AGL GRUP

at your service globally.

NitrAG®

DISPOSABLE POWDER FREE
EXAMINATION **GLOVE**

PERSONAL PROTECTIVE EQUIPMENT
A PROTECTION AND SAFETY SUPPLIER

SOFT TOUCH

www.aglgrup.com.tr

www.nitrag.com.tr

RANGE OF APPLICATION

RESTAURANTS

HOSPITALS

HEALTHCARE INSTITUTIONS

SHOPPING MARKETS

HOME TASKS

URBAN LIFE

OFFICES

CABINE CREWS

SCHOOLS

SOFT TOUCH

FEATURES

The Soft Touch Termaplus Poly gloves prevent any allergic reactions among workers and customers. Made from polyethylene (LDPE) with 7.5/8 Micron, the gloves do not release any unwanted chemicals and therefore allow direct contact with food or any other sensitive items.

As an excellent alternative to expensive gloves made from various other materials, NitrAG gloves are suitable for safety use in Food & Beverage industries, Consumer Services as SPA, beauty centers, barbers and daily life.





- √ Excellent fit, maximum sensitivity and dexterity for fine tasks. The entire glove is finely textured (including palms and fingers) to provide consistent grip on glassware, small objects, instruments and tools.
- √ Isolate odors and dust to keep your hands clean
- √ Ideal for all kinds of uses that require a safe and hygienic environment
- √ Ideal for almost any application including tattooing, food preparation, painting, cleaning, pet care, home improvement, hobbies, arts and crafts
- √ Convenient dispense pack keeps gloves clean and organized while providing easy access

SOFT TOUCH

PACKAGING FORM

AVAILABLE COLOURS Black Blue Pink White

AVAILABLE SIZES S M L XL

100 GLOVES

24 BOXES

72 CARTONS

33 PALLETS

1 Box 100 PCS | 1 Carton 24 Box | 1 Palatte 72 Carton | 1 Truck 57.024 Box

SOFT TOUCH

TECHNICAL DATA SHEET

Artical Number	130001 (S), 130002 (M), 130003 (L), 130004 (XL)
Packaging	100 PCS/Box | 24 Boxes/Carton | 2400 PCS/Carton
Glove Specifications	**Material:** TPE | **Color:** Blue **Surface:** Texturierte Fingerstip | **Cuff Design:** Rolled Edge | **Latex:** Free
Thickness	**Fingertips:** 0,7 mm
Physical Properties	**EN 455-1** **Freedom From Holes:** 1,5 AQL **EN 455-2** **Physical Properties** : Long, 240 mm | Width, 110 mm **Dimensions** : Force and break: 6,5 N Force and break after : 6,2 N **EN 455-3** **Powder Fee** : 0,3 mg Per Glove
Chemical Resistance for Degradation	**TS EN 374-4 + EN 374-1**
Resistance to Permation by Chemicals	**EN 374-4, TS EN 16523-1, TS EN 659**
PPE Certification	Module B Catagory 3
Virus Penetration	BS ISO 16604 + TS EN 14126, Part4.1.4.1 + EN 374-5, Part 5.3
Color and Sizes	**BLUE** SMALL | MEDIUM | LARGE | X-LARGE
Dimensions	**Box:** B 196 mm x 110 mm x 48 mm **Carton:** B 420 mm x 235 mm x 310 mm
Directive	Prepared according to 2016/425 Personal Protective Equipment Directive
Expiration Time	36 Months after production
Country of Manufacture	TURKEY

SOFT TOUCH

DISPOSABLE POWDER FREE **GLOVE**

NitrAG®

SMALL **BLUE**

MEDIUM **BLUE**

LARGE **BLUE**

X-LARGE **BLUE**

SOFT TOUCH

DISPOSABLE POWDER FREE **GLOVE**

NitrAG®

SMALL **BLACK**

MEDIUM **BLACK**

LARGE **BLACK**

X-LARGE **BLACK**

SOFT TOUCH

DISPOSABLE POWDER FREE **GLOVE**

NitrAG®

SMALL **WHITE**

MEDIUM **WHITE**

LARGE **WHITE**

X-LARGE **WHITE**

SOFT TOUCH

DISPOSABLE POWDER FREE **GLOVE**

NitrAG®

SMALL **PINK**

MEDIUM **PINK**

LARGE **PINK**

X-LARGE **PINK**

SOFT TOUCH

EU DECLARATION OF CONFORMITY

AGL GRUP

Declaration Number : 208-21-01-R02-01

The manufacturer : AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ. GIDA SAN. TİC. LTD. ŞTİ.
TUGAY YOLU CD. OFİSİM İSTANBUL PLAZA B BLOK NO.: 88 KAT: 15
34844 MALTEPE, İSTANBUL, TURKEY

Declare that the product : TPE disposable powder free examination and protective gloves **NitrAG PLUS, NitrAG**

Directive : Prepared according to 2016/425 Personal Protective Equipment Directive
Class : 3
Module : B

These are EN4551- 2- 3 and EN 374 1-2-3-4-5 ,CE 2841 class 3 approved gloves and are an alternative to nitrile. Manufactured with the new generation technology and sets itself apart from any other product in the industry. The silver ions it contains allow for not only better touch sensitivity but also a more comfortable prolonged use. Being powder-free attracts demand for consumers looking to use anti-allergic products in various domains including healthcare, food, home and sanitary.

Our Thermaplus Poly gloves prevent any allergic reactions amongst users and customers. Made from polyethylene (LDPE) with 7.5/8 Micron, the gloves do not release any unwanted chemicals and therefore allow direct contact with food or any other sensitive items.

Our gloves are suitable for use safely in domestic and commercial environments including Food & Beverage industries, Healthcare & Hospitality, Spas, Beauty Centres, Hairdressers, Barbers, etc.

Benefits of the gloves:
√ Excellent fit, maximum sensitivity and dexterity for fine tasks. The entire glove is finely textured (including palms and fingers) to provide consistent grip on glassware, small objects, instruments and tools.
√ Isolate odours and dust to keep your hands clean
√ Ideal for all kinds of uses that require a safe and hygienic environment
√ Ideal for almost any application including tattooing, food preparation, painting, cleaning, pet care, home improvement, hobbies, arts and crafts
√ Convenient dispense pack keeps gloves clean and organized while providing easy access

Colours available: White, Black, Blue & Pink
Sizes: S-M-L-XL

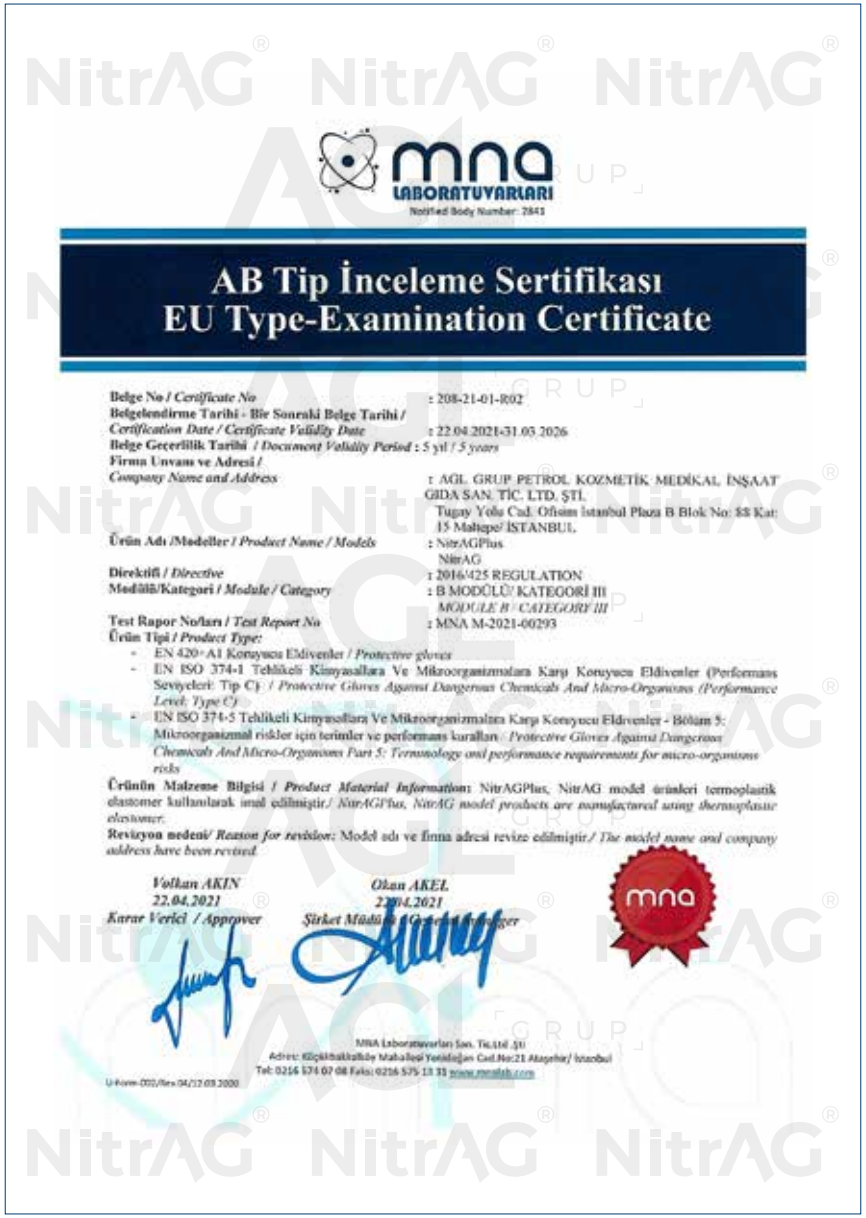
100 gloves in a box

Is conformal to the following directives and standards:
EN 420 Protective Gloves
EN ISO 374-1 Protective Gloves against hazardous chemicals and microorganisms
EN ISO 374-5 Protective Gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
EN 455-2 Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

CE 2841

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ. GIDA SAN. TİC. LTD. ŞTİ.
Cumhuriyet Mh. Gülsünya Sk. M.Şebnap Apt.
No: 4/1 Kartal / İSTANBUL
Yakacık Vergi Dairesi: 009 144 6578

SOFT TOUCH



mna LABORATUVARLARI
Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / *Certificate No* : 208-21-01-R02
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / *Certification Date / Certificate Validity Date* : 22.04.2021-31.03.2026
Belge Geçerlilik Tarihi / *Document Validity Period* : 5 yıl / *5 years*
Firma Unvanı ve Adresi / *Company Name and Address* : AGL GRUP PETROL KOZMETİK MEDİKAL İNŞAAT GIDA SAN. TİC. LTD. ŞTİ.
Tugay Yolu Cad. Ofisim İstanbul Plaza B Blok No: 88 Kat: 15 Maltepe/ İSTANBUL
Ürün Adı /Modeller / *Product Name / Models* : NitrAGPlus
NitrAG
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-2021-00293
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:* NitrAGPlus, NitrAG model ürünleri termoplastik elastomer kullanılarak imal edilmiştir./ *NitrAGPlus, NitrAG model products are manufactured using thermoplastic elastomer.*
Revizyon nedeni/ *Reason for revision:* Model adı ve firma adresi revize edilmiştir./ *The model name and company address have been revised.*

Volkan AKIN
22.04.2021
Karar Verici / Approver

Okan AKEL
22.04.2021
Şirket Müdürü / Company Manager

MNA Laboratuvarları San. Tic.Ltd .Şti
Adres: Küçükhacıalibey Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul
Tel: 0216 574 07 08 Faks: 0216 575 13 33 www.mnalab.com

U-Form-002/Rev.04/12.03.2020

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Notified Body Number: 2841

ATTACHMENTS (208-21-01-R02)

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 : NitrAGPlus, NitrAG

PPE SPECIFICATION	PERFORMANCE LEVELS
Dexterity	5
Material Resistance To Permeation By Chemicals	1 (Type C)
Phi-X174 Bacteriophage	Appropriate
Degradation (EN ISO 374-4:2019)	%40 NaOH: -5,65 %

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

MANUFACTURER: AGL GRUP PETROL KOZMETİK MEDİKAL İNŞAAT GIDA SAN. TİC. LTD. ŞTİ.
PPE TYPE:

- EN 420+ A1 Protective gloves
- EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms
- EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

PRODUCT SIZE / MODEL: NitrAGPlus, NitrAG (S, M, L, XL)
PICTOGRAM AND PERFORMANCE LEVELS:

EN 420+A1	EN ISO 374-1/2016 Type C	EN ISO 374-5/2016
CE NB 2841	K	VIRUS

MNA LABORATUVARLARI SAN. TİC. 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.

