Sizes	Min 240																				
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S	84 ± 3																							
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Physical Properties	<table border="1"> <thead> <tr> <th rowspan="2">Description</th> <th colspan="2">Standard</th> </tr> <tr> <th>Before Aging</th> <th>After Aging</th> </tr> </thead> <tbody> <tr> <td>Elongation at Break %</td> <td>Min 650</td> <td>Min 500</td> </tr> <tr> <td>Tensile Strength</td> <td>Min 18</td> <td>Min 14</td> </tr> </tbody> </table> <p>(See table 2)</p>	Description	Standard		Before Aging	After Aging	Elongation at Break %	Min 650	Min 500	Tensile Strength	Min 18	Min 14	1.5	PASS										
Description	Standard																							
	Before Aging	After Aging																						
Elongation at Break %	Min 650	Min 500																						
Tensile Strength	Min 18	Min 14																						
Freedom From Holes ( Air Pump Test)	<p>The sample sizes allowable number of non-conforming gloves in the samples shall be determined in accordance to sampling plane ISO 2859-1 single normal using inpection and acceptable quality level as stated in section II: performance requirements.</p> <p>(See table 3)</p>	1.5	PASS																					
Visual Defects	<p>The sample size and allowable number of non-conforming gloves in the sampels for both major and minor defects shall be determined in accordance to sampling plane ISO 2859-1 single normal using inspection and acceptable quality level as stated in section II performance requirements.</p> <p>(See table 3)</p>	2.5-4	PASS																					

	<b>Packaging Defects</b>	The Sample size and allowable number of non-conforming in the sample for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859- 1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirement (Gloves Counting = 100 pcs by weight per Dispenser).	4	PASS
	<b>Powder Free Residue</b>	Maximum 2 mg per glove. (See table 4)	--	PASS

RESULT

Table 1

Sample No	Size	Length (mm)	Width (mm)	Thickness (mm)	
				Fingertip	Palm
1	S	260	86	0.16	0.18
2		263	89	0.17	0.16
3		266	90	0.17	0.15
4		261	88	0.15	0.16
5	M	260	100	0.16	0.14
6		264	98	0.16	0.14
7		266	97	0.16	0.16
8		263	100	0.17	0.15
9	L	260	120	0.18	0.15
10		264	119	0.18	0.16
11		266	121	0.16	0.17
12		261	120	0.17	0.15
13		265	120	0.17	0.14



Table 2

Sample No	Size	Before Aging		After Aging	
		Tensile Strength (MPa)	Elongation (%)	Tensile Strength (MPa)	Elongation (%)
1	S	20.5	563	19.4	512
2		21.2	554	21.1	520
3		18.9	571	17.6	536
4		19.3	567	18.9	542
5	M	22.4	617	21.3	590
6		23.1	605	22.0	557
7		22.8	611	19.3	582
8		21.6	620	21.4	586
9	L	20.9	583	20.7	537
10		23.2	591	22.8	530
11		22.8	582	21.5	546
12		21.7	590	20.9	570
13		20.9	585	20.3	544

Table 3

Size	Holes			Visual defect						Result
	Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	Major defect, AQL 2.5			Minor defects, AQL 4.0			
				Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	
S	260	7	3	200	10	5	200	14	6	PASS
M	260	7	3	200	10	6	200	14	7	PASS
L	260	7	2	200	10	5	200	14	7	PASS

Table 4

Size	mg/Glove	Result
S	--	PASS
M	--	PASS
L	--	PASS



IMAGE



\*\*\*END OF REPORT\*\*\*

**Report No:** 2020120102  
**Applicant:** **MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.**  
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**Sample Accepted on:** 23.11.2020  
**Report Date:** 02.12.2020  
**Total number of pages:** 16 (Pg)

**Sample ID:** **MB 1200 EXAMINATION GLOVE**

	TEST	METHOD	Specimen	RESULT
*	Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks	EN 374-1	MB 1200 EXAMINATION GLOVE	PASS
*	Protective gloves against dangerous chemicals and micro-organisms Part 4: Determination of resistance to degradation by chemicals	EN 374-4	MB 1200 EXAMINATION GLOVE	PASS
*	TS EN ISO 374-5 Protective gloves against dangerous chemicals and microorganisms - Part 5: Terms and performance rules for microorganism risks.	EN 374-5	MB 1200 EXAMINATION GLOVE	PASS



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Customer Representative  
Hasan KUTLULaboratory Manager  
Hava SARIYDIN



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## Environment

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X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

## EN 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms – Part 1: Terminology And Performance Requirements For Chemical Risks

### Scope

This part of ISO 374 specifies requirements for protective gloves that are intended to protect the user against dangerous chemicals and defines the terms to be used

### General

#### Sampling for permeation

Each material sample to be tested must meet the requirements of EN 16523-1: 2015, Section 7, so that the material can be sealed in the test cell.

Three samples are to be taken from the palm of the hand. If the glove is 400 mm or longer and protection against chemical risks is specified for the cuff, take three additional samples with the middle 80 mm from the cuff.

#### Sampling for the penetration test

Sampling for penetration must be carried out in accordance with EN 374-2: 2014, Section 5.

#### Sampling for the degradation test

Sampling for degradation must be carried out in accordance with 4.1 and EN 374-4: 2013, Section 5.1.

### General requirements

Protective gloves against dangerous chemicals must meet the requirements in EN 420: 2009, Section 4, Section 5 and Section 7.

### Penetration

Protective gloves must not leak when testing according to EN 374-2: 2014, 7.2 and 7.3.

### Degradation

The degradation (DR) must be determined in accordance with EN 374-4 for each chemical that is specified on the label and listed in the user information.

For gloves that are longer than 400 mm and in which the palm of the hand and the cuff have different performance levels, the lower performance level must be specified on the label for each chemical.

Protective gloves against chemicals are classified into three types according to their permeation performance: Type A, Type B or Type C.

**EN 16523-1 Determination Of Material Resistance To Permeation By Chemicals - Part 1: Permeation By Potentially Hazardous Liquid Chemicals Under Conditions Of Continuous Contact**

**Test Method**

The resistance of a protective glove material to permeation by a solid or liquid chemical is determined by measuring the breakthrough time of the chemical through the glove material

The sample shall be conditioned for 24 h at a temperature of (23±2) °C and The standard test temperature shall be (23±1) °C.


Gloves Type	Requirement
TYPE A	Breakthrough time ≥ 30 min against at least 6 chemicals of the new list
TYPE B	Breakthrough time ≥ 30 min against at least 3 chemicals of the new list
TYPE C	Breakthrough time ≥ 30 min against at least 3 chemicals of the new list

**EN ISO 374-1 glove permeation test list**

Code Letter	Chemical	Cas Number	Class
A	Methanol	67-56-1	Primary Alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile Compound
D	Dichloromethane	75-09-2	Chlorinated Paraffin
E	Carbon disulphide	75-15-0	Sulphur Containing Organic
F	Toluene	108-88-3	Aromatic Hydrocarbon
G	Diethylamine	109-89-7	Amine
H	THF	109-99-9	Heterocyclic and Ether
I	Ethyl Acetate	141-78-6	Ester
J	N-Heptane	142-82-5	Saturated Hydrocarbon
K	Sodium Hydroxyde %40	1310-73-2	Inorganic Base
L	Sulphuric Acid %96	7664-93-9	Inorganic Mineral Acid
M	Nitric Acid %65	7697-37-2	Inorganic Acide , oxidizing
N	Acetic Acide %99	64-19-7	Organic acid
O	Ammonia %25	1336-21-6	Organic Base
P	Hydrogen peroxide %30	7722-84-1	Peroxide
S	Hydrogen flüoride %4,	7664-39-3	Inorganic Mineral Acid
T	Formaldehyde %37	50-00-0	Aldehyde



**Test Results**

Specimen	Chemical	Observation	Gloves Type
MB 1200 EXAMINATION GLOVE	Formaldehyde %37	Not permeable	EN ISO 374-1:2016 TYPE B  NTHBC
MB 1200 EXAMINATION GLOVE	Acetonitrile	Not permeable	
MB 1200 EXAMINATION GLOVE	Acetone	Not permeable	
MB 1200 EXAMINATION GLOVE	THF	Not permeable	
MB 1200 EXAMINATION GLOVE	Acetic acide	Not permeable	
MB 1200 EXAMINATION GLOVE	Sulphuric acide	There is permeability	

**EN 374-2 Protective Gloves Against Dangerous Chemicals And Micro-Organisms - Part 2: Determination Of Resistance**
**To Penetration**
**SCOPE**

This standard describes the criteria that protective gloves should have, especially in terms of contact risks with microorganisms such as bacteria, fungi and viruses.

