DISPOSABLE ISOLATION GOWN

TM-007

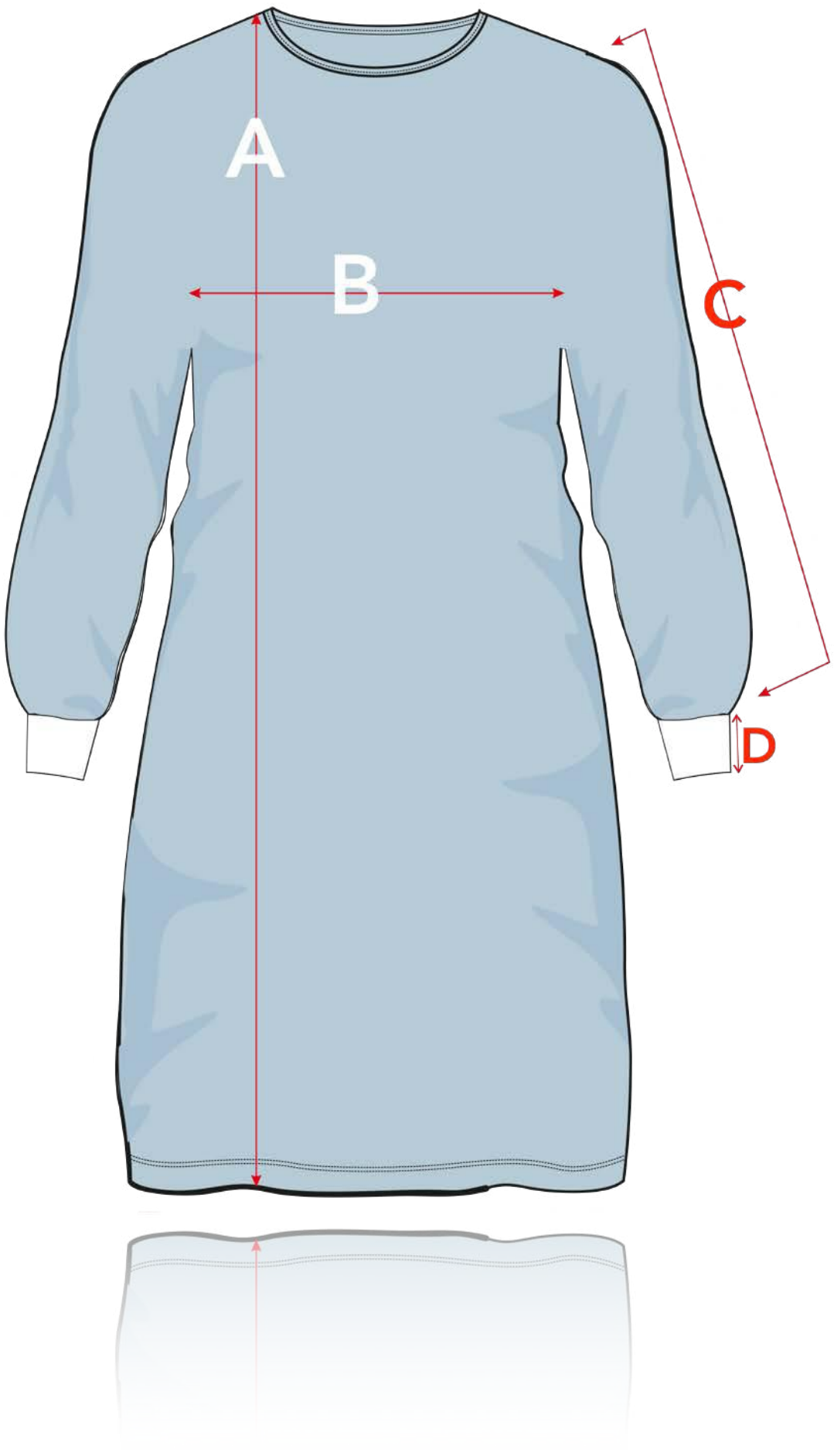
DOĞA MİNERAL

TM-007

CE

FDA DOĞA MİNERAL

size & dimensions



Disposable Non-Woven Isolation Gown Size S - M - L - XL

AAMI Level 1,2,3,4 light, mid & heavy weight isolation gowns.