MNA Laboratuvarları San. Tic.Ltd .Şti
Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul
Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com

SOFT TOUCH

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Notified Body Number: 2841

ATTACHMENTS (208-21-01-R02)

PRODUCT PICTURES

NitrAGPlus, NitrAG

DOCUMENTS IN THE TECHNICAL FILE
- Basic Health Safety Requirements - Risk Assessment - Test Reports - Technical Report

MNA Laboratuvarları San. Tic.Ltd .Şti
Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir İstanbul
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U-Form-002/Rev.04/12.03.2020

SOFT TOUCH

MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (208-21-01-R02)

Report No :208-21-01-R02

Report Date :22.04.2021

Application No :208-21-01

1. **COMPANY INFORMATION:**
   AGL GRUP PETROL KOZMETİK MEDİKAL İNŞAAT GIDA SAN. TİC. LTD. ŞTİ.
   Tugay Yolu Cad. Ofisim İstanbul Plaza B Blok No: 88 Kat: 15 Maltepe/ İSTANBUL
   Tel: +90 216 457 13 00
   Mail: info@aglgrup.com.tr

2. **PPE INFORMATION:**
   Disposable and non-sterile thermoplastic elastomer glove.

3. **PPE TYPE IDENTIFICATION**
   EN 420+A1 Protective gloves
   EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms
   EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

4. **PPE PICTURES**

NitrAG Plus
NitrAG

5. **PPE DIMENSIONS:**
   NitrAGPlus, NitrAG model product has been found to be produced using S, M, L, XL sizes.

6. **PPE PRODUCT MATERIAL INFORMATION:**
   The product is made of thermoplastic elastomer.

MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (208-21-01-R02)

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- Visual examination has been made for ergonomics according to EN 420.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials are determined by visual inspection according to EN 420 + A1 Article 4.1.
- pH content is determined according to EN 420 + A1 clause 4.3.2.
- The glove's ability has been tested and evaluated according to EN 420 + A1.
- The measurement of hand and glove has been done, it has been evaluated according to EN 420 + A1.
- The analysis of the glove has been made according to EN 420 + A1 and EN ISO 374-1. Protective gloves against hazardous chemicals and microorganisms have been evaluated according to EN ISO 374-1.
- Determination of Organotin Compounds (DOT In-House Method: modified from EN ISO 16179), Phthalate Determination (ISO / TS 16181) are analyzed according to the standard.
- Analyzes against harmful chemicals have been performed and evaluated according to the REACH regulation.
- Gloves have been analyzed and evaluated according to the requirements of EN ISO 374-5 standard against microbial risks.

8. ANALYSIS AND EVALUATIONS:

EN 420+A1

ANALYSIS	PERFORMANCE LEVEL 1	2	3	4	5	RESULT	PERFORMANCE LEVEL	EVALUATION
pH	3.5<value<9.5					7,12	3.5<value<9.5	PASS
Dexterity	11 mm	9,5 mm	8 mm	6,5 mm	5 mm	5 mm	5	PASS
Organotin Compounds (DOT)	<1000 ppm					<10 ppm	<1000 ppm	PASS
Phthalates	<1000 ppm					<50 ppm	<1000 ppm	PASS

Size	Circumference (mm)	Length (mm)	RESULT Circumference (mm)	RESULT Length (mm)	EVALUATION
9	229	192	301	210	PASS

* The product is produced according to special dimensions.

Size	Glove length (mm)	RESULT	EVALUATION
9	250	255	PASS

* The product is produced according to special dimensions.

mna

MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (208-21-01-R02)

EN ISO 374-1

ANALYSIS	PERFORMANCE LEVEL	RESULT	EVAULATION
Part 4: Determination of resistance to degradation by chemicals	There is no performance value. Only reporting is made.	%-5,65	-
Part 2: Determination of resistance to penetration (Air leak test)	No leak to be detected	No leak	PASS
Part 2: Determination of resistance to penetration (Water leak test)	No leak to be detected	No leak	PASS
Determination of material resistance to permeation by chemicals	2 (>30 min no leak. Sodium Hydroxide 40 %)	No leak	PASS

EN ISO 374-5

ANALYSIS	PERFORMANCE LEVEL	RESULT	EVAULATION
Clothing for protection against contact with blood and body fluids.	No leak to be detected according to ISO 16604 Procedure B.	No leak (0 PFU/ml)	PASS

9. DECISION PROPOSAL

Analysis and examinations NitrAGPlus, NitrAG model coded personal protective equipment; EN 420+A1 Protective gloves, EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms, EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks, Experiments and Marking standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- User Instruction

Reason for revision : **The model name and company address have been revised.**

CONTROLLER : VOLKAN AKIN

SING :

DATE : 22.04.2021

mna

Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTON CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (208-21-01-R02-01)

Report No : 208-21-01-R02-01

Report Date : 22.04.2021

Application No : 208-21-01-R02-01

1. **COMPANY INFORMATION:**
   AGL GRUP PETROL KOZMETIK MEDIKAL INSAAT GIDA SAN. TIC. LTD. STI.
   Tugay Yolu Cad. Ofisim Istanbul Plaza B Blok No: 88 Kat: 15 Maltepe/ ISTANBUL
   Tel: +90 216 457 13 00
   Mail: info@aglgrup.com.tr

2. **PPE INFORMATION:**
   Disposable and non-sterile thermoplastic elastomer glove.

3. **PPE TYPE IDENTIFICATION**
   EN 420+A1 Protective gloves
   EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms
   EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

4. **PPE PICTURES**

NitrAGPlus
NitrAG

5. **PPE DIMENSIONS:**
   NitrAGPlus, NitrAG model product has been found to be produced using S, M, L, XL sizes.

6. **PPE PRODUCT MATERIAL INFORMATION:**
   The product is made of thermoplastic elastomer.

Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTON CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (208-21-01-R02-01)

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS
- Visual examination has been made for ergonomics according to EN 420.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials are determined by visual inspection according to EN 420 + A1 Article 4.1.
- pH content is determined according to EN 420 + A1 clause 4.3.2.
- The glove's ability has been tested and evaluated according to EN 420 + A1.
- The measurement of hand and glove has been done. It has been evaluated according to EN 420 + A1.
- The analysis of the glove has been made according to EN 420 + A1 and EN ISO 374-1. Protective gloves against hazardous chemicals and microorganisms have been evaluated according to EN ISO 374-1.
- Determination of Organotin Compounds (DOT In-House Method: modified from EN ISO 16179), Phthalate Determination (ISO / TS 16181) are analyzed according to the standard.
- Analyzes against harmful chemicals have been performed and evaluated according to the REACH regulation.
- Gloves have been analyzed and evaluated according to the requirements of EN ISO 374-5 standard against microbial risks.

8. ANALYSIS AND EVALUATIONS:

EN 420+A1

ANALYSIS	PERFORMANCE LEVEL 1	2	3	4	5	RESULT	PERFORMANCE LEVEL	EVALUATION
pH	3.5<value<9.5					7,15	3.5<value<9.5	PASS
Dexterity	11 mm	9,5 mm	8 mm	6,5 mm	5 mm	5 mm	5	PASS
Organotin Compounds (DOT)	<1000 ppm					<10 ppm	<1000 ppm	PASS
Phthalates	<1000 ppm					<50 ppm	<1000 ppm	PASS

Size	Circumference (mm)	Length (mm)	RESULT Circumference (mm)	RESULT Length (mm)	EVALUATION
9	229	192	302	211	PASS

* The product is produced according to special dimensions.

Size	Glove length (mm)	RESULT	EVALUATION
9	250	254	PASS

* The product is produced according to special dimensions.

mna
Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTON CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (208-21-01-R02-01)

EN ISO 374-1

ANALYSIS	PERFORMANCE LEVEL	RESULT	EVAULATION
Part 4: Determination of resistance to degradation by chemicals	There is no performance value. Only reporting is made.	%6,90	-
Part 2: Determination of resistance to penetration (Air leak test)	No leak to be detected	No leak	PASS
Part 2: Determination of resistance to penetration (Water leak test)	No leak to be detected	No leak	PASS
Determination of material resistance to permeation by chemicals	2 (>30 min no leak. Sodium Hydroxide 40 %)	No leak	PASS

EN ISO 374-5

ANALYSIS	PERFORMANCE LEVEL	RESULT	EVAULATION
Clothing for protection against contact with blood and body fluids.	No leak to be detected according to ISO 16604 Procedure B.	No leak (0 PFU/ml)	PASS

9. DECISION

Analysis and examinations NitrAGPlus, NitrAG model coded personal protective equipment; EN 420+A1 Protective gloves, EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms, EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks, Experiments and Marking standards are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2021-00036)
- User Instruction

CONTROLLER : VOLKAN AKIN
SING :
DATE : 22.04.2021

Page 3 / 3

TECHNICAL DOCUMENTATION FOR PPE TYPE EXAMINATION AND PROTECTIVE GLOVES ACCORDANCE WITH STANDARDS EN 420:2003+A1:2009 AND EN ISO 374-1:2016/A1:2018

ID: TCF-D- PFN -2020
Version: 01
Issued date: 05.09.2020

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ. GIDA SAN. TİC. LTD. ŞTİ.
Cumhuriyet Mh. Gülbahçe Sk. H.Şebnap Apt.
No: 4/1-2 Kartal / İSTANBUL
Yakacık Vergi Dairesi: 009 144 6578

TABLE OF CONTENT

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ. GIDA SAN. TİC. LTD. ŞTİ.

0. PURPOSE

THE PPE TYPE EXAMINATION AND PROTECTIVE GLOVES, designed with the intention of protecting the user against dangerous chemicals, is manufactured by AGL GRUP PETROL KOZMETİK MEDİKAL İNŞAAT GIDA SAN. TİC. LTD. ŞTİ. at the address of Cumhuriyet Mah. Güldünya Sk. H.Şebap Apt. No: 119 Kartal/ İSTANBUL with the general health and safety requirements specified in Regulation (EU) 2016/425, in particular, the specifications contained in standards EN 420:2003+A1:2019 and EN ISO 374-1:2016/A1:2018 published by the European Committee for Standardisation, as CATEGORY III PPE.