**Air Leak Test Method**

- The glove is fastened to the circular mandrel and is inflated after immersion at ambient temperature, with air, to a gauge pressure of X kPa (see Table 1) plus an overpressure of 1 kPa per 100 mm of immersion measured at the fingertips closest to the bottom of the water tank.
- The inflation pressure shall be reached with a  $\pm 10\%$  limit deviation within 2 min and the control of possible air bubbles shall take an additional  $(30 \pm 5)$  s.

**Table 1**

Nominal glove thickness (e) mm As provided by the manufacturer	Air pressure (X) kPa
$e \leq 0,3$	0,4
$0,3 < e \leq 0,5$	2,0
$0,5 < e \leq 1,0$	5,0
$e > 1,0$	5,0

**Test Result**

Specimen	Total Air Pressure (kPa)	Observation	Result
MB 1200 ELDİVEN	2,7	No leaks detected	<b>PASS</b>

**Water Leak Test Method**

- The glove is attached to an open-ended plastic tube by bringing the edge of the cuff to the 40 mm mark and fastening it with the elastic strap to make a watertight seal.
- A minimum of 1 000 ml of water is added through the tube to fill the glove completely and to reach at least the 40 mm mark level of the liquid proof area of the glove. The water shall be at ambient temperature
- The gloves are examined immediately for water leaks. The glove should not be squeezed. Only minimal handling is required to detect leaks. Water droplets may be blotted to confirm leakage, or talcum powder may be used to enhance droplet visibility.

**Test Results**

Specimen	Observation	Result
MB 1200 EXAMINATION GLOVE	No leaks detected	<b>PASS</b>

**EN 374-4 Protective gloves against dangerous chemicals and microorganisms - Part 4: Determination of resistance to degradation by chemicals****Principle**

The resistance of a protective glove material to degradation by a liquid chemical is determined by measuring the change in puncture resistance of the glove material after continuous contact of the external surface with the challenge test chemical. The test is applicable to gloves made of natural or synthetic polymer.

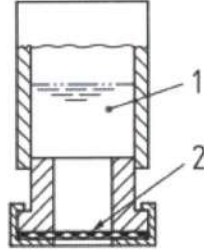
**Procedure**

The test shall be conducted at  $(23 \pm 2)$  °C (preparation, chemical, exposure to chemical, and puncture test).

Place a glove specimen on top of the septum with its normal external surface facing towards the interior of the vial. Place the aluminium cap with the specimen on top of the vial. Seal the vial using the hand crimper and invert it so that the challenge chemical is in contact with the specimen (see Figure 1). Record the time. Place the vial in the punched-out sample holder.

The punched-out sample holder has a twofold purpose:

- It allows air to circulate under the sample film, and
- if the pressure from the challenge chemical forces the sample into a convex shape, the flask will still stand



#### Key

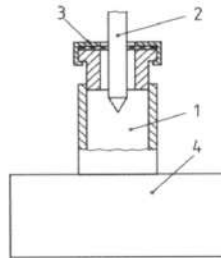
1 challenge chemical

2 outer surface of the glove specimen which is in contact with the challenge chemical, it is a circular area of  $(12,5 \pm 0,5)$  mm diameter

**Figure 1 — Position of the vial during contact time between the specimen and the challenge chemical**

#### Puncture testing

Install the puncture stylus on the dynamometer load cell. Set the carriage speed to 100 mm/min and screw the vial support onto the table. Place a vial into the support. Puncture the specimen and record the peak force required (see Figure 2). Repeat for each of the specimens; test each of the exposed specimens one hour after the exposure on that specimen was started.



#### Key

1 20 ml crimp vial

2 puncture stylus 3 specimen 4 sample vial support (to be maintained by the dynamometer jaw)

**Figure 2 — Position of the vial during puncture test**

#### Test Results

The following degradation data (see Table A.1) have been obtained in laboratory.

**Table A.1 — Results in % of correlation trial with other gloves materials**



Laboratory	Acetone	Sulfuric Acid
	Mean value for Nitrile glove	Mean value for Nitrile glove
1	61	87
2	60	88
3	63	91
4	61	94
5	61	88
6	65	90

## Weight Charge Test

### Test Conditions

The glove should be conditioned at  $(23 \pm 2)$  °C for at least 24 h. The specimens should be taken from three gloves. Put the glove flat on a surface and measure  $(60 \pm 2)$  mm from fingertip. The specimens should consist of a cut-off of the same finger of each glove.

### Procedure

Start the timer and immerse the finger specimen in a beaker containing the test chemical. The weighed test tube will hold the specimen upright in the beaker. The beaker should be filled to a depth of  $(42 \pm 2)$  mm with the test chemical (see Figure B.1). The quantity of the test chemical should be adapted during the test to keep the beaker filled to the marking. Multiple finger specimens can be started at approximately 1 minute timed intervals to allow for weighing of the specimens.

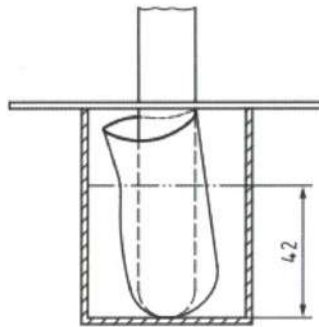


Figure B.1 — Typical arrangement of weight change test apparatus

The weighing of the finger specimen should be carried out as quickly as possible after the 60 min chemical exposure.

## Result

After the Weight Charge Test, there was not observed any changes such as swelling, shrinking, brittleness, hardening, softening, flaking, disintegration, colour change/bleeding on the sample.

## TS EN ISO 374-5:2016 Protective Gloves Against Dangerous Chemicals And Microorganisms - Part 5: Terms And Performance Rules For Microorganism Risks

### Scope

This International Standard describes a laboratory test method for measuring the resistance of materials used in protective clothing to penetration by blood-borne pathogens. This test method uses a surrogate microbe under conditions of continuous liquid contact.

### Test Conditions

Condition each protective clothing specimen for a minimum of 24 h by exposure to a temperature of  $(21 \pm 5)$  °C and a relative humidity of  $(60 \pm 10)$  %.


### Procedure

This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at  $21 \pm 5$ °C and  $60 \pm 10$ % relative humidity (RH), and then tested for viral penetration using a  $\phi$ X174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of  $\phi$ X174 bacteriophage.

The viral penetration method complies with ISO 16604. All test method acceptance criteria were met.

## Result

### Specimen: Nitrile Examination Glove

Tested Specimen Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Observation	Result	Marking
1-6	$3.50 \times 10^8$	$3.10 \times 10^8$	$<1^a$	Not Observed Improperly	PASS	EN ISO 374-5 :2016
Negative Control	$3.50 \times 10^8$	$3.10 \times 10^8$	$<1^a$	Not Observed Improperly	Acceptable	 VIRUS
Positive Control	$3.50 \times 10^8$	$3.10 \times 10^8$	TNTC <sup>b</sup>	Yes	Acceptable	

<sup>a</sup> A value of  $<1$  plaque forming units (PFU)/mL is reported for assay plates showing no plaques.

<sup>b</sup>TNTC = PFU were too numerous to count.

IMAGE OF SAMPLE



\*\*\* End Of Report\*\*\*





**Report No:** 2020120719  
**Applicant:** **MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.**  
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**Contact Person:** Melih BALKANLI  
**Contact Telephone:** -  
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**Sample Accepted on :** 30.11.2020  
**Report Date:** 07.12.2020  
**Total number of pages:** 7 (pg)  
**Sample ID :** **MB EXAMINATION 1200 GLOVE**

	TEST	METHOD	Specimen	RESULT
*	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	EN 2859-1	MB EXAMINATION 1200 GLOVE	<b>PASS</b>



Seal

Customer Representative  
Hasan KUTLU  
Laboratory Manager  
Hava Saraydin

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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



## EN 2859-1 Sampling Procedures For Inspection By Attributes – Part 1: Sampling Schemes Indexed By Acceptance Quality Limit (AQL) For Lot-By-Lot Inspection

### Scope

The purpose of this standard is to use the economic and psychological pressure that arises from the rejection of an inspection lot to get a supplier to maintain an average quality level of the process that is at least as good as the specified acceptable quality limit. The customer's upper risk limit ensures that the occasional bad inspection lot is accepted.