non-sterile or sterile

custom size available

Size	A	B	C	D
S	120 cm 47,24 "	70 cm 27,56 "	55 cm 21,65 "	7 cm 2,76 "
M	122 cm 48,03 "	72 cm 28,35 "	55 cm 21,65 "	7 cm 2,76 "
L	125 cm 49,21 "	74 cm 29,13 "	55 cm 21,65 "	7 cm 2,76 "
XL	127 cm 50,0 "	76 cm 29,92 "	55 cm 21,65 "	7 cm 2,76 "

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product&fabric

	Level 1	Level 2	Level 3	Level 4
AAMI Level / Performance Requirements at 4% AQL	Spray Impact Penetration < 4.5g	Spray Impact Penetration < 1.0g Hydrostatic Pressure > 20cm	Spray Impact Penetration < 1.0g Hydrostatic Pressure > 50cm	
Gown Characteristics (Weight)	Light-weight SMS Medium-weight SS fabric	Medium-weight SMS fabric Light-weight SMMS fabric	Heavy-weight SMS+PE or SMMS+PE Medium-weight SSMMS+PE	Heavy-weight SMMS+PE Heavy-weight SSMMS+PE fabric
Recommended Areas of Use	Med/Surg Unit Laundry Housekeeping	ICU, Dialysis, Med/Surg Unit Nursery Lab Pathology Laboratories Hyperbaric	Trauma Burn Units Critical Care Units	Trauma Burn Units Critical Care Units

CE FDA DOĞA MİNERAL

production capacity

Product	Daily	Weekly	Monthly
Gown	125.000 pcs	625.000 pcs	2.500.000 pcs

sales&packaging

	Unit	Size (cm)	
Bag	1 unit/bag	30 x 40	
Box	80 unit/box	60 x 40 x 40	
20'' Container (Euro Pallet 80x120)	240 box/Container		
40'' Container (Euro Pallet 80x120)	504 box/Container		
Payment rule	%30 Down payment %70 BOL		
Selected Product		***Non-Sterile***	***Sterile***
	Level 1		
	Level 2		
	Level 3		
	Level 4		

Minimum Order

20.000 pcs

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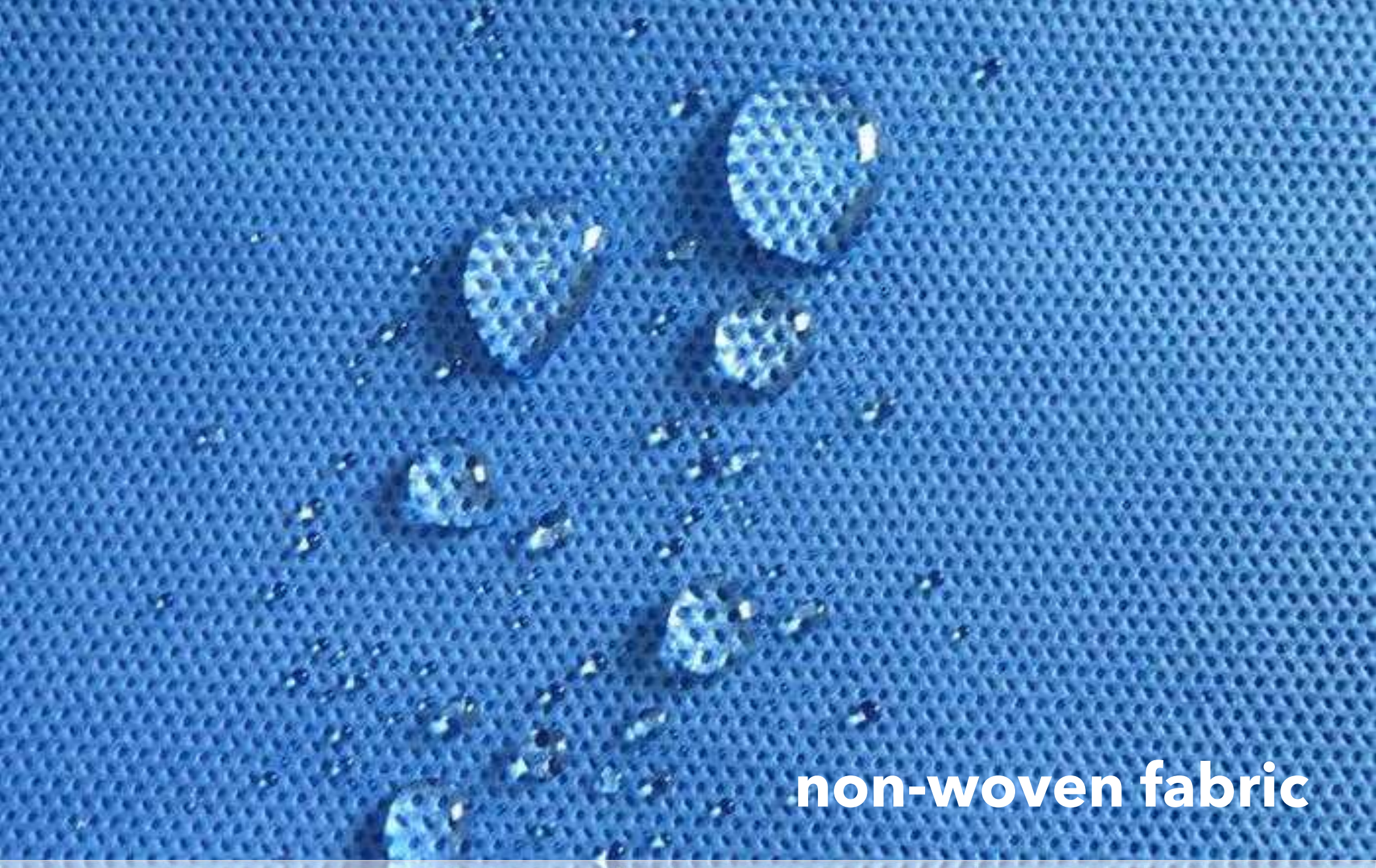