1. GENERAL REQUIREMENTS

1.1 Design principles

The PPE are protective gloves which are used to protect the user against dangerous chemicals. The protective gloves are designed and manufactured so that under normal conditions of use without exposure to additional risks, except in the event of the user's individual hypersensitivity, the wearers can perform the activity as normally as possible with approriate protection.

The ergonomic design takes into consideration the activities that the wearers might perform under normal conditions of use without exposure to additional risks, except in the event of the user's individual hypersensitivity.

1.2 Innocuousness

The gloves' materials and their decomposition products do not adversely affect user hygiene or health. Specifically, the contact surface of the glove with the hand is free of roughness, sharp edges, projection and the likes which may cause excessive irritation or injuries. These gloves have good finger dexterity and do not impede the user movement or sensory perception.

1.3 Comfort and effectiveness

The gloves are light, yet strong under foreseeable condition of use. It offers better puncture resistance than similar natural rubber latex glove.

The pH of the gloves is close to neutral and does not cause irritation.

1.4 Manufacture's instruction and information

See Annex II for the information to be included.

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ. GIDA SAN. TİC. LTD. ŞTİ. Cumhuriyet Mah. Güldünya Sk. H.Şebap Apt. No: 119 Kartal / İSTANBUL Yakacık Vergi Dairesi: 009 144 6578

2. ADDITIONAL REQUIREMENTS

THE PPE TYPE EXAMINATION AND PROTECTIVE GLOVES complies with the design and fitting systems, adjustment systems, ageing and protection against cutaneous and ocular contact defined below.

2.1 Design and fitting systems

The PPE's design and fitting systems enable it to adapt to the morphology of the user as shown in the following documents:

- Description of the PPE in accordance with Annex I.
- Specification of materials and components in accordance with Annex I.

2.2 Ageing

The obsolenscence deadline is 3 years from the date of manufacture, the month and year of obsolenscence is indelibly and unambiguously marked on its packaging.

2.3 Protection against cutaneous and ocular contact

The gloves intended to prevent the surface contact of the hands with substances and mixtures which are hazardous to health must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the gloves are intended.

3 SCOPE OF APPLICATION OF RECOMENDATION FOR USE EN 420:2003+A1:2009 AND EN ISO 374-1:2016/A1:2018

A EXAMINATION AND PROTECTIVE GLOVES can only be approved when its individual components satisfy the requirements of the test specifications which may be a complete standard or part of it, and practical behavior tests have been carried out satisfactorily on the complete equipment, as specified in the appropriate standard.

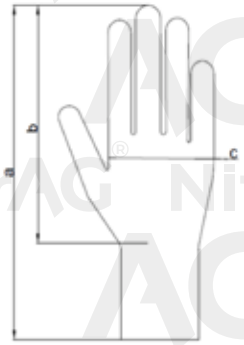
Specifically, these gloves is in accordance with the requirements of EN 420:2003+A1:2009 AND EN ISO 374-1:2016/A1:2018 for protective gloves intended to protect the user against dangerous chemicals and defines terms to be used.

AGL GRUP PETROL KOZMETİK
MEDİKAL İNŞ. GIDA SAN. TİC. LTD. ŞTİ.
Cumhuriyet Mh. Gülbahçe Sk. H.Şahap Apt.
No: 4/1 Kartal / İSTANBUL
Yakacık Vergi Dairesi: 009 144 6578

4 GENERAL REQUIREMENTS OF RECOMENDATION FOR USE EN 420:2003+A1:2009 AND EN ISO 374-1:2016/A1:2018

4.1 Design:

The protective gloves cover and protect the hands from the wrist to the fingers. These gloves are intended to be used only as a physical barrier against brief contact with chemicals, and they need to be removed and discarded immediately after they become contaminated.



a= Glove Length
b= Hand Length
c= Peripheral Length

1) WERGARD, NitrAG

Available sizes: 6, 7, 8, 9, 10, 11

SIZE (minimum)	6	7	8	9	10	11
GLOVE LENGTH(a)(mm)	220	230	240	250	260	270
HAND LENGTH(b)(mm)	160	171	182	192	204	215
PERIPHERAL LENGTH(c)(mm)	152	178	203	229	254	279

5 SPECIFIC REQUIREMENTS OF RECOMENDATION FOR USE EN 420:2003+A1:2009 AND EN ISO 374-1:2016/A1:2018

5.1 Packaging

Protective gloves are supplied for sale packed in such a way that they are protected against mechanical damage and contamination before use.

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Yakacık Vergi Dairesi: 009 144 65 78

5.2 Material

The materials used is suitable to withstand handling and use during the period of time for which protective gloves have been designed.

5.3 Finishing of the parts

The parts of the device that will be in contact with the wearer have not sharp edges or burrs.

5.4 Measurement of glove length

Before testing, samples shall be conditioned for at least 24h at 23 ± 2°C and 50 ± 5% relative humidity and testing shall be started within 10 min after removal from conditioning.

For each size, 3 gloves shall be tested. Measure the length by freely suspending the glove with the middle finger on a vertical graduated ruler having a rounded tip so as to fit the shape of the finger tip of the glove. Remove wrinkles and folds without stretching the glove. Turn the glove around the pin and record the minimum measured length to the nearest milimetre.

5.5 Penetration

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

5.6 Degradation

The degradation shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction.

5.7 Permeation

5.7.1 General

All the results should be reported in the user instruction.

Each combination of protective glove/ test chemical shall be classified according to Table 1, using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time.

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Table 1 - Permeation performance levels

Measured breakthrough time (min)	Permeation performance level
>10	1
>30	2
>60	3
>120	4
>240	5
>480	6

The test chemical(s) shall be taken from the list of test chemicals in Table 2. Other test chemicals could be used depending on the application of the gloves.

Table 2- List of test chemicals

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 hydrocarbon
E	Carbon disulphide	75-15-0	Sulphur containing organic compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofuran	109-99-9	Heterocyclic and ether compound
I	Ethyl acetate	141-78-6	Ester
J	n-Heptane	142-82-5	Saturated hydrocarbon
K	Sodium hydroxide 40%	1310-73-2	Inorganic base
L	Sulphuric acid 96%	7664-93-9	Inorganic mineral acid, oxidizing
M	Nitric acid 65%	7697-37-2	Inorganic mineral acid, oxidizing
N	Acetic acid 99%	64-19-7	Organic acid
O	Ammonium hydroxide 25%	1336-21-6	Organic base
P	Hydrogen peroxide 30%	7722-84-1	Peroxide
S	Hydrofluoric acid 40%	7664-39-3	Inorganic mineral acid
T	Formaldehyde 37%	50-00-0	Aldehyde

The situation described in EN 16523-1:2015, 8.5.1.4 is considered a fail due to non-homogeneity of the samples.

According to the permeation performance, chemical protective gloves are classified into three types: type A, type B, type C.

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5.7.2 Type A

The permeation performance shall be at least level 2 against a minimum of six test chemical listed in Table 2.

5.7.3 Type B

The permeation performance shall be at least level 2 against minimum of three test chemical listed in Table 2.

5.7.4 Type C

The permeation performance shall be at least level 1 against minimum of one test chemical listed in Table 2.

5.7.5 Requirement for glove type A, B and C

The requirements are mentioned in Table 3.

Table 3 - Requirements for different protection types of gloves

	5.1	5.2	5.4.2	5.4.3	5.4.4
Type A	X	X	X		
Type B	X	X		X	
Type C	X	X			X
X = required					

6 SAMPLES SUBMITTED

The following were submitted:

- 50 pairs type EXAMINATION AND PROTECTIVE GLOVES

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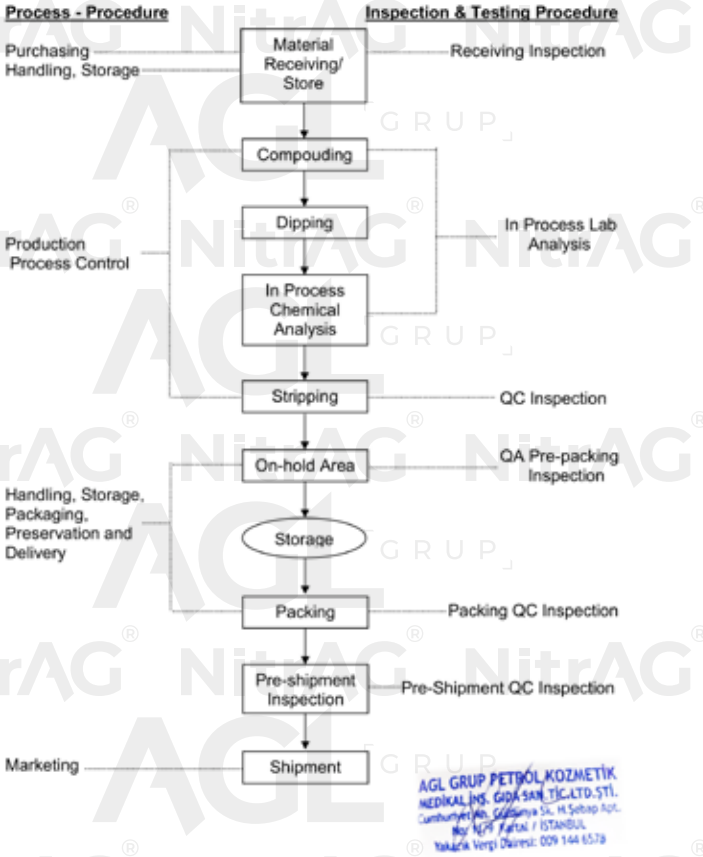
7 MEANS OF CONTROL

The model EXAMINATION AND PROTECTIVE GLOVES is subject to the following control mechanisms:

7.1 Manufacturing process



AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ. GIDA SAN. TİC. LTD. ŞTİ.

7.2 Quality control system

7.2.1 Incoming Material Inspection

All Incoming raw materials (that will affect the product's quality) that are subjected to inspection are placed under quarantine area in the store.

Incoming materials are selected randomly as per ISO 2859 simpling plan and inspected by Incoming Material Inspector.

Incoming materials that meet In-house specifications are attached with "Passed" Sticker.

Incoming materials that do not meet In-house specifications are quarantined pending management disposition decision.

- The Incoming materials are needed to be screened are attached with "Rejected Sticker and with "SCREEN" stamp on it.
- The Incoming materials that can be "Used as it is (substandard material but without functional implication and actual affect on quality) are attached with "Rejected" Sticker and with "UAI" stamp on it.
- Incoming materials that cannot be used and needed to be returned back to supplier are attached with "Reject" sticker.

All Reject Materials are return immediately to Supplier or stored in "Reject Area" pending return to supplier.

7.2.2 Milling and Compounding of Raw Material

Only the materials that with "Passed" Sticker can be used for milling process. The milled chemical is analyzed by laboratory personnel.

Only the milled chemical that has passed laboratory analysis will be released to be used in Compounding Process.

The milled chemical that has failed laboratory analysis shall be re-milled and quarantined to be used until it passes laboratory analysis.

Only the approved milled chemicals and chemicals with "Passed" sticker are used for compounding process.