### General

AQL is an industry standard. It is a statistical sampling process for evaluating quality. According to the International Standards Organization (ISO) (2859-1), AQL is "the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling". Process average is the typical percentage gloves in the lots/batches sampled of defective.

### Procedure

AQL is a pass/fail where a predetermined sample size of a manufactured lot is tested following the sampling plan and protocols established by the various international standards or more stringent standards set by manufacturers to ensure stricter and higher quality is delivered to the customer.

The sampling plan is an inspection procedure of a sample size that is used to determine acceptance or rejection criteria from an inspection batch or lot.

First the manufacturer will need to know the size of the lot being manufactured; this is the amount of gloves produced without any conditions changing in a single run. Based on the lot size, the standards will determine the sampling size, which is the number of gloves inspection, which randomly selected to be tested. The gloves tested, according with Statistical Quality Control, have all been through 'identical' processing and are truly representative of the total lot or batch. In this test, the gloves are filled with 1000 ml of water, bound or sealed at the cuff and hung upside down for two minutes and checked for leaks under sustained pressure. This is the recognised test method for global glove standards.

Requirements	
Glove Type	AQL
Examination gloves	1.5-2.5

The lower the AQL, the lower the chance of finding a defect in the batch of gloves and the higher the quality of the product.



Specimen	Characteristics	Requirements	Acceptable Quality Level (AQL)	Result																				
MB 1200 EXAMINATION GLOVE	Dimentions	<table border="1"> <thead> <tr> <th>Description</th> <th>Size</th> <th>Standard</th> </tr> </thead> <tbody> <tr> <td>Length (mm)</td> <td>All Sizes</td> <td>Min 240</td> </tr> <tr> <td rowspan="5">Palm width (mm)</td> <td>Xs</td> <td>76 ± 3</td> </tr> <tr> <td>S</td> <td>84 ± 3</td> </tr> <tr> <td>M</td> <td>94 ± 3</td> </tr> <tr> <td>L</td> <td>105 ± 3</td> </tr> <tr> <td>XI</td> <td>113 ± 3</td> </tr> <tr> <td>Thickness (mm)</td> <td>All Sizes</td> <td>Finger: 0.05 ± 0.05 (Typical value: 0.11-0.14)  Palm: 0.05 ± 0.05 (Typical value: 0.10-0.12)</td> </tr> </tbody> </table> <p style="text-align: center;">(See table 1)</p>	Description	Size	Standard	Length (mm)	All Sizes	Min 240	Palm width (mm)	Xs	76 ± 3	S	84 ± 3	M	94 ± 3	L	105 ± 3	XI	113 ± 3	Thickness (mm)	All Sizes	Finger: 0.05 ± 0.05 (Typical value: 0.11-0.14)  Palm: 0.05 ± 0.05 (Typical value: 0.10-0.12)	1.5	PASS
		Description	Size	Standard																				
		Length (mm)	All Sizes	Min 240																				
		Palm width (mm)	Xs	76 ± 3																				
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Thickness (mm)	All Sizes	Finger: 0.05 ± 0.05 (Typical value: 0.11-0.14)  Palm: 0.05 ± 0.05 (Typical value: 0.10-0.12)																						
Physical Properties	<table border="1"> <thead> <tr> <th rowspan="2">Description</th> <th colspan="2">Standard</th> </tr> <tr> <th>Before Aging</th> <th>After Aging</th> </tr> </thead> <tbody> <tr> <td>Elongation at Break %</td> <td>Min 650</td> <td>Min 500</td> </tr> <tr> <td>Tensile Strength</td> <td>Min 18</td> <td>Min 14</td> </tr> </tbody> </table> <p style="text-align: center;">(See table 2)</p>	Description	Standard		Before Aging	After Aging	Elongation at Break %	Min 650	Min 500	Tensile Strength	Min 18	Min 14	1.5	PASS										
Description	Standard																							
	Before Aging	After Aging																						
Elongation at Break %	Min 650	Min 500																						
Tensile Strength	Min 18	Min 14																						
Freedom From Holes ( Air Pump Test)	<p>The sample sizes allowable number of non-conforming gloves in the samples shall be determined in accordance to sampling plane ISO 2859-1 single normal using inpection and acceptable quality level as stated in section II: performance requirements.</p> <p style="text-align: center;">(See table 3)</p>	1.5	PASS																					
Visual Defects	<p>The sample size and allowable number of non-conforming gloves in the sampels for both major and minor defects shall be determined in accordance to sampling plane ISO 2859-1 single normal using inspection and acceptable quality level as stated in section II performance requirements.</p> <p style="text-align: center;">(See table 3)</p>	2.5-4	PASS																					

	Packaging Defects	The Sample size and allowable number of non-conforming in the sample for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859- 1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirement (Gloves Counting = 100 pcs by weight per Dispenser).	4	PASS
	Powder Free Residue	Maximum 2 mg per glove. (See table 4)	--	PASS

RESULT

Table 1

Sample No	Size	Length (mm)	Width (mm)	Thickness (mm)	
				Fingertip	Palm
1	S	260	86	0.16	0.18
2		263	89	0.17	0.16
3		266	90	0.17	0.15
4		261	88	0.15	0.16
5	M	260	100	0.16	0.14
6		264	98	0.16	0.14
7		266	97	0.16	0.16
8		263	100	0.17	0.15
9	L	260	102	0.16	0.14
10		263	107	0.17	0.14
11		261	104	0.17	0.15
12		260	103	0.16	0.15
13	XL	263	114	0.15	0.16
14		261	113	0.17	0.15
15		261	111	0.15	0.16
16		624	113	0.15	0.16
17	XXL	260	120	0.18	0.15
18		264	119	0.18	0.16
19		266	121	0.16	0.17
20		261	120	0.17	0.15



**Table 2**

Sample No	Size	Before Aging		After Aging	
		Tensile Strength (MPa)	Elongation (%)	Tensile Strength (MPa)	Elongation (%)
1	S	20.5	563	19.4	512
2		21.2	554	21.1	520
3		18.9	571	17.6	536
4		19.3	567	18.9	542
5	M	22.4	617	21.3	590
6		23.1	605	22.0	557
7		22.8	611	19.3	582
8		21.6	620	21.4	586
9	L	20.9	583	20.7	537
10		23.2	591	22.8	530
11		22.8	582	21.5	546
12		21.7	590	20.9	570
13	XL	20.9	585	20.3	544
14		21.6	570	21.4	566
15		22.1	568	21.7	561
16		20.8	605	20.6	597
17	XXL	22.2	612	21.9	603
18		23.1	598	22.6	587
19		23.8	616	23.1	608
20		23.5	599	23.0	593

**Table 3**

Size	Holes			Visual defect						Result
	Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	Major defect, AQL 2.5			Minor defects, AQL 4.0			
				Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	
S	260	7	3	200	10	5	200	14	6	PASS
M	260	7	3	200	10	6	200	14	7	PASS
L	260	7	2	200	10	5	200	14	7	PASS
XL	260	7	2	200	10	5	200	14	6	PASS
XXL	260	7	2	200	10	6	200	14	6	PASS



Table 4

Size	mg/Glove	Result
S	--	PASS
M	--	PASS
L	--	PASS
XL	--	PASS
XXL	--	PASS

IMAGE



\*\*\*END OF REPORT\*\*\*



Report No: 2020120102  
Applicant: MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ.  
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Sample Accepted on: 23.11.2020  
Report Date: 02.12.2020  
Total number of pages: 10 (Pg)

Sample ID: MB 1200 EXAMINATION GLOVE

	TEST	METHOD	Specimen	RESULT
*	Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks	EN 374-1	MB 1200 EXAMINATION GLOVE	PASS
*	Protective gloves against dangerous chemicals and micro-organisms Part 4: Determination of resistance to degradation by chemicals	EN 374-4	MB 1200 EXAMINATION GLOVE	PASS
*	TS EN ISO 374-5 Protective gloves against dangerous chemicals and microorganisms - Part 5: Terms and performance rules for microorganism risks.	EN 374-5	MB 1200 EXAMINATION GLOVE	PASS



Seal



Customer Representative  
Hasan KUTLU



Laboratory Manager  
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**Environment**

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X	Industrial environment
X	Medical environment



## **EN 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms – Part 1: Terminology And Performance Requirements For Chemical Risks**

### **Scope**

This part of ISO 374 specifies requirements for protective gloves that are intended to protect the user against dangerous chemicals and defines the terms to be used

### **General**

#### **Sampling for permeation**

Each material sample to be tested must meet the requirements of EN 16523-1: 2015, Section 7, so that the material can be sealed in the test cell.