non-woven fabric

attention please

	Do not dry clean		Keep away from flames and heat
	Do not iron		TS EN 13795
	Do not wash	ISO 9001	ISO 9001 : 2015 Quality Management System
	Do not tumble dry	CE	2001/95/EEC General Product Safety Directive 93/42 EEC Medical Device Directive
	Do not bleach	ISO	ISO 13485 : 2016 Medical Devices Quality Management System
Do not reuse		Suitable for single use only	

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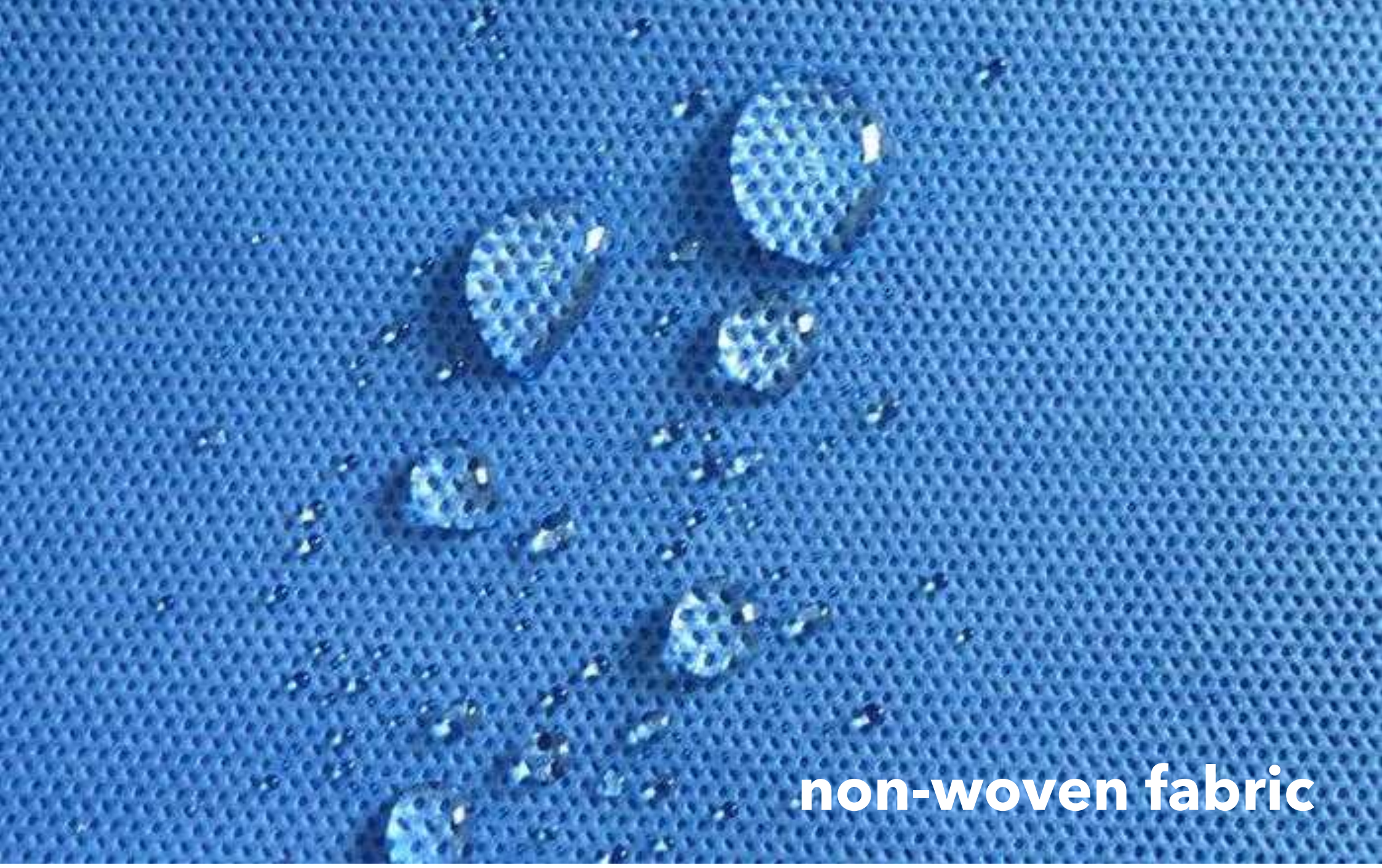