The TPE compounds are analyzed by laboratory personnel.

The TPE compounds that pass all the In-house specification will be release to be use in production.

The TPE compounds that fail the In-house specification will be quarantined be used and shall wait for management disposition decision.

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All adjustments made on the TPE compounds will be documented in a work sheet and shall be analyzed by laboratory personnel again.

7.2.3 Production On-line Goods

Each bin of gloves is issued with a Travel Card and is controlled to 8 kgs.

Samples are taken and inspected as per ISO 2859 table I and II-A.

Every 6 bins, grouped as one Lot shall be tested as follow;

Inspect On	Inspection Level	AQL
i) Pin-hole	80 pcs	4.0
ii) Dimension	S2	1.5
iii)Visual Major	80 pcs	4.0
iv) Visual Minor	80 pcs	6.5

The bins that have passed the above inspection will be marked as grade AQL 4.0 on the Travel card.

The bins that had failed the above inspection will be segregated and quarantined and stored in a specified area in store.

The passed bins will proceed to WIP Store or Packing Department.

7.2.4 Packing QC Inspection

At packing, Packing QC conduct line clearance inspection before commence packing and at every hourly.

7.2.5 Production On-line Goods

The pallets of finish packed gloves are inspected by pre-shipment QA.

The samples are randomly picked and inspected as per ISO 2859 table I and II-A for:

Inspect On	Inspection Level	AQL
i) Pin-hole (Watertight)	S4	4.0
ii) Dimension	S2	4.0
iii)Visual Major	S4	4.0
iv) Visual Minor	S4	6.5
v) pH of Glove	N=3	-

The pallets of packed gloves that have passed Pre-shipment QA Inspection ar ready to deliver and store in outgoing store.

The pallets of packed gloves that have failed Pre-shipment QA Inspection shall be reworked by Packing Department.

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SOFT TOUCH

The sorted gloves will be quarantined and stored in specified area and wait management disposition decision.

7.3 Control And Test Facilities

Description of the Control and Test Facilities

Area	Control and Test Facilities
a) Laboratory	1) Chemical concentration testing apparatus.
b) Quality Control (QC) Section	1) Water-tight Test Equipment. 2) Stainless Steel Ruler. 3) Thickness Gauge.
c) Pre-Packing QA Section	1) Water-tight Test Equipment. 2) Stainless Steel Ruler.
d) Pre-shipment QA Section	1) Water-tight Test Equipment. 2) Stainless Steel Ruler. 3) Thickness Gauge.

8 ESSENTIAL REQUIREMENTS

Regulation 2016/425, Annex II	**Clause(s)/ sub-clause(s) of EN 420:2003+A1:2009**	**Clause(s)/ sub-clause(s) of EN ISO 374-1:2016**
1.2.1.1 Innocuousness of PPE- suitable constituent materials	4.2	
1.2.1.3 Maximum permissible user impediment	5.2	
1.4 Information supplied by the manufacturer	7.3	7
2.4 PPE subject to ageing	4.3 7.2.1.1 f) & 7.2.2 g)	
2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety	7.2.1.1 d) – 7.2.2 e) – 7.3.5	6
3.10 Protection against dangerous substances and infective agents 3.10.2 Protection against cuteneous and ocular contact		5.2, 5.3, 5.4, 5.5

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9 RISK ASSESMENT

Risk assessment according to **EN ISO 374-1:2016** Prevention of occupational hazards.

RISK AGAINST WHAT IT PROTECTS	TYPE OF WORK	PROBABILITY OF A DANGER / INJURY HAPPENING	QUALIFY THE SERIOUSNESS OF THE DANGER/INJURY	GENERAL CALIFICATION	PROTECTION DEGREE	STANDARD FOR EVALUATIONG THE LEVEL OF PROTECTION	SOURCE THAT CONTRIBUTES TO THE EXHIBITION
Determination of material resistance to permeation by chemicals	Sanitary ambient, hospitals , laboratory	Very high	High	IMPORTANT RISK	Determination of material resistance to permeation by %40 NaOH (> 30min, PERFORMANCE LEVEL:2	5.2, 5.3, 5.4, 5.5 EN 374-1	Inadequate risk assessment
						7 EN 374-1 7.3 EN 420:2003+A1:2009	Inappropriate use as indicated in the information leaflet
						6 EN 374-1	Inappropriate use as indicated in the information glove mark

10 MARKING

Each glove should be marked so that the following information is easily readable by the user and remains readable throughout its intended use:

1- Standard EN 374-1/Type C
2- Manufacturer's name or brand: AGL GRUP PETROL KOZMETİK MEDİKAL İNŞAAT GIDA SAN. TİC. LTD. ŞTİ.
3- PPE reference: WERGARD, NitrAG
4- CE marking: CE
5- Production control body: 2841
6- Classification: CATEGORY III

11 INFORMATION LEAFLET

The leaflet that accompanies each EXAMINATION AND PROTECTIVE GLOVES, an example of which is attached in Annex II, is written in the official language of the Member State in which it is sold, as well as other possible languages.

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Yakacık Vergi Dairesi: 009 144 6578

ANNEX I

PPE DESCRIPTION

1.1 General Description

1.1.1 Glove Type
EXAMINATION AND PROTECTIVE GLOVES.
Variants : Applicable for smooth or textured or finger-textured surface and meet the product specification.
Standard EN 374-1/Type C

1.1.2 Feature
Ambidextrous, Disposable, Beaded Cuff

1.1.3 Material
Made from Thermoplastic elastomer

1.1.4 Colour
Blue colored

1.1.5 Shelf-Life
3 years from date of manufacture.

1.2 Intended Use
This disposable Personal Protective Equipment (PPE) TPE glove is intended to be worn by an individual for prevention the surface contact of the hands with substances and mixtures which are hazardous to health

1.3 Classification
CATEGORY III

1.4 Applicable Harmonised Standards

- EN 420:2003+A1:2009 Protective gloves – General requirements and test methods
- EN ISO 374-1:2016/A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks

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No: 4/1-F Kartal / İSTANBUL
Yakacık Vergi Dairesi: 009 144 6578

1.5 Product Specification

No	Tests	Limit Value	Reference Test method	Evaluation
1	Determination of material resistance to permeation by chemicals (METHANOL)	>10 min	TS EN 16523-1	PERFORMANCE LEVEL:0
2	Dexterity	5 mm	TS EN 420 + A1 Part 6.2	PERFORMANCE LEVEL:5
3	Determination of organotin compounds (DOT)	<1000 ppm	ISO TS 16179	PASS
4	Determination of Phthalates	<1000 ppm	ISO/TS 16181	PASS
5	Determination of pH	3.5 < Result < 9.5	EN 420 + A1 Part 4.3.2 TS EN ISO 3071	PASS
6	Air leak test	Should be no	TS EN 374-2 Part 5.2	PASS
7	Water leak test	Should be no	TS EN 374-2 Part 5.3	PASS
8	Determination of resistance to degradation by chemicals (ACETONE)	-	TS EN 374-4	-
9	Determination of material resistance to permeation by chemicals (%40 NaOH)	> 30 min	TS EN 16523-1	PERFORMANCE LEVEL:2
10	Determination of material resistance to permeation by chemicals (%96 H2SO4)	> 10 min	TS EN 16523-1	PERFORMANCE LEVEL:0
11	Chemichal determaination of formaldehyde content	75 mg/kg	TS EN ISO 17226-1	PASS

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Yakacık Vergi Dairesi: 009 144 6578

EXAMINATION AND PROTECTIVE GLOVES
ID: TCF-D- PFN -2020
Version: 01
Issued date: 05.09.2020

ANNEX II: INFORMATION LEAFLET (MANDATORY)

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞAAT GIDA SAN. TİC. LTD. ŞTİ.
TUGAY YOLU CD. OFİSİM İSTANBUL PLAZA B BLOK NO.: 88 KAT: 15 34844 MALTEPE, İSTANBUL, TURKEY

CE 2841

EXAMINATION AND PROTECTIVE GLOVES
Model: WERGARD, NitrAG

This product has been manufactured in compliance with Regulation (EU) 2016/425, for basic use, EN 420+ A1:2020 Protective gloves – General requirements and test methods and EN ISO 374-1:2016/A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. This disposable Personal Protective Equipment (PPE) TPE glove is intended to be worn by an individual for prevention the surface contact of the hands with substances and mixtures which are hazardous to health. Requirements, testing, marking, in compliance with certificate **nº xxxxxx by** MNA LABORATUVARLARI SANAYI TICARET LIMITED, No:21 Atasehir/Istanbul/Turkey, Notified Body 2841

Recommendations for use:

- The PPE is Made from thermo plastic elastomer
- Powder-free
- Not made with natural rubber latex
- Ambidextrous

Warnings
- Gloves not valid in an explosive atmosphere
- This product is not flame resistant and must not be used in areas with open flames
-The user must know the use and gloves handling
-Do not use risk zones of explosion
-This PPE must not be used against risks other than those previously described.
- only one use

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Yakacık Vergi Dairesi: 009 144 6578

"Those protective gloves are designed with the intention of preventing the surface contact of the hands with substances and mixtures which are hazardous to health."

Obtained levels

OBTAINED VALUE: EN 374-1/Type C

Determination of material resistance to permeation by chemicals (%40 NaOH):

Evaluation	Limit Value
PERFORMANCE LEVEL:2	> 30 min

Storage: Keep the gloves away from unnecessary exposure to sunlight, in dry places and protected against any aggressive agents.

Packaging: 50 pairs of gloves on a Paper box.

PICTOGRAMS EXPLANATIONS:

The permeation performance against Sodium hydroxide 40%

yyyy/mm
(usable life)

Maximum relativity humidity of storing

40ºC

10ºC
Temperature range of storing

See information supplied by the manufacturer

16

Technique for donning and removing gloves

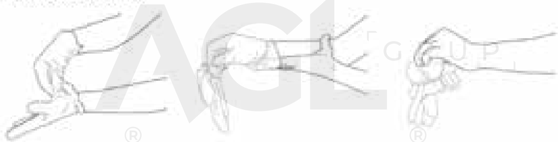
When the hand hygiene indication occurs before a contact requiring glove use, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water

I. HOW TO DON GLOVES:

1. Take out a glove from its original box
2. Touch only a restricted surface of the glove corresponding to the wrist (at the top edge of the cuff)
3. Don the first glove

4. Take the second glove with the bare hand and touch only a restricted surface of glove corresponding to the wrist
5. To avoid touching the skin of the forearm with the gloved hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand, thus permitting to glove the second hand
6. Once gloved, hands should not touch anything else that is not defined by indications and conditions for glove use

II. HOW TO REMOVE GLOVES:



1. Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel away from the hand, thus allowing the glove to turn inside out
2. Hold the removed glove in the gloved hand and slide the fingers of the ungloved hand inside between the glove and the wrist. Remove the second glove by rolling it down the hand and fold into the first glove
3. Discard the removed gloves

4. Then, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water

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ANNEX III: GLOVES MARKING

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EXAMINATION & PROTECTIVE GLOVES
EN ISO 374-1:2016/TYPE C
CE 2841

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Cumhuriyet Mah. Gülbahçe Sk. H.Şebnap Apt.
No: 16/1 Kartal / İSTANBUL
Yakacık Vergi Dairesi: 009 144 6578