Three samples are to be taken from the palm of the hand. If the glove is 400 mm or longer and protection against chemical risks is specified for the cuff, take three additional samples with the middle 80 mm from the cuff.

#### **Sampling for the penetration test**

Sampling for penetration must be carried out in accordance with EN 374-2: 2014, Section 5.

#### **Sampling for the degradation test**

Sampling for degradation must be carried out in accordance with 4.1 and EN 374-4: 2013, Section 5.1.

### **General requirements**

Protective gloves against dangerous chemicals must meet the requirements in EN 420: 2009, Section 4, Section 5 and Section 7.

### **Penetration**

Protective gloves must not leak when testing according to EN 374-2: 2014, 7.2 and 7.3.

### **Degradation**

The degradation (DR) must be determined in accordance with EN 374-4 for each chemical that is specified on the label and listed in the user information.

For gloves that are longer than 400 mm and in which the palm of the hand and the cuff have different performance levels, the lower performance level must be specified on the label for each chemical.

Protective gloves against chemicals are classified into three types according to their permeation performance: Type A, Type B or Type C.

**EN 16523-1 Determination Of Material Resistance To Permeation By Chemicals - Part 1: Permeation By Potentially Hazardous Liquid Chemicals Under Conditions Of Continuous Contact****Test Method**

The resistance of a protective glove material to permeation by a solid or liquid chemical is determined by measuring the breakthrough time of the chemical through the glove material


The sample shall be conditioned for 24 h at a temperature of (23±2) °C and The standard test temperature shall be (23±1) °C.

Gloves Type	Requirement
TYPE A	Breakthrough time ≥ 30 min against at least 6 chemicals of the new list
TYPE B	Breakthrough time ≥ 30 min against at least 3 chemicals of the new list
TYPE C	Breakthrough time ≥ 30 min against at least 3 chemicals of the new list

**EN ISO 374-1 glove permeation test list**

Code Letter	Chemical	Cas Number	Class
A	Methanol	67-56-1	Primary Alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile Compound
D	Dichloromethane	75-09-2	Chlorinated Paraffin
E	Carbon disulphide	75-15-0	Sulphur Containing Organic
F	Toluene	108-88-3	Aromatic Hydrocarbon
G	Diethylamine	109-89-7	Amine
H	THF	109-99-9	Heterocyclic and Ether
I	Ethyl Acetate	141-78-6	Ester
J	N-Heptane	142-82-5	Saturated Hydrocarbon
K	Sodium Hydroxyde %40	1310-73-2	Inorganic Base
L	Sulphuric Acid %96	7664-93-9	Inorganic Mineral Acid
M	Nitric Acid %65	7697-37-2	Inorganic Acid , oxidizing
N	Acetic Acide %99	64-19-7	Organic acid
O	Ammonia %25	1336-21-6	Organic Base
P	Hydrogen peroxide %30	7722-84-1	Peroxide
S	Hydrogen flüoride %4,	7664-39-3	Inorganic Mineral Acid
T	Formaldehyde %37	50-00-0	Aldehyde

**Test Results**

Specimen	Chemical	Exposure Time	Observation	Gloves Type
MB 1200 EXAMINATION GLOVE	Formaldehyde %37	30 min (Level 2)	Not permeable	EN ISO 374-1:2016 TYPE B  NTHBC
MB 1200 EXAMINATION GLOVE	Acetonitrile	30 min (Level 2)	Not permeable	
MB 1200 EXAMINATION GLOVE	Acetone	30 min (Level 2)	Not permeable	
MB 1200 EXAMINATION GLOVE	THF	30 min (Level 2)	Not permeable	
MB 1200 EXAMINATION GLOVE	Acetic acide %99	30 min (Level 2)	Not permeable	
MB 1200 EXAMINATION GLOVE	Sulphuric acide %96	1 min (--)	There is permeability	

**EN 374-2 Protective Gloves Against Dangerous Chemicals And Micro-Organisms - Part 2: Determination Of Resistance To Penetration**

**SCOPE**

This standard describes the criteria that protective gloves should have, especially in terms of contact risks with microorganisms such as bacteria, fungi and viruses.

**Air Leak Test Method**

- The glove is fastened to the circular mandrel and is inflated after immersion at ambient temperature, with air, to a gauge pressure of X kPa (see Table 1) plus an overpressure of 1 kPa per 100 mm of immersion measured at the fingertips closest to the bottom of the water tank.
- The inflation pressure shall be reached with a  $\pm 10\%$  limit deviation within 2 min and the control of possible air bubbles shall take an additional  $(30 \pm 5)$  s.

**Table 1**

Nominal glove thickness (e) mm As provided by the manufacturer	Air pressure (X) kPa
$e \leq 0,3$	0,4
$0,3 < e \leq 0,5$	2,0
$0,5 < e \leq 1,0$	5,0
$e > 1,0$	5,0



**Test Result**

Specimen	Total Air Pressure (kPa)	Observation	Result
MB 1200 ELDİVEN	2,7	No leaks detected	<b>PASS</b>

**Water Leak Test Method**

- The glove is attached to an open-ended plastic tube by bringing the edge of the cuff to the 40 mm mark and fastening it with the elastic strap to make a watertight seal.
- A minimum of 1 000 ml of water is added through the tube to fill the glove completely and to reach at least the 40 mm mark level of the liquid proof area of the glove. The water shall be at ambient temperature
- The gloves are examined immediately for water leaks. The glove should not be squeezed. Only minimal handling is required to detect leaks. Water droplets may be blotted to confirm leakage, or talcum powder may be used to enhance droplet visibility.

**Test Results**

Specimen	Observation	Result
MB 1200 EXAMINATION GLOVE	No leaks detected	<b>PASS</b>

**EN 374-4 Protective gloves against dangerous chemicals and microorganisms - Part 4: Determination of resistance to degradation by chemicals****Principle**

The resistance of a protective glove material to degradation by a liquid chemical is determined by measuring the change in puncture resistance of the glove material after continuous contact of the external surface with the challenge test chemical. The test is applicable to gloves made of natural or synthetic polymer.

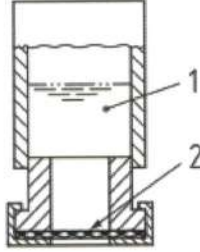
**Procedure**

The test shall be conducted at  $(23 \pm 2)$  °C (preparation, chemical, exposure to chemical, and puncture test).

Place a glove specimen on top of the septum with its normal external surface facing towards the interior of the vial. Place the aluminium cap with the specimen on top of the vial. Seal the vial using the hand crimper and invert it so that the challenge chemical is in contact with the specimen (see Figure 1). Record the time. Place the vial in the punched-out sample holder.

The punched-out sample holder has a twofold purpose:

- It allows air to circulate under the sample film, and
- if the pressure from the challenge chemical forces the sample into a convex shape, the flask will still stand



**Key**

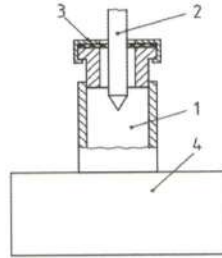
1 challenge chemical

2 outer surface of the glove specimen which is in contact with the challenge chemical, it is a circular area of  $(12,5 \pm 0,5)$  mm diameter

**Figure 1 — Position of the vial during contact time between the specimen and the challenge chemical**

**Puncture testing**

Install the puncture stylus on the dynamometer load cell. Set the carriage speed to 100 mm/min and screw the vial support onto the table. Place a vial into the support. Puncture the specimen and record the peak force required (see Figure 2). Repeat for each of the specimens; test each of the exposed specimens one hour after the exposure on that specimen was started.