requested tests & reuslts

	RESULT	EXPECTED VALUE
MICROBIOLOGICAL TESTS		
Microbial Cleanliness Bioburden	17 cfu/100cm2	<= 300 cfu/100 cm2
Wet Bacterial Penetration	5,3	>= 2,8
Dry Bacterial Penetration	4 cfu/g	<= 300 cfu/g
PHYSICAL PROPERTIES TEST		
TENSILE STREGHT/DRY		
Width	61.4N	>= 20N
Lenght	145.9N	>= 20N
TENSILE STREGHT/WET		
Width	60.9N	>= 20N
Lenght	145.2N	>= 20N
BURSTING STRENGTH		
Dry	199.4 k pa	>= 40 kpa
Height at Burst	13,4 mm	
BURSTING STRENGTH		
Wet	172.4 k pa	>=40 kpa
Height at Burst	12,8 mm	

UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD - 239

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993.

The products manufactured for

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Şifa Mah. Göksoku Sok. No:8/A Sıtmapınarı / MALATYA / TURKEY

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Model: TM-007
are evaluated for the conformity to the standard by the following tests

For the assessment of conformity, the following documents were also reviewed:
Laboratory test results for Microbial Penetration, Bioburden,
Bursting and Tensile Strengths

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 27/08/2020 and valid until 26/08/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL – 27/08/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

NVA QUALITY CERTIFICATION

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SERTİFİKA / CERTIFICATE

DOĞA MİNERAL MAD. END. İNŞ. TAŞ. PET. ÜRÜN. İTH. İHR. SAN. VE DIŞ. TİC. LTD. ŞTİ.
B.HÜSEYİNBEY MAH. CEZMİ KARTAY CAD. NO: 34 A
BATTALGAZİ / MALATYA / TURKEY

DOĞA MİNERAL

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI" **Kapsamı için**

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ISO 9001:2015

KALİTE YÖNETİM SİSTEMİ
Quality Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / *Certificate Number*	: **20042406**
Sertifika Kodu / *Certificate Code*	: **DOĞA MİNERAL**
Sertifika Yayın Tarihi / *Certificate Issue Date*	: **24.04.2020**
Sertifika Geçerlilik Tarihi / *Certificate Validity Date*	: **24.04.2021**
Sertifika Periyodu / *Certificate Period*	: **1 Yıl** / *1 Year*

Certification Manager
Belgelendirme Müdürü

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B.HÜSEYİNBEY MAH. CEZMİ KARTAY CAD. NO: 34 A
BATTALGAZİ / MALATYA / TURKEY

DOĞA MİNERAL

In our delivered version, we declare that the product described below complies with the essential safety and health requirements of the **Medical Devices Directive 93/42/EEC-General Product Safety Directive 2001/95/EEC** regulations as circulating by us. This declaration will cease to be valid if the product specified below is replaced