ANNEX IV: PACKAGING

PICTOGRAMS EXPLANATIONS:

The permeation performance against Sodium hydroxide 40%

yyyy/mm
(usable life)

Maximum relativity humidity of storing

40°C

10°C
Temperature range of storing

See information supplied by the manufacturer

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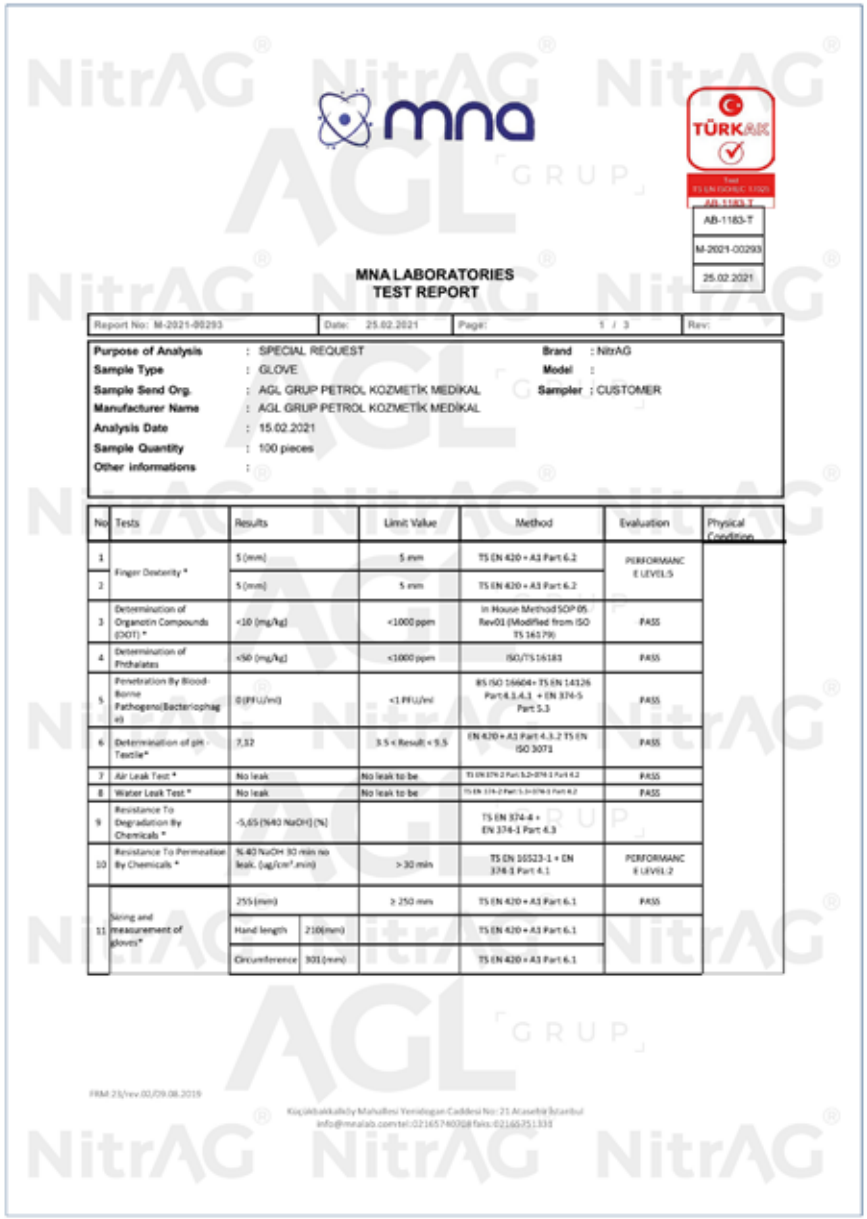
Yakacık Vergi Dairesi: 009 144 6578



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AB-1183-T

M-2021-00293

25.02.2021

MNA LABORATORIES
TEST REPORT

Report No: M-2021-00293	Date: 25.02.2021	Page: 1 / 3	Rev:

Purpose of Analysis	: SPECIAL REQUEST	**Brand**	: NitrAG
Sample Type	: GLOVE	**Model**	:
Sample Send Org.	: AGL GRUP PETROL KOZMETİK MEDİKAL	**Sampler**	: CUSTOMER
Manufacturer Name	: AGL GRUP PETROL KOZMETİK MEDİKAL		
Analysis Date	: 15.02.2021		
Sample Quantity	: 100 pieces		
Other informations	:		

No	Tests	Results	Limit Value	Method	Evaluation	Physical Condition
1	Finger Dexterity *	5 (mm)	5 mm	TS EN 420 + A1 Part 6.2	PERFORMANCE LEVEL:5	
2		5 (mm)	5 mm	TS EN 420 + A1 Part 6.2		
3	Determination of Organotin Compounds (DOT) *	<10 (mg/kg)	<1000 ppm	In House Method SOP 05 Rev01 (Modified from ISO TS 16179)	PASS	
4	Determination of Phthalates	<50 (mg/kg)	<1000 ppm	ISO/TS 16183	PASS	
5	Penetration By Blood-Borne Pathogens(Bacteriophage)	0 (PFU/ml)	<1 PFU/ml	BS ISO 16604+ TS EN 14126 Part 4.1.4.1 + EN 374-5 Part 5.3	PASS	
6	Determination of pH - Textile*	7,12	3.5 < Result < 9.5	EN 420 + A1 Part 4.3.2 TS EN ISO 3071	PASS	
7	Air Leak Test *	No leak	No leak to be	TS EN 374-2 Part 5.2+374-1 Part 4.2	PASS	
8	Water Leak Test *	No leak	No leak to be	TS EN 374-2 Part 5.1+374-1 Part 4.2	PASS	
9	Resistance To Degradation By Chemicals *	-5,65 (%40 NaOH) (%)		TS EN 374-4 + EN 374-1 Part 4.3		
10	Resistance To Permeation By Chemicals *	%40 NaOH 30 min no leak. (µg/cm².min)	> 30 min	TS EN 16523-1 + EN 374-1 Part 4.1	PERFORMANCE LEVEL:2	
11	Sizing and measurement of gloves*	255 (mm)	≥ 250 mm	TS EN 420 + A1 Part 6.1	PASS	
		Hand length 210(mm)		TS EN 420 + A1 Part 6.1		
		Circumference 101(mm)		TS EN 420 + A1 Part 6.1		

FRM 23/rev.02/09.08.2019

Koçakbakkaloğlu Mahallesi Yenidoğan Caddesi No: 21 Acıselvi İstanbul
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M-2021-00293

26.02.2021

MNA LABORATORIES
TEST REPORT

Report No: M-2021-00293	Date: 26.02.2021	Page: 2 / 3	Rev:

Purpose of Analysis	: SPECIAL REQUEST		**Brand**	: NitrAG	
Sample Type	: PROTECTIVE GLOVE		**Model**	:	
Sample Send Org.	: AGL GRUP PETROL KOZMETİK MEDİKAL		**Sampler**	: CUSTOMER	
Manufacturer Name	: AGL GRUP PETROL KOZMETİK MEDİKAL				
Analysis Date	: 15.02.2021				
Sample Quantity	: 100 pieces				
Other informations	:				

12	Sizing and measurement of gloves*	288 (mm)		≥ 240 mm	TS EN 420 + A1 Part 6.1	PASS
		Hand length	321(mm)		TS EN 420 + A1 Part 6.1	
		Circumference	90(mm)		TS EN 420 + A1 Part 6.1	

SAMPLE PLACE

1. Line Sample place for finger dexterity: Size 9
12 Line Sample place for sizing and measurement of gloves: Size 10
11 Line Sample place for sizing and measurement of gloves: Size 9
2. Line Sample place for finger dexterity: Size 10

1583.T/rev.02/29.06.2018

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AB-1183-T
M-2021-00293
26.02.2021

MNA LABORATORIES
TEST REPORT

Report No: M-2021-00293	Date: 26.02.2021	Page: 3 / 3	Rev:

Purpose of Analysis	: SPECIAL REQUEST	**Brand**	: NitrAG
Sample Type	: PROTECTIVE GLOVE	**Model**	:
Sample Send Org.	: AGL GRUP PETROL KOZMETİK MEDİKAL	**Sampler**	: CUSTOMER
Manufacturer Name	: AGL GRUP PETROL KOZMETİK MEDİKAL		
Analysis Date	: 15.02.2021		
Sample Quantity	: 100 pieces		
Other informations	:		

Operating as an experimental laboratory, MNA Laboratories have been accredited by TURKAK with AB-1183-T and TS_EN_ISO / IEC_17025: 2017 standard. Turkish Accreditation Agency (TÜRKAK) signed a multilateral agreement with the European Accreditation Association (EA) on the recognition of test reports and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).
* Analysis is under accreditation.

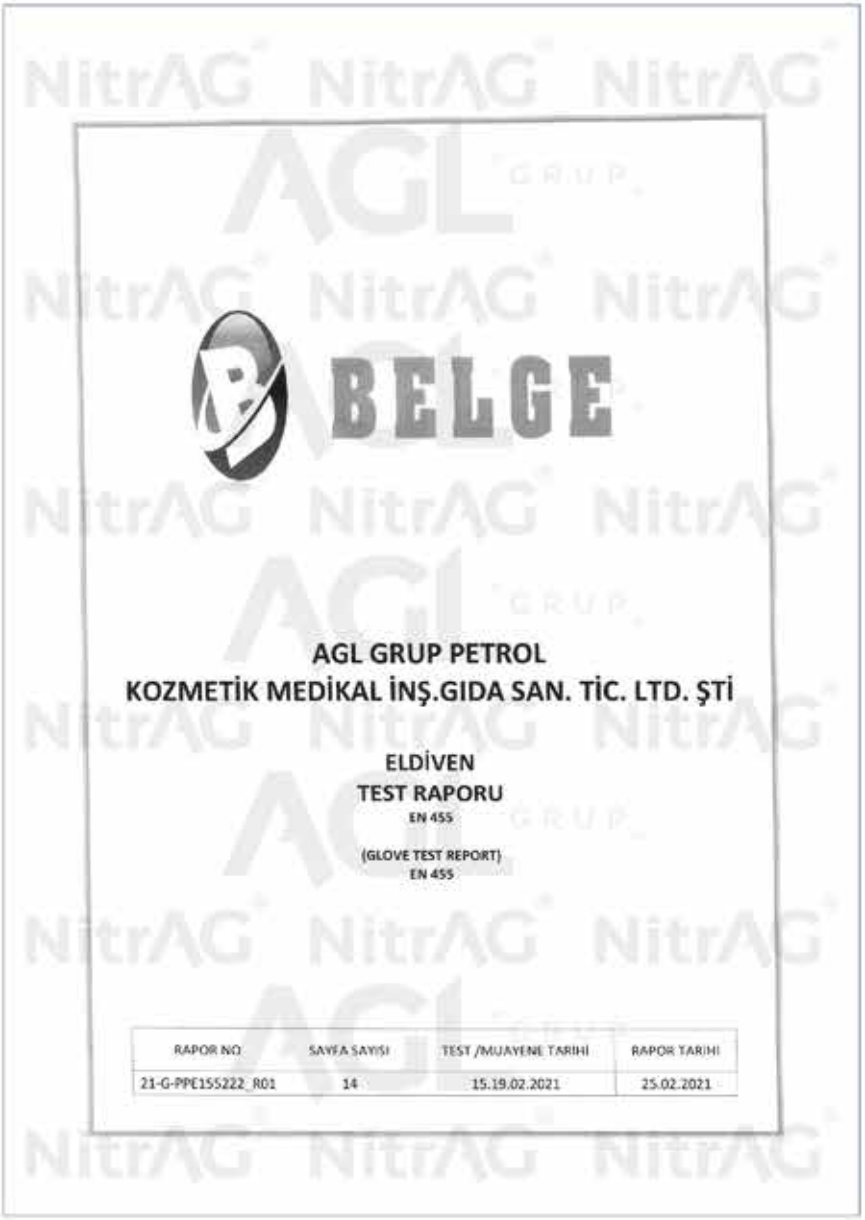
Note :