**Key**

1 20 ml crimp vial

2 puncture stylus 3 specimen 4 sample vial support (to be maintained by the dynamometer jaw)

**Figure 2 — Position of the vial during puncture test**

**Test Results**

The following degradation data (see Table A.1) have been obtained in laboratory.

Table A.1 — Results in % of correlation trial with other gloves materials

Laboratory	Acetone	Sulfuric Acid
	Mean value for Nitrile glove	Mean value for Nitrile glove
1	%61	%87
2	%60	%88
3	%63	%91
4	%61	%94
5	%61	%88
6	%65	%90

## Weight Charge Test

### Test Conditions

The glove should be conditioned at  $(23 \pm 2)$  °C for at least 24 h. The specimens should be taken from three gloves. Put the glove flat on a surface and measure  $(60 \pm 2)$  mm from fingertip. The specimens should consist of a cut-off of the same finger of each glove.

### Procedure

Start the timer and immerse the finger specimen in a beaker containing the test chemical. The weighed test tube will hold the specimen upright in the beaker. The beaker should be filled to a depth of  $(42 \pm 2)$  mm with the test chemical (see Figure B.1). The quantity of the test chemical should be adapted during the test to keep the beaker filled to the marking. Multiple finger specimens can be started at approximately 1 minute timed intervals to allow for weighing of the specimens.

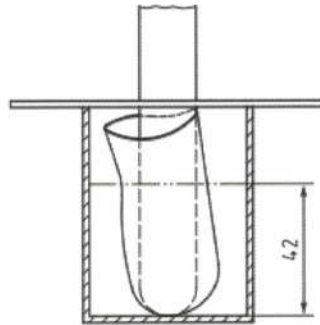


Figure B.1 — Typical arrangement of weight change test apparatus

The weighing of the finger specimen should be carried out as quickly as possible after the 60 min chemical exposure.



## Result

After the Weight Charge Test, there was not observed any changes such as swelling, shrinking, brittleness, hardening, softening, flaking, disintegration, colour change/bleeding on the sample.

## TS EN ISO 374-5:2016 Protective Gloves Against Dangerous Chemicals And Microorganisms - Part 5: Terms And Performance Rules For Microorganism Risks

### Scope

This International Standard describes a laboratory test method for measuring the resistance of materials used in protective clothing to penetration by blood-borne pathogens. This test method uses a surrogate microbe under conditions of continuous liquid contact.

### Test Conditions

Condition each protective clothing specimen for a minimum of 24 h by exposure to a temperature of  $(21 \pm 5)$  °C and a relative humidity of  $(60 \pm 10)$  %.


### Procedure

This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at  $21 \pm 5$  °C and  $60 \pm 10$  % relative humidity (RH), and then tested for viral penetration using a  $\phi$ X174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of  $\phi$ X174 bacteriophage.

The viral penetration method complies with ISO 16604. All test method acceptance criteria were met.

## Result

### Specimen: Nitrile Examination Glove

Tested Specimen Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Observation	Result	Marking
1-6	$3.50 \times 10^8$	$3.10 \times 10^8$	$<1^a$	Not Observed Improperly	PASS	EN ISO 374-5 :2016
Negative Control	$3.50 \times 10^8$	$3.10 \times 10^8$	$<1^a$	Not Observed Improperly	Acceptable	 VIRUS
Positive Control	$3.50 \times 10^8$	$3.10 \times 10^8$	TNTC <sup>b</sup>	Yes	Acceptable	

<sup>a</sup> A value of  $<1$  plaque forming units (PFU)/mL is reported for assay plates showing no plaques.

<sup>b</sup>TNTC = PFU were too numerous to count.

**IMAGE OF SAMPLE**



**\*\*\* End Of Report\*\*\***

AB-1183-T

M-2020-00679

30.12.2020

**MNA LABORATUVARI  
ANALİZ RAPORU**

İstek Numarası : M-2020-00679	Tarih: 30.12.2020	Raporun Sayfa Sayısı : 2 / 2	Rev:
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<b>Analizin Amacı</b> : ÖZEL İSTEK	<b>Markası</b> :
<b>Numunenin Cinsi</b> : NİTRİL ELDIVEN	<b>Modeli</b> : MB-1200
<b>Numuneyi Gönd. Kuruluş</b> : MB YATIRIM GRUP İÇ VE DIŞ TİC.LTD.ŞTİ	<b>Numuneyi Alan</b> : MÜŞTERİ
<b>Üretici Firma Adı</b> : MB YATIRIM GRUP İÇ VE DIŞ TİC.LTD.ŞTİ	
<b>Analiz Tarihi</b> : 16.12.2020	
<b>Numune Miktarı</b> : 100 adet	
<b>Diğer Bilgiler</b> : MB-1200	

12. Satır Elin ve Eldivenin Ölçüm Testi Analizi için örnek alım yeri : BEDEN.9

Deney laboratuvarı olarak faaliyet gösteren MNA Laboratuvarları, TÜRKAK 'tan AB-1183-T ile TS\_EN\_ISO/IEC\_17025:2017 standardına göre akredite edilmiştir. Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınırlığı konusunda Avrupa Akreditasyon Birliği (EA) ile çok taraflı anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanınma antlaşmasını imzalamıştır.

\*Analiz akreditasyon kapsamındadır.

**Not :**

1. Bu analiz raporunun hiçbir bölümü tek başına veya ayrı ayrı kullanılamaz ve laboratuvarın yazılı izni olmadan kısmen kopyalanıp çoğaltılamaz, üçüncü şahıslara ve reklam aracı olarak kullanılamaz.
2. Analiz sonuçları MNA Laboratuvarı firma/kurum/shahıs tarafından gönderilen yukarıda belirtilen numune için geçerlidir. Bütünü temsil etmeyebilir.
3. İmzasız ve Mühürsüz raporlar geçersizdir.
4. Bu analiz raporu adli-idari işlemlerde ve reklam amacıyla kullanılamaz.
5. Sonuçlar numunenin teslim alındığı hali için geçerlidir.
6. Karar kuralı belirlenmiş bir spesifikasyona uygunluğunu belirtirken, ölçüm belirsizliğinin nasıl hesaba katılacağını belirleyen kuraldır. TLM-052 Karar Kuralı Uygulama talimatına göre müşteri ile mutabık kalınarak seçilen Karar Kuralı Uygulama Yöntemi raporda açık bir şekilde beyan edilmiştir.
7. Limit Değerleri analiz metotlarından alınarak belirlenmiştir.
8. Müşteri tarafından sağlanan bilgiler sonuçların geçerliliğini etkilemesi durumunda, laboratuvar sorumlu değildir.
9. Deney ve/veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (olması halinde) ve deney metotları bu sertifikanın tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir.
10. Su geçirmezlik Tayini Hidrostatik Basınç Tayini TS ISO 811(Hidrostatik Basınç Tayini Cihazı E/N:53) Analizi, Dikiş Kopma Dayanımı EN ISO 13965-2 (Mukavemet Test Cihazı E/N:50) Analizi ve sıvı kimyasal geçirmeye dayanım TS EN 659-A1 Madde 3.18 (Sıvı Kimyasal Geçirme Cihazı E/N:107) Analizi şartlandırma odasında gerçekleştirilmekte olup ortam şartları için ISO 139 MADDE 3.2 koşulları ( 23 ± 2° C sıcaklık ve %50 ± 4 bağıl nem) uygulanır.
11. Analiz edilen fitalatlar listesi aşağıdadır.  
Di-iso-nonyl phthalate (DINP), CAS number: 28553-12-0 or 68515-48-0  
Di-(2-ethylhexyl) phthalate (DEHP), CAS number: 117-81-7  
Di-n-octyl phthalate (DNOP), CAS number: 117-84-0  
Di-iso-decyl phthalate (DIDP), CAS number: 26761-40-0 or 68515-49-1  
Butyl benzyl phthalate (BBP), CAS number: 85-68-7  
Di-butyl phthalate (DBP), CAS number: 84-74-2

Selin GERGİN  
Numune Kabul ve Raporlama  
Sorumlusu

**MNA LABORATUVARLARI**  
**SAN. TİC. LTD. ŞTİ.**

Küçükbakkalköy Mah. Yenidoğan Cad. No:21/1  
Ataşehir / İSTANBUL TEL: 0216 574 07 08  
Kırtane No: VD-1230307322

Tasdik Olunur

30/12/2020

Volkan AKIN

Laboratuvar Müdürü

Erhan ÜSTÜNE  
Kimya KDD Lab. Bölüm  
Sorumlusu



## MNA LABORATUVARI ANALİZ RAPORU

İstek Numarası : M-2020-00679	Tarih: 30.12.2020	Raporun Sayfa Sayısı : 1 / 2	Rev:
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<b>Analizin Amacı</b> : ÖZEL İSTEK	<b>Markası</b> :
<b>Numunenin Cinsi</b> : NİTRİL ELDİVEN	<b>Modeli</b> : MB-1200
<b>Numuneyi Gönd. Kuruluş</b> : MB YATIRIM GRUP İÇ VE DIŞ TIC.LTD.ŞTİ	<b>Numuneyi Alan</b> : MÜŞTERİ
<b>Üretici Firma Adı</b> : MB YATIRIM GRUP İÇ VE DIŞ TIC.LTD.ŞTİ	
<b>Analiz Tarihi</b> : 16.12.2020	
<b>Numune Miktarı</b> : 100 adet	
<b>Diğer Bilgiler</b> : MB-1200	

No	Yapılan Analizler	Analiz Sonucu	Limit Değer	Metod	Değerlendirme	Fiziksel Durum
1	Eldivenli Parmak Yeteneğinin Tayini *	5 (mm)	5 mm	TS EN 420 + A1 Madde 6.2	PERFORMANS SEVİYESİ:5	
2	ORGANİK KALAY BİLEŞİKLERİNİN TAYİNİ (DOT) *	<10 (mg/kg)	<1000 ppm	İŞLETME İÇİ METOD SOP 05 Rev01 (ISO TS 16179 dan modifiye edilmiştir)	UYGUN	
3	FİTALAT TAYİNİ(KAPLAMALI TEKSTİLLER) *	< 50 (mg/kg)	< 1000 ppm	ISO/TS 16181	UYGUN	
4		0 (PFU/ml)	<1 PFU/ml	BS ISO 16604+ TS EN 14126 Madde 4.1.4.1		
5	Hidrostatik Basınç Altında Patojenlerin Penetrasyonuna Direnç (Bakteriyofaj)	0 (PFU/ml)	<1 PFU/ml	BS ISO 16604+ TS EN 14126 Madde 4.1.4.1	UYGUN	
6		0 (PFU/ml)	<1 PFU/ml	BS ISO 16604+ TS EN 14126 Madde 4.1.4.1		
7	Ph Tayini - Tekstil *	6,91	3.5 < Sonuç < 9.5	EN 420 + A1 Madde 4.3.2 TS EN ISO 3071	UYGUN	
8	Hava Sızdırmazlık Tayini *	Sızma olmadı	Sızma olmalı	TS EN 374-2 Madde 5.2	UYGUN	
9	Su Sızdırmazlık Tayini *	Sızma olmadı	Sızma olmalı	TS EN 374-2 Madde 5.3	UYGUN	
10	Kimyasal Maddeler ile Bozulmaya Karşı Direncin Tayini *	73,59 (Aseton) (%)		TS EN 374-4		
11	Sürekli Temas Şartları Altında Sıvı Kimyasal Maddelerin Sızması *	% 40 NaOH da 30 dk boyunca sızma olmadı. (ug/cm <sup>2</sup> .dk)	> 30 dk	TS EN 16523-1	PERFORMANS SEVİYESİ:2	
12	Elin ve Eldivenin Ölçüm Testi *	250 (mm)	≥ 250 mm	TS EN 420 + A1 Madde 6.1	UYGUN	
		Elin Uzunluğu	189 (mm)	TS EN 420 + A1 Madde 6.1		
		Elin Çevresi	227 (mm)	TS EN 420 + A1 Madde 6.1		

### ÖRNEK ALINAN YER

1. Satır Eldivenli Parmak Yeteneğinin Tayini Analizi için örnek alım yeri : BEDEN:9



MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

### AGREEMENT NO:

### 1. PARTIES

#### **1.1 MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. acting as the Service Provider**

(shall hereinafter be referred to as "MNA")

Address : Küçükbakkalköy Mah. Yenidoğan Cad. No: 21 Ataşehir- İSTANBUL  
Telephone : +9 (0) 216 574 07 08  
Fax : +9 (0) 216 535 13 31  
E-mail : [info@mnalab.com](mailto:info@mnalab.com)  
Web : [www.mnalab.com](http://www.mnalab.com)

#### **1.2 MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ. acting as the Service Receiver**

(shall hereinafter be referred to as the "CUSTOMER")

Address : Koza Mah. 1638 Sok. Çiğdem Sit. 1. Blok Apt. No:5 K:11 Esenyurt /  
İSTANBUL / TURKEY  
Telephone : 0212 854 00 91  
Fax : 0212 854 15 04  
E-mail : [info@mbyatirim.com](mailto:info@mbyatirim.com)

### 2. SUBJECT MATTER

The subject matter of this agreement is the determination of the rights and obligations of the parties about conformity assessment, product certification and performance of annual supervisions by MNA and the fees payable for these services in accordance with the conditions directly related to the product as indicated in the standards, directives and other normative documents such as technical specifications which are set forth in the PRODUCT CERTIFICATION APPLICATION FORM by the Customer and defined in the certification program.

This agreement designates the provisions for licence rules regarding the certificate of conformity related to the products which deserve to get a certification right upon the entitlement of the Customer to certification and the use of certification marks. MNA gives all certification marks to the Customers who have a usage right in accordance with the provisions hereof in a revocable manner. Usage right is not a property right for the Customers. The Customer is authorized to use the certification marks only for the purpose of showing that the products within the scope of the certificate have successfully completed and maintain the certification process.

MNA LABORATUVARLARI	SEAL / SIGNATURE
For and on behalf of MNA LABORATUVARLARI SAN. TİC. LTD. Küçükbakkalköy Mah. Yenidoğan Cad No:21 Ataşehir / İSTANBUL Tel: (0216) 574 07 08 Fax: (0216) 575 13 31 Kozyatağı V.D. 023 030 7322	Trade name of the customer MB YATIRIM GRUP İÇ VE DIŞ TİC. LTD. ŞTİ. Koza Mah. 1638. Sok. Çiğdem Sit. 1. Blok Apt. No: 5 K: 11 Esenyurt / İST. Mersis No: 0813 0070 1220 0010 Beylikdüzü V.D. 613 087 9122









MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

notified to it all the time besides fulfilling the requirements in the certification agreement and certification program.

4.2 In the event that the certification is applied to an ongoing production, the Customer shall fulfil the requirements provided in the standards, directives or other normative documents such as technical specifications as defined in the certification program.

4.3 The Customer shall provide convenience to MNA and undertake all arrangements for the review of existing documentation and records, access to relevant equipment, hardware, place, area, personnel and subcontractors, complaint inquiry and involvement of observers, if required, during the audit and supervision.

4.4 The requests and statements of the Customer related to certification shall comply with the scope of certification.

4.5 The Customer shall not use the product certification in such a manner that may destroy the reputation of MNA nor make any statement with regard to product certification which may be considered to be misleading and unauthorized by MNA.

4.6 In the event that the certification is suspended, recalled or terminated, the Customer shall cease making references to or using the certificate and certification marks in any advertising materials. It shall not use the same as an advertising material in any way and take the precautions required by the certification plan. Upon the request of MNA, it shall further return all documents related to certification and take other precautions which are deemed necessary by MNA.

4.7 The Customer must ensure the integrity of the documents whenever it is supposed to give the copies of certification documents to others or reproduce the same as specified in the certification programs.

4.8 The Customer shall comply with the requirements of MNA and the conditions set forth in relevant certification programs when it makes references to the product certification in documents, brochures or such communication platforms as advertisement.