1. No part of this analysis report can be used alone or separately, and may not be partially copied or reproduced, used to third parties and as a means of advertising without the written permission of the laboratory.
2. Analysis results are valid for the above mentioned sample sent by MNA Laboratory company / institution / person. It may not represent the whole.
3. Unsigned and unsealed reports are invalid.
4. This analysis report cannot be used in judicial-administrative procedures and for advertising purposes.
5. Results are valid for the sample as received.
6. The decision rule is the rule that determines how measurement uncertainty is taken into account when specifying the PASS density to a specified specification. According to the TLM-052 Decision Rule Implementation Instruction, the Decision Rule Implementation Method selected in agreement with CUSTOMER is clearly stated in the report.
7. Limit Values are determined by taking from analysis methods.
8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.
9. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pages, which are the supplementary part of this certificate.
10. Water Repellency Determination Hydrostatic Pressure Determination TS ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13960-2 (Strength Test Device E / N: 90) Analysis and resistance to liquid chemical permeation TS EN 559 , A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2 conditions (23 ± 2 ° C temperature and 50 ± 4% relative humidity) are applied for ambient conditions.
11. List of phthalates analyzed is below.
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
Sampling and Reporting Officer

Erhan ÜSTÜNEL
PPE Laboratory Responsible

Confirmed/
25.02.2021
Volkan AKIN
Laboratory Manager



BELGE

AGL GRUP PETROL
KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ

ELDİVEN
TEST RAPORU
EN 455

(GLOVE TEST REPORT)
EN 455

RAPOR NO	SAYFA SAYISI	TEST /MUAYENE TARİHİ	RAPOR TARİHİ
21-G-PPE155222_R01	14	15.19.02.2021	25.02.2021

BELGE	Belge Mühendislik Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri TS EN ISO/IEC 17025:2017	ALAB-T-011 21-G-PPE155222_R01 02/2021

BELGE
MUAYENE

BÖLÜM 1 / SECTION 1
RAPOR / REPORT

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ

ELDİVEN TEST RAPORU

EN 455

(GLOVE TEST REPORT)
EN 455

21-G-PPE155222

BELGE

Belge Mühendislik
Muayene – Teknik Kontrol
Denetim ve Belgelendirme Hizmetleri

TS EN ISO/IEC 17025:2017

ALAB-T-011
21-G-PPE155222_R01
02/2021

02/2021

Belge Mühendislik – Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri Ltd Şti

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TEST RAPORU – *TESTING REPORT*

FİRMA BİLGİLERİ

Müşteri Adı *Client Name*	AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ	**Adres** *Address*	Tugayyolu Caddesi, No:88, B Blok, Kat :15 Maltepe/İstanbul
Firma Yetkilisi	Emre AĞAOĞLU	**Teklif No**	PPE155222
İletişim *Contact*	+90 533 013 11 13	**e-mail**	info@aglgrup.com.tr
Telefon	+90 (216) 457 13 00	**Test Tarihi**	15-19.02.2021
Fax	+90 (216) 457 13 00	**Rapor No**	21-G-PPE155222
e-mail	info@aglgrup.com.tr	**Rapor Tarihi**	25.02.2021
web	www.aglgrup.com.tr	**Testi Yapılan Ürünler**	**Tek kullanımlık Pudrasız Eldiven** (Disposable Powder-Free Glove)
Marka	**NİTRAG**	**Model**	**S, L, M, XL (Mavi, Siyah)** S, L, M, XL (Blue, Black)

Rapor Tipi *Report Type*	□ **İlk** *First*	□ **Ara** *Intermediate*	x **Final** *Final*
Revizyon *Revision*	00		
Açıklamalar *Remarks*			

Lot No/s: S202102-1512, M202102-15018, L202102-15017, XL202102-15016

NITRAG Size: S – M – L – XL (Mavi / Blue - Siyah/Black)

ÖLÇÜM LABORATUVARI BELGE

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[illegible]

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BELGE

Belge Mühendislik
Muayene – Teknik Kontrol
Denetim ve Belgelendirme Hizmetleri

TS EN ISO/IEC 17025:2017

AGAB-T-013
21-G-PPE155222_R01
02/2021

TEST /KURULUŞU / TESTING COMPANY

ADI, GÖREVİ / NAME AND POSITION		TARİH / DATE	İMZA / SIGNATURE
HAZIRLAYAN WRITTEN BY	Önder KÜÇÜKALP Deney Personeli	15.02.2021	

MÜŞTERİ KURULUŞ CUSTOMER COMPANY

AGL GRUP PETROL
KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ

ADI, GÖREVİ / NAME AND POSITION		TARİH / DATE	İMZA / SIGNATURE
ONAYLAYAN APPROVED BY	Emre AĞAOĞLU	15.02.2021	
ONAYLAYAN APPROVED BY			
ONAYLAYAN APPROVED BY			

ÖLÇÜM LABORATUVARI

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BELGE

Belge Mühendislik
Muayene – Teknik Kontrol
Denetim ve Belgelendirme Hizmetleri

TS EN ISO/IEC 17025:2017

ALAB T-011
21-G-PPE151222_R01
02/2021

TEST TARİHİ / TEST DATE: **15-19.02.2021**

MÜŞTERİ KURULUŞ CLIENT COMPANY

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ

Marka: Brand	Modeli Model	Seri No: Serial No
NITRAG	Tek kullanımlık Eldiven (Disposable Powder-Free Glove))	LOT No:

İMALATÇISI MANUFACTURE

AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ

Marka: Brand	Modeli Model	Seri No: Serial No
NITRAG	Tek kullanımlık Eldiven (Disposable Powder-Free Glove)	LOT No:

TEST ÖRNEKLERİ AÇIKLAMASI
DESCRIPTION OF SAMPLES

No	Ürün Açıklaması: Product Description	Marka Model Brand/ Model	Renk Colour	Parti No: Lot No	Boyut Size	Örnek Adedi Sample received (pieces)	Üretici Manufacturer
1	Tek kullanımlık Eldiven (Disposable Powder-Free Glove)	NITRAG	Mavi Blue	S202102 - 15012	S	300	AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ
				M202102 - 15018	M	300	
				L202102- 15016	L	300	
				XL202102 - 15017	XL	300	

Malzeme / Material: PE

TEST ÖRNEKLERİ AÇIKLAMASI
DESCRIPTION OF SAMPLES

No	Ürün Açıklaması: Product Description	Marka Model Brand/ Model	Renk Colour	Parti No: Lot No	Boyut Size	Örnek Adedi Sample received (pieces)	Üretici Manufacturer
1	Tek kullanımlık Eldiven (Disposable Powder-Free Glove)	NITRAG	Siyah Black	S202102 - 15012	S	300	AGL GRUP PETROL KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ
				M202102 - 15018	M	300	
				L202102- 15016	L	300	
				XL202102 - 15017	XL	300	

AGL PETROL_R01 S

Bu Test raporunda verilen sonuçlar belirtilen teknik şartlar şartlarında numuneyi gerçekleştiren laboratuvara aittir. Kısmi ve tamamı bu sonuçlar, yazılı onayı olmadan çoğaltılır. Bu rapor Belge Mühendislik – Muayene – Teknik Kontrol Direktörü ve Belgelendirme Hizmetleri'nin yazılı izni olmadan kısmen veya yayınlanamaz. Promosyon ve reklamlarda kullanılamaz.

RAP.42.10.06.2020 Rev:04

BELGE

Belge Mühendislik
Muayene – Teknik Kontrol
Denetim ve Belgelendirme Hizmetleri

TS EN ISO/IEC 17025:2017

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Malzeme / *Material*: PE

Müşteri tarafından belirtilen lot büyüklüğü: **15.001 ile 50.000 parça**
Lot size as specified by client 15.001 to 50.000 pieces

TEST YÖNTEMİ:
METHOD OF TEST:

EN 455-1	Tek kullanımlık tıbbi eldivenler Bölüm 1: Deliksizlik için gereksinimler ve test	*Medical gloves for single use Part 1: Requirements and testing for freedom from holes*
EN 455-2	Tek kullanımlık tıbbi eldivenler Bölüm 2: Fiziksel özellikler için gereksinimler ve test	*Medical gloves for single use Part 2: Requirements and testing for physical properties*
EN 455-3	Tek kullanımlık tıbbi eldiven Bölüm 3: Biyolojik değerlendirme için gereksinimler ve test	*Medical glove for single use Part 3: Requirements and testing for biological evaluation*
EN 455-4	Tek kullanımlık tıbbi eldiven Bölüm 4: Raf ömrünün tayini için kurallar ve deneyler	*Medical glove for single use Part 4: Rules and tests for determination of shelf life*
93/42 EC	Tıbbi Cihaz Direktifi	*Medical Device Directive*
2016/425 EC	Kişisel Koruyucu Ekipman Direktifi	*PPE Directive*
ASTM D6319 - 19	Tıbbi Uygulama için Nitril Muayene Eldivenleri için Standart	*Standard Specification for Nitrile Examination Gloves for Medical*
ASTM D5151 - 19	Tıbbi Eldivenlerdeki Deliklerin Tespiti için Standart Test Yöntemi	*Standard Test Method for Detection of Holes in Medical Gloves*
ASTM D6124 - 06	Tıbbi Eldivenler Üzerindeki Artık Toz için Standart Test Yöntemi	*Standard Test Method for Residual Powder on Medical Gloves*

SONUÇLAR
RESULTS:

Tablo – 1 EN 455-1 Sonuçları
Table 1 Results for EN 455-1

Madde *Clause*	**Test** *Test*	**Beden** *Size*	**Şartlar** *Requirements*	**Kabul Edilebilir Uyumsuz Sayısı** *non-compliers allowed (pieces)*	**Test Edilen Numune** *Number tested (pieces)*	**Karşılaştırma Dışı Sayısı** *non-compliers found (pieces)*	**Sonuç** *inferred results*
4. 5.	**Serbest Delik** *Freedom from holes*	S	**Sızıntı yapmayacak** *Shall not leak*	1	50	1	Geçti *Passed*
		M		1	50	1	Geçti *Passed*
		L		1	50	1	Geçti *Passed*
		XL		1	50	1	Geçti *Passed*

ÖLÇÜM LABORATUVARI BELGE

AGL PETROL_R01 6

Bu Test raporunca verilen sonuçlar [illegible] **Belge Mühendislik – Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri**'nin yazılı izni olmadan [illegible]

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BELGE

Belge Mühendislik
Muayene – Teknik Kontrol
Denetim ve Belgelendirme Hizmetleri

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	7 days at (70±2)°C	XL		20	9,6	Geçti *Passed*