4.9 The Customer shall comply with the requirements of the certificate concerning the information about the usage of the conformity mark and the product itself.

4.10 If the Customer procures a service from a legal entity/entities for production, the certification body shall have a right to carry out an audit for such legal entity/entities.

4.11 The Customer must keep a record of all complaints related to compliance with the certification requirements and make the same available to MNA upon request. It shall take proper actions against these complaints and the defects identified on the products which may affect compliance with the certification requirements and document the actions taken accordingly.

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For and on behalf of MNA LABORATUVARLARI SAN. TIC. LTD. Kozaköy Mah. Yenidogan Cad No: 21 Atasehir / ISTANBUL Tel: (0216) 974 07 08 Fax: (0216) 575 13 3. Kozataşi V.D. : 023 030 7322 Beylikdüzü V.D.: 731 989	Trade name of the customer MEY YATIRIM GRUP İÇ VE DİŞ TIC. LTD. ŞTİ. Kozaköy Mah. 1638 Sokak Çiğdem Sit. 1. Blok Apt. No: 5 K: 11 Beşyurt / İST. Mersis No: 0618 8879 1220 0010 Beylikdüzü V.D.: 643 087 9122	



MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

4.12 The validity period and periodical surveillance period of the certificate of conformity of the product are indicated in relevant certification program.

4.13 In case of an application outside Turkey, the manufacturer or its representative must submit the document showing that it is a legal corporation. For any changes within this scope during the certification process, the Customer shall fulfil this obligation within the time period allocated by the legal authority and submit a copy of respective documents to MNA.

4.14 The Customer inform MNA without delay about any changes which may affect its capability to comply with the certification requirements.

4.15 Within the scope of any product certification service provided by MNA, TÜRKAK may visit the Customer of MNA onsite in order to audit the service rendered by MNA, if required and applicable, and the Customer agrees to provide any information/document requested by TÜRKAK with respect to the audit conducted by MNA.

### 5. APPLICATION, ASSESSMENT AND CERTIFICATION

5.1 The Customer shall submit a file related to the product or product groups for which an application of certification will be made to MNA at the application stage.

5.2 The content of such file is specified in the certification program for relevant product or product group. The time period for the completion of any deficiencies identified in this file is limited to not more than 3 (three) months. In case of a technical obligation, the applicant is liable to notify such obligation in writing. Otherwise, the file is closed.

5.3 The Customer shall inform MNA within not later than 15 (fifteen) days about the actions to be taken for any unconformities resulting from the audit assessment which is carried out according to the type conformity request based on the quality assurance of the production process. The Customer shall inform MNA about its corrective actions taken for the unconformities identified during the audit within not later than 3 (three) months. MNA may check the corrective actions or carry out a follow-up audit to see their effectiveness, if it deems necessary.

5.4 If MNA identifies any conformity in the certification process where it has inspected the technical design of the PPE product of the Customer and verified and approved that such design complies with relevant rules of the Directive, it notifies such conformity to the Customer and advises the correction of the same within 3 months. In case that the Customer rejects correcting, it carries out certification in accordance with the identified performance parameters of the PPE product. The application is rejected in the Customer rejects both options.

5.5 The Customer shall provide convenience to the product certification officers of MNA for the sake of certification including access to the production plant and facility, records and documentation and provision of the requested information.

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For and on behalf of MNA LABORATUVARLARI SAN. TIC. LTD. Kültürparkköy Maslak Yenidogan Cad No: 2 Ataşehir / İSTANBUL Tel: (0216) 514 07 08 Fax: (0216) 575 13 31 Kuşyatağı V.D. 023 030 7322 Tic. Sic. No: 273128	MB YATIRIM GRUP MENKUL DEĞERLER A.Ş. LTD. ŞTİ. Tic. Sic. No: 273128 Koza His. 1639. Sok. Çiğdem Sit. 1. Blok Apt. No: 5 K: 11 Esenyurt / İST. Mersis No: 0813 0879 1220 0010 Beylikdüzü V.D. 013 087 9122





MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

5.6 In the event that MNA discloses any confidential information due to a legal obligation stipulated by the certification body or under the power granted by the regulations provided herein, it shall notify the disclosed information to the Customer unless there is a legal hindrance. In case of a legal hindrance, the Customer shall not be informed thereon.

5.7 The information related to the certified product may not be provided to a third party in any case except written consent of the Customer.

5.8 If this information is provided to a third party, the Customer is legally informed in writing.

### 6. AMENDMENTS ON THE CERTIFICATION AGREEMENT OR CERTIFIED PRODUCTS

6.1 The Customer shall inform MNA without delay about any changes in its management structure, structural status, organizational and legal changes during the validity period of the certificate which may affect certification.

6.2 The Customer shall inform MNA without delay about any changes in the design and production method of the certified product, contact details, production plants or quality system which may affect certification.

6.3 Under the C2 module, the CUSTOMER will immediately inform the certification body when it ceases to manufacture the certified product.

### 7. SUPERVISION

7.1 A) **Supervision of the Product:** Supervision is carried out by means of sampling through the samples taken from the shelves of the sales channels declared by the Customer in order to check whether the product still has the performance characteristics on the certification date 1 year later than the product certification.

B) **Supervision of the Production Line:** Supervision is carried out by means of taking samples in order to check whether the production line still maintains the quality management system and has the performance characteristics of the product resulting from this production 1 year later than the commencement of supervision.

7.2 The Customer agrees that MNA shall carry out a supervision under the following circumstances:

- At the intervals indicated in relevant product certification program,
- When a supervision decision is taken on the basis of complaints,
- For the purpose of assessing the Customer's suppliers,
- In case of a change which may affect certification.

7.3 All costs incurred during the supervision, product cost, analysis fee, cargo cost, certificate fee, transportation cost and accommodation, if applicable, and other necessary

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For and on behalf of MNA LABORATUVARLARI SAN. TİC. LTD. No.2 Atasehir / ISTANBUL (0216) 514 07 08 Fax (0216) 575 13 3. Kozyasagi V.D. 023 030 7322	<b>MEYVA/IRIM</b> Trade name of the customer <b>GRUP TIC. LTD. ŞTİ.</b> Koza Mah. / 1878 Sok. Cidem Sit. 1. Blok Apt. Nov 5 / K: 11 Eşenyurt / İST. Mersis No: 0813 0879 1220 0010 Seyitkulu V.D.: 613 087 9122





MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

expenditures are borne by the Customer. All expenditures shall be notified to the Customer in a single invoice.

### **8. VALIDITY, SUSPENSION, RECALL, TERMINATION OF VALIDITY OF THE CERTIFICATE**

**8.1 Validity period of the certificate:** The validity period of the certificate of conformity for the product is stated in relevant product certification program. Any additional tests conducted during this period does not extend the validity of the certificate. The usage right of certification marks commences on the issue date of the certificate. If the validity period of the certificate of conformity for the product is requested to be extended, an application shall be made to MNA 3 (three) months prior to the expiry of the validity period. Otherwise, the certification shall terminate at the end of the validity period. If the Customer requests the maintenance of the certification, the certification process is repeated under the current conditions.

**8.2 Suspension or recall of the certificate:** If the provisions of the certification agreement are not fulfilled, the Customer is informed in writing and immediate correction is requested. The certification is suspended unless the required arrangements are made. The suspension period for the certification is not more than 3 (three) months. The scope of certification is narrowed down or the certificate is recalled upon the expiry of this period.

**8.3** The time period allocated for correcting any unconformities is limited to 3 (three) months for initial application or surveillance audits. If this time period is exceeded, a further 3 (three) months additional period is allocated to the Customer for initial audits. Upon the expiry of this period, the certification process is terminated. If the certification request survives, the Customer is asked to make an application again.

**8.4** The certificate is suspended upon the expiry of the correction period of 3 (three) months for any unconformities as intended for surveillance audits. The suspension period of the certificate is not more than 3 (three) months. The certificate is recalled upon the expiry of this period.

**8.5** Invalidity of the documents shall terminate the usage of the certificate of conformity for the product and certification marks under the following circumstances:

- Expiry of the validity period of the certificate (with the exception of an extension application),
- Non-existence of the preliminary conditions required for the issuance of a certificate,
- Suspension of production of the certified product,
- A termination request for the certificate of conformity for the product by the Customer,
- Recall of the certification.

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For and on behalf of MNA LABORATUVARLARI SAN. TİC. LTD. Kırcıkpakka Köyü Mah. Sıhhiye Cad. No:21 Ataşehir / İSTANBUL Tel: (0216) 574 07 08 Fax: (0216) 575 13 3. Kuzyatıcı V.D. 023 030 7322		MEY YATIRIM GRUP İÇİŞİLERİ TİC. LTD. ŞTİ. Koza Mah. 1536. Sok. Çiğdem Sit. 1. Blok Apt. No: 5 K: 11 Zaanyurt / İST. Mersis No: 0813 0875 1220 0010 Beylikdüzü V.D. 0813 087 9122



MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

### 9. CONFIDENTIALITY

9.1 MNA shall not disclose any findings resulting from its certification activities to a third party in any way without written consent of the Customer. It shall inform the Customer in writing if such disclosure to a third party is legally required.

9.2 The Customer shall not disclose any information, informative document or business manner provided to it by MNA during the certification process to any third party or particularly other certification bodies.

### 10. USAGE OF THE CERTIFICATE OF CONFORMITY FOR THE PRODUCT

10.1 Detailed definitions related to the usage of the certificate of conformity and conformity marks are provided in the Certificate and Logo Usage Procedure. The Customer who undersigns the request-proposal form is deemed to accept this agreement.

### 11. USAGE OF THE CERTIFICATION MARKS:

11.1 The certification marks which are authorized by the product certification body to be used are related only to the usage right and they are not in the nature of a property right. They may be revoked at any time by MNA if the validity period expires. Detailed definitions related to the usage of the certificate of conformity and conformity marks are provided in the Certificate and Logo Usage Procedure. The Customer who undersigns the Product Certification Agreement (present agreement) is deemed to accept these rules as well.

### 12. FEES AND PAYMENT

12.1 Pricing for all activities required for product certification is applied at the proposal stage in accordance with TLM-001 INSTRUCTIONS FOR THE PRODUCT CERTIFICATION FEE.

12.2 Any test and supervision costs incurred for additional assessments by MNA within the scope of certification shall be borne by the Customer.

12.3 These fees do not include any transportation, accommodation and boarding expenses for the visits to be undertaken by MNA officers to the facilities of the Customer for assessment. These costs shall be borne by the Customer.

12.4 The payments shall be deposited into the .....  
IBAN numbered account of MNA. Any changes in bank account information shall be notified to the Customer.

12.5 Any taxes, duties and charges which may arise from this agreement shall be borne by the Customer.

MNA LABORATUVARLARI		SEAL / SIGNATURE
For and on behalf of MNA LABORATUVARLARI SAN. TİC. LTD.		
K. No. 2 / Ataşehir / İSTANBUL Tel: (0216) 574 07 08 Fax: (0216) 575 13 31 Kuzeybatı V.D. 023 030 7322		AMB YATIRIM Trade name of the customer GRUP İÇ VE DİŞ TİC. LTD. ŞTİ. Koza Mah. / 16887 Sok. / Çiğdem Sit. 1. Blok Apt. No: 5 / K: 11 / Esenyurt / İST. Mersis No: 0813 0879 1220 0010 Beylikdüzü V.D. 013 087 9122









MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

**16.2** The certificate is an integral part of the agreement and in the usage of the Customer stated therein; however, it is in the possession of MNA. The certificate may not be assigned to another institution or legal entity. Any liability arising from unauthorized usage of the certificate by third parties is assumed by the Customer.

**16.3** The Customer shall fulfil its responsibility related to the management systems by means of appointing by an officer who is clearly defined and authorized to maintain contact with MNA.

**16.4** The Customer is entitled to raise an objection and file a complaint against any decision to be taken by MNA during the certification process on condition of grounding such objection or complaint on tangible and legal justifications. These objections and complaints are submitted to MNA through its website ([www.mnalab.com](http://www.mnalab.com)) or in writing or via e-mail. Objections are recorded through U-FRM-008 Objection Registry Form or U-FRM-007 Complaint Registry Form. Application for complaints and objections and the way of obtaining information about these processes subsequently are provided in U-PRD-007 Complaint and Objection Assessment Procedure. The procedure is available in the website.

**16.5** The Customer must necessarily cease making the references to the certification and using the logo in case of suspension or cancellation of the certificate or termination of the agreement between the Customer and MNA. It shall immediately take all brochures, packages, flags, vehicles, promotional materials etc. which bear the logo out of circulation. Otherwise, all legal rights of MNA are reserved.

**16.6** TÜRKAK may witness the audit to be conducted by MNA for the Customer at its will. The Customer is obliged to agree this witnessing process. No additional cost shall be charged to the Customer with respect to the participation of TÜRKAK team.

**16.7** If MNA notifies a change to the Customer in the certification conditions, the Customer must comply with these new conditions.

**16.8** The Customer agrees the suspension / cancellation of its certificate in the event that it fails to comply with the certification requirements defined in this agreement and referenced documents.

### **17. PRODUCT CERTIFICATION FEE**

The duration of the certification and supervision service to be provided within the scope of this agreement is designated in accordance with the "Product Certification Procedure". The fee thereof, on the other hand, shall be accrued pursuant to the "Instructions for the Product Certification Fee".

**17.1** Annual certificate usage fee is not included in these fees and any additional cost is not requested for the usage of the certificate.

MNA LABORATUVARLARI	SEAL / SIGNATURE	MB YATIRIM
For and on behalf of MNA LABORATUVARLARI SAN. TIC. LTD. Kuşçuköy Mah. Yıldırım Çay No 21 Ataşehir / İSTANBUL Tel: (0216) 574 07 08 Fax: (0216) 575 13 3. Kuşçuköy V.D. 023 030 7322		GRUP İÇ VE DİŞİ TIC. LTD. ŞTİ. Koza Mah. Tuzluköy Çiğdem Sk. 1. Blok Apt. No: 5 / H. H. Esenyurt / İST. Mersis No: 0813 0879 1220 0010 Boylukduzu V.D.: 013 087 9122



MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ.

## PRODUCT CERTIFICATION AGREEMENT

17.2 Any fees related to the certified products are invoices to the Customer on the issue date of the certificate and they shall be collected in advance.

17.3 If there is a change in the statements of the Customer, it is obliged to inform such changes to MNA. In this case, a fee adjustment may be made.

The transportation and accommodation costs of the audit team of MNA shall be borne by the Customer.

### 18. OTHER PROVISIONS

18.1 The proposal form to which this agreement is attached as well as the standard(s) referenced in the proposal form, RULES FOR THE USAGE OF CERTIFICATES AND CONFORMITY MARKS, correspondences with the Customer are integral parts of this agreement and bind the Customer. The Customer is obliged to comply with this agreement and its annexes.

18.2 The language of the certification agreement is Turkish. However, it may be provided in English upon the request of the Customer. In case of a dispute, the Turkish text shall take the precedence.

18.3 TÜRKAK documents and the provisions of the Code of Obligations and Turkish Commercial Code shall be applied for any issues not contained herein.

18.4 Istanbul Courts and Execution Offices shall have jurisdiction over any disputes.

18.5 The cost of cargo for all kinds of deliveries (document, agreement, legal papers etc.) during the certification process shall be borne by the Customer.

18.6 Consisting on 18 (eighteen) articles and 10 (ten) pages, this agreement has been drawn up in 2 (two) original copies and read and executed by the parties on 02.12.2019. This agreement takes effect on the execution date.

MNA LABORATUVARLARI	SEAL / SIGNATURE
For and on behalf of MNA LABORATUVARLARI SAN. TIC. LTD. Kurtulmuşköy Mağ. Yenidoğan Cad SİTİ Kozyatağı V.D. 023 030 7322	MB YATIRIM GRUP İÇİN SAN. TIC. LTD. ŞTİ. Kozan Mah. 1638/50K. Çiğdem Şti. 1. Blok Apt. No: 5 K: 21 Esenyurt / İST. Mersis No: 0612 0879 1220 0010 Beylikdüzü V.D.: 613 087 9122