SONUÇLAR
RESULTS

Tablo – 3 EN 455-2 Madde 7 Sonuçları
Table-3 Results for EN 455-2 Clauses 7

Madde *Clause*	Test *Test*	Şartlar *Requirements*	Sonuç *results*	Çıkarılan Sonuç *Inferred results*
7	**Etiketleme** *Labeling*	**EN ISO 15223-1 ve EN 1041 uyarınca İmalatçılar eldiveni ve / veya üretim tarihi ile paketleme Üretim tarihi paketleme tarihi olarak tanımlanır.** *Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1 and EN 1041 Date of manufacture is defined as the packaging date*	Gözlemlenen *Observed*	Geçti *Passed*

SONUÇLAR
RESULTS

Tablo – 4 EN 455-3 Madde 4.2 – 4.5 Sonuçları
Table-4 Results for EN 455-3 Clauses 4.2 – 4.5

Madde *Clause*	Test *Test*	Şartlar *Requirements*	Sonuç/ Açıklama *Results / Remarks*		Çıkarılan Sonuç *Inferred results*
4.2	**Kimyasallar** *Chemicals*	**Eldivende Talk Pudrası olmamalıdır (Magnezyum silikat)** *Gloves shall not be dressed with talcum powder (magnesium silicate)*	**Müşteri beyanına göre pudrasız eldivendir.** *Glove is powder free glove, based on client's declaration letter version*		Uygulanmaz *N/A*
		Diğer Kimyasallar *Other chemicals*	**Kimyasal Madde Listesi Müşteri Tarafından bildirilecektir.** *Manufacturer shall disclose upon request a list of chemical ingredients*		Uygulanmaz *N/A*
4.3	**Endotoksinler** *Endotoxins*	**<20 EU/Çift Düşük endotoksin içeriği etiketlenmiş** *< 20 EU/pair for gloves labelled with 'low endotoxin content'*	**"Düşük" olarak etiketlenmemiş endotoksin içeriği** *Not labelled with 'low endotoxin content'*		Uygulanmaz *N/A*
4.4 5.2	**Pudrasız Eldivenler** *Powderfree gloves*	**Pudrasız Eldiven için Toplam toz kalıntısı 2 mg geçmeyecek** *For powder-free gloves. The total quantity of powder residues shall not exceed 2 mg per glove.*	S	0.052 mg **Eldiven başına**/per glove	Geçti *Passed*
			M	0.051 mg **Eldiven başına**/per glove	Geçti *Passed*
			L	0.31 mg **Eldiven başına**/per glove	Geçti *Passed*
			XL	0.33 mg **Eldiven başına**/per glove	Geçti *Passed*
4.5 5.3	**Proteinler, Süzülebilir** *Proteins, leachable*	**İmalatçı doğal kauçuk lateks içeren eldivenler için sızabilir protein seviyesini en aza indirmeli** *The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex*	**Doğal olmayan kauçuk lateks eldiven** *Non-natural rubber latex glove*		Uygulanmaz *N/A*

ÖLÇÜM LABORATUVARI BELGE

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Bu Test raporunda verilen sonuçlar [illegible] **Belge Mühendislik – Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri** [illegible]

[illegible] RAP.49 30-06-2020 Rev.04

BELGE

Belge Mühendislik
Muayene – Teknik Kontrol
Denetim ve Belgelendirme Hizmetleri

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SONUÇLAR
RESULTS

Tablo – 5 EN 455-3 Madde 4.6 Sonuçları
Table-5 Results for EN 455-3 Clauses 4.6

Madde *Clause*	**Test** *Test*	**Şartlar** *Requirements*	**Sonuç** *Results*
4.6	**Etiketleme** *Labelling*	**EN 1041 uyarınca Etiketlemeye ek olarak EN ISO 15223-1 uyarınca semboller aşağıdaki gereksinimleri içermelidir.** *In addition to the labelling specified in EN 1041 and the relevant symbols given in EN ISO 15223-1, the following requirements apply:*	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1 symbol for latex.	**Uygulanmaz** N/A
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses'.	**Uygulanmaz** N/A
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free.	**Uygun** Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions'.	**Uygulanmaz** N/A
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unqualified indication of the presence of allergens.	**Uygulanmaz** N/A
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	**Uygulanmaz** N/A
		Çıkarılan Sonuç *Inferred results*	**Geçti** *Passed*

Testi Yapan Deney Personeli	**Raporu Hazırlayan**	**Onaylayan Teknik Müdür**
İsim – Soyisim / İmza	İsim – Soyisim / İmza	İsim – Soyisim / İmza
Önder KÜÇÜKALP 25.02.2021	Önder KÜÇÜKALP 25.02.2021	Kıyçasu CANLISOY 25.02.2021

AGL PETROL_R01

Bu Test raporunda verilen sonuçlar belirtilen [illegible] Belge Mühendislik – Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri'nin [illegible]

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BELGE	Belge Mühendislik Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri **TS EN ISO/IEC 17025:2017**	AJAB T-011 21-G-PPE355222_R01 02/2021

Deney ve /veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (olması halinde) ve deney metotları bu sertifikanın tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir. *The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report*

Açıklamalar:

Remarks:

1. S, M, L, XL, Deliksizlik testi müşteri beyanına göre yapılmıştır.
   Freedom from holes test for S, M, L, XL, were tested in manufacturer's declaration
2. Etiketleme gereksinimleri müşteri beyanı ile sunulan ambalaj resmine göre değerlendirilmiştir.
   Labelling requirements are assessed based on submitted packaging artwork together with client's declaration
3. Uygulanamaz: Gönderilen numune için geçerli değildir.
   NA: Not applicable for the submitted sample.

Önder KÜÇÜKALP	Ayçasu CANLISOY
Deney Personeli/Rapor Sorumlusu	Teknik Müdür

Tek kullanımlık Pudrasız Eldiven Mavi - Black (NITRAG - S202102 -15018)

(Disposable Powder Free Glove) Blue -Black (NITRAG - S202102 -15018)

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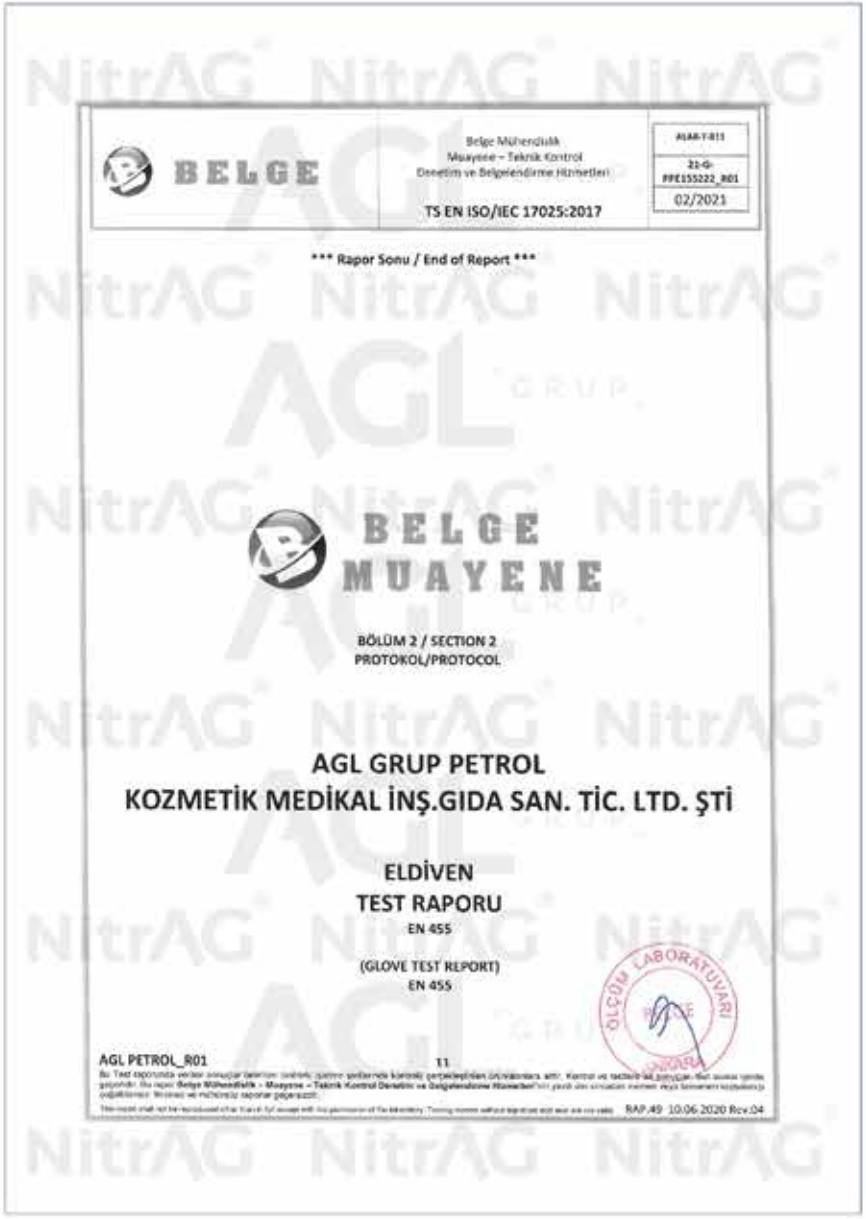

BELGE

Belge Mühendislik
Muayene – Teknik Kontrol
Denetim ve Belgelendirme Hizmetleri

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AIAR-T-R11
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*** Rapor Sonu / End of Report ***

BELGE MUAYENE

BÖLÜM 2 / SECTION 2
PROTOKOL/PROTOCOL

AGL GRUP PETROL
KOZMETİK MEDİKAL İNŞ.GIDA SAN. TİC. LTD. ŞTİ

ELDİVEN
TEST RAPORU
EN 455

(GLOVE TEST REPORT)
EN 455

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PROTOKOL/PROTOCOL
TEST YÖNTEMLERİ VE AÇIKLAMALARI

ASTM D6124 - 06	Tıbbi Eldivenler Üzerindeki Artık Toz için Standart Test Yöntemi	*Standard Test Method for Residual Powder on Medical Gloves*
1.1 Bu test yöntemi, giriş bölümünde açıklandığı gibi bir tıbbi eldiven numunesinde bulunan ortalama toz veya filtre tutulan kütlenin belirlenmesini kapsar. 1.2 Eldiven başına ortalama toz kütlesi miligram cinsinden bildirilir. 1.3 Tıbbi eldivenlerin güvenli ve doğru kullanımı bu test yönteminin kapsamı dışındadır.		*1.1 This test method covers the determination of average powder or filter-retained mass found on a sample of medical gloves as described in the introduction. 1.2 The average powder mass per glove is reported in milligrams. 1.3 The safe and proper use of medical gloves is beyond the scope of this test method.*
ASTM D6319 - 19	Tıbbi Uygulama için Nitril Muayene Eldivenleri için Standart	*Standard Specification for Nitrile Examination Gloves for Medical*
1.1 Bu spesifikasyon, tıbbi muayenelerin ve teşhis ve tedavi prosedürlerinin yürütülmesinde kullanılan nitril kauçuk eldivenler için belirli gereksinimleri kapsar. 1.2 Bu spesifikasyon, bedene göre her iki ele, eşleştirilmiş eldivenlere ve eldivenlere uyan nitril kauçuk muayene eldivenlerini kapsar. Aynı zamanda paketlenmiş steril veya steril olmayan veya yığın halinde steril olmayan nitril kauçuk muayene eldivenleri sağlar.		*1.1 This specification covers certain requirements for nitrile rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures. 1.2 This specification covers nitrile rubber examination gloves that fit either hand, paired gloves, and gloves by size. It also provides for packaged sterile or nonsterile or bulk nonsterile nitrile rubber examination gloves.*
ASTM D5151 - 19	Tıbbi Eldivenlerdeki Deliklerin Tespiti için Standart Test Yöntemi	*Standard Test Method for Detection of Holes in Medical Gloves*
1.1 Bu test yöntemi, tıbbi eldivenlerdeki deliklerin tespitini kapsar. 1.2 Bu test yöntemi, test koşulları altında su sızıntısına izin veren deliklerin tespiti ile sınırlıdır. 1.3 Tıbbi bir eldivende su sızıntısına neden olacak en küçük delik boyutu belirlenmemiştir ve bu test yönteminin kapsamı dışındadır. 1.4 Tıbbi eldivenlerin güvenli ve doğru kullanımı bu test yönteminin kapsamı dışındadır. 1.5 SI birimlerinde belirtilen değerler standart olarak kabul edilecektir. Bu standarda başka ölçü birimleri dahil edilmemiştir.		*1.1 This test method covers the detection of holes in medical gloves. 1.2 This test method is limited to the detection of holes that allow water leakage under the conditions of the test. 1.3 The smallest hole size that will allow water leakage in a medical glove has not been determined and is beyond the scope of this test method. 1.4 The safe and proper use of medical gloves is beyond the scope of this test method. 1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.*

Çekme testi, elastomerik malzemeler (ASTM D412) / Eldiven çekme testi, yaşlandırılmış ve apılmamış (ASTM D3578) [illegible] test numunesi ASTM D412 kalıp C ile kesilir. [illegible] hesaplanmasında üç kalınlık ölçümünün medyanı kullanıldı. [illegible] ve numune, çenelere yerleştirilir. [illegible]

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Bu Test raporunda verilen sonuçlar [illegible] Belge Mühendislik – Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri [illegible]

This report shall not be reproduced [illegible] RAP.49 10.06.2020 Rev.04

BELGE	Belge Mühendislik Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri **TS EN ISO/IEC 17025:2017**	AL48-F-R01 21-G-PPE155222_R01 02/2021

[illegible] **Tensile test, elastomeric materials (ASTM D412) / Glove tensile test, aged and unaged (ASTM D3578)**: [illegible]

Tüm eldiven viral bariyer (NFPA 1999): [illegible] **Whole glove viral barrier (NFPA 1999)**: [illegible]

Eldiven ısıyla yaşlanma bozunma testi (ASTM D573, NFPA 1999): [illegible]

Eldivenlerdeki sızıntının değerlendirilmesi (ASTM D5151): [illegible]

Delinme direnci (ASTM F1342): [illegible]

Eskimiş ve yaşlanmamış artık toz için eldiven testi (ASTM D6124): [illegible]

Eldivenin fiziksel boyutları (ASTM D3578-91, ASTM D573, ASTM D5250): [illegible]

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[illegible]

RAP.49 30.06.2020 Rev.04

BELGE	Belge Mühendislik Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri **TS EN ISO/IEC 17025:2017**	AL49-T401 21-G-PPE155222_R01 02/2021

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9.0	≥ 6.0	≥ 3.6

a) Requirements for all surgical gloves.
b) Requirements for all examination gloves except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).
c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

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YAPILAN DEĞİŞİKLİK DESCRIPTION of CHANGES	**ÖNCEDEN BELİRLENMİŞ OLAN KABUL KRİTERİ** PRE-DETERMINED ACCEPTANCE CRITERIA	**YENİ KABUL KRİTERİ** NEW ACCEPTANCE CRITERIA	**DEĞİŞİKLİĞİN GEREKÇESİ** REASON of THE CHANGE

DEĞİŞİKLİKLERİN ONAYLANMASI / APPROVAL of THE CHANGES: Yapılan değişiklikler, protokolü ilk imzalayan kişiler tarafından onaylanacaktır / The changes must be approved by persons who have signed the protocol first.

ÖLÇÜM LABORATUVARI

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Bu Test raporunda verilen sonuçlar [illegible] Kontrol ve test [illegible] Bu rapor **Belge Mühendislik – Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri** [illegible]

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BELGE	Belge Mühendislik Muayene – Teknik Kontrol Denetim ve Belgelendirme Hizmetleri **TS EN ISO/IEC 17025:2017**	AL48-T-011 21-G-PPE155222_R01 02/2021

	ONAYLAYAN ADI, GÖREVİ / APPROVAL NAME AND POSITION	TARİH / DATE	İMZA / SIGNATURE
TEST KURULUŞU TESTING COMPANY	Ayçasu CANLISOY	25.02.2021	
MÜŞTERİ KURULUŞ CLIENT COMPANY	Emre AĞAOĞLU	25.02.2021	

ÖLÇÜM LABORATUVARI BELGE ANKARA

AGL PETROL_R01 15

RAF.49 10.06.2020 Rev.04

UKS ULUSLARARASI KALİTE SİSTEMLERİ VE BELGELENDİRME LTD. ŞTİ.

EC DECLARATION OF CONFORMITY
AB UYGUNLUK BEYANI

CE

Üretici / Manufacturer
AGL GRUP PETROL KİMYA TİC. MADDE İMAL. GIDA SAN. TİC. LTD. ŞTİ.

Adres / Address
TUGAY YOLU CD. OFİSİM İSTANBUL PLAZA B BLOK NO : 88 KAT: 15
34844 MALTEPE, İSTANBUL, TURKEY

Ürünün Markası / Brand of Product
NitrAG

Ürünün İsmi / Name Of Product
ÇOK AMAÇLI TEK KULLANIMLIK TIPE ELDİVEN
MULTIPURPOSE DISPOSABLE TIPE GLOVES

Tip – Model / Type-Model
SINIF 1 – TİP I / CLASS 1 – TYPE I

Harmonize Standartlar / Harmonized Standards
EN 420+A1 :2010, EN ISO 374-1:2016
EN ISO 374-2:2019, EN ISO 374-5:2016 (TS EN 16523-1+A1)
EN ISO 374-4:2019, EN ISO 374-5:2016, EN 455-1:2020,
EN 455-2:2015, EN 455-3:2015

Direktif ve Yönetmelikler / Directives and Regulations
2007/47/EC KONSEY DİREKTİFİ - 2007/47/EC COUNCIL DIRECTIVE
93/42/EEC TIBBİ CİHAZLAR YÖNETMELİĞİ - 93/42/EEC MEDICAL DEVICES DIRECTIVE

The Certificate is issued under the following conditions:

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

Sertifika No / Certificate No: CE0096
Sertifika Tarihi / Certificate Date: 20.01.2021
Sertifika Bitiş Tarihi / Expiration Date: 19.01.2022

Genel Müdür / General Manager

www.uksbelgelendirme.com.tr

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34844 MALTEPE, İSTANBUL
TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

ISO 10002:2018

The Quality Management -Customer Satisfaction System is applicable to;

Ffp2 Ffp3 Surgical Mask, Overalls, Apron, Nitrag TPE Examination Gloves, Laminated Protective Boots Production

Category / Sub Category	: —
Certificate No	:MSC-0026
Certificate First Issue Date	:09th February 2021
Decision Date	:09th February 2021
Certificate Issue Date	:09th February 2021
Expiration Date	:08th February 2022

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Has been assessed by UKS and found to be in compliance with the following standard

ISO 13485:2016

The Medical Devices Management System is applicable to;

Ffp2 Ffp3 Surgical Mask, Overalls, Apron, Nitrag TPE Examination Gloves, Laminated Protective Boots Production

Category / Sub Category	: ---
Certificate No	:MDQ-0116
Certificate First Issue Date	:09th February 2021
Decision Date	:09th February 2021
Certificate Issue Date	:09th February 2021
Expiration Date	:08th February 2022

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CAS-MS-0011

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34844 MALTEPE, İSTANBUL
TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

TS EN ISO 9001:2015

The Quality Management System is applicable to;

Ffp2 Ffp3 Surgical Mask, Overalls, Apron, Nitrag TPE Examination Gloves, Laminated Protective Boots Production

Category / Sub Category	: —
Certificate No	: MSQ-0265
Certificate First Issue Date	:05th February 2021
Decision Date	:05th February 2021
Certificate Issue Date	:05th February 2021
Expiration Date	:04th February 2022

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34844 MALTEPE, İSTANBUL
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Has been assessed by UKS and found to be in compliance with the following standard

GMP

Good Manufacturing Practice

The Good Manufacturing Practice System is applicable to;

Ffp2 Ffp3 Surgical Mask, Overalls, Apron, Nitrag TPE Examination Gloves, Laminated Protective Boots Production

Category / Sub Category	: ---
Certificate No	:MSU-0017
Certificate First Issue Date	:09th February 2021
Decision Date	:03th February 2021
Certificate Issue Date	:09th February 2021
Expiration Date	:08th February 2022

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34844 MALTEPE, İSTANBUL
TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

TS ISO 45001:2018

The Occupational Health And Safety Management System is applicable to:

Ffp2 Ffp3 Surgical Mask, Overalls, Apron, Nitrag TPE Examination Gloves, Laminated Protective Boots Production

Category / Sub Category	: —
Certificate No	:OHS-0047
Certificate First Issue Date	:09th February 2021
Decision Date	:09th February 2021
Certificate Issue Date	:09th February 2021
Expiration Date	:08th February 2022

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34844 MALTEPE, İSTANBUL
TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

TS EN ISO 22000:2018

The Food Safety Management System is applicable to;

Ffp2 Ffp3 Mask, Food Contact Overalls, Aprons, TPE Gloves Production

Category / Sub Category	: JU-I
Certificate No	: MSF-0353
Certificate First Issue Date	: 12th February 2021
Decision Date	: 12th February 2021
Certificate Issue Date	: 12th February 2021
Expiration Date	: 11th February 2022

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34844 MALTEPE, İSTANBUL
TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

GHP
Good Hygiene Practice

The Good Hygiene Practice System is applicable to;

Ffp2 Ffp3 Surgical Mask, Overalls, Apron, Nitrag TPE Examination Gloves, Laminated Protective Boots Production

Category / Sub Category	: ---
Certificate No	:MSH-0005
Certificate First Issue Date	:09th February 2021
Decision Date	:09th February 2021
Certificate Issue Date	:09th February 2021
Expiration Date	:08th February 2022

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34844 MALTEPE, İSTANBUL
TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

TS EN ISO 14001:2015

The Environmental Management System is applicable to;

Ffp2 Ffp3 Surgical Mask, Overalls, Apron, Nitrag TPE Examination Gloves, Laminated Protective Boots Production

Category / Sub Category	: —
Certificate No	: MSE-0115
Certificate First Issue Date	: 09th February 2021
Decision Date	: 09th February 2021
Certificate Issue Date	: 09th February 2021
Expiration Date	: 08th February 2022

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