*Teslim edilen versiyonumuzda aşağıda açıklanan ürünün, tarafımızda dolaşıma sokulduğu şekliyle **Tıbbi Cihazlar Direktifi 93/42/EEC-Genel Ürün Güvenliği Direktifi 2001/95/EEC** yönetmeliklerinin temel güvenlik ve sağlık gerekliliklerine uygun olduğunu beyan ederiz. Aşağıda bilgileri belirtilen ürünün değiştirilmesi halinde bu beyan geçerliliğini yitirecektir.*

Description Of The Product ***Ürünün Tanımı***	**: NONWOVEN DISPOSABLE SURGERY GOWNS** ***NONWOVEN TEK KULLANIMLIK CERRAHİ ÖNLÜK***
Product Commercial Brand / *Marka*	**: TÜRKMASK**
Applicable EC Directives ***Geçerli AT Direktifleri***	**: GENERAL PRODUCT SAFETY DIRECTIVE 2001/95/EEC** **MEDICAL DEVICES DIRECTIVE 93/42/EEC** ***GENEL ÜRÜN GÜVENLİĞİ DİREKTİFİ 2001/95/EEC*** ***TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC***
Applicable Harmonised Standards ***Geçerli Uyumlaştırılmış Standartlar***	**: TS EN 464, TS EN 13795-1, TS EN 13795-2, EN 14126, EN 1149-1, EN 1149-5, EN ISO 13485, EN 13034**

Applicable National Technical Standards and Specifications
Uygulanabilir Ulusal Teknik Standartlar ve Özellikler

Classifications / *Sınıflandırma*	**: CLASS-I / NON STERIL**
Certificate Number / *Sertifika Numarası*	**: 20042413**
Certificate Code / *Sertifika Kodu*	**: DOĞA MİNERAL**
Certificate Issue Date / *Sertifika Yayın Tarihi*	**: 24.04.2020**
Certificate Validity Date / *Sertifikanın Geçerlilik Tarihi*	**: 24.04.2021**

EU Representative / *AB Temsilcisi*
(Authorized Signature and Title) / *(Yetkili İmza ve Ünvan)*

Certification Manager
Belgelendirme Müdürü

DOĞA MİN. MAD. END. İNŞ. TAŞ. PET. ÜRÜN. İTH. İHR. SAN. VE DIŞ. TİC. LTD. ŞTİ. declares that the Medical Devices Directive 93/42/EEC-General Product Safety Directive 2001/95/EEC has fulfilled the applicable requirements and responsibility has been taken for the above-described product groups.The product groups described above have been controlled depending on internal production controls.

***DOĞA MİN. MAD. END. İNŞ. TAŞ. PET. ÜRÜN. İTH. İHR. SAN. VE DIŞ. TİC. LTD. ŞTİ.** olarak yukarıda tanımlanmış olan ürün grupları için Tıbbi Cihazlar Direktifi 93/42/EEC-Genel Ürün Güvenliği Direktifi 2001/95/EEC' nin uygulanabilen gerekliliklerini yerine getirdiğini ve sorumluluğun alınmış olduğunu beyan etmektedir. Yukarıda tanımlanan ürün grupları, iç üretim kontrollerine bağlı olarak kontrol edilmiştir.*

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Certificate Code / *Sertifika Kodu*	**: DOĞA MİNERAL**
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Certificate Validity Date / *Sertifikanın Geçerlilik Tarihi*	**: 24.04.2021**

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ISO 14001:2015

ÇEVRE YÖNETİM SİSTEMİ

Environmental Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / ***Certificate Number***	**: 20042410**
Sertifika Kodu / ***Certificate Code***	**: DOĞA MİNERAL**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 24.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 24.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

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ISO 13485 : 2016

TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ

Medical Devices Quality Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / ***Certificate Number***	**: 20042409**
Sertifika Kodu / ***Certificate Code***	**: DOĞA MİNERAL**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 24.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 24.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

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DOĞA MİNERAL

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI"

Kapsamı için

For scope "*SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES*"

ISO 45001:2018

İŞ SAĞLIĞI VE GÜVENLİĞİ YÖNETİM SİSTEMİ

Occupational Health and Safety Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / ***Certificate Number***	**: 20042408**
Sertifika Kodu / ***Certificate Code***	**: DOĞA MİNERAL**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 24.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 24.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
Belgelendirme Müdürü

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SERTİFİKA / CERTIFICATE

DOĞA MİNERAL MAD. END. İNŞ. TAŞ. PET. ÜRÜN. İTH. İHR. SAN. VE DIŞ. TİC. LTD. ŞTİ.

B.HÜSEYİNBEY MAH. CEZMİ KARTAY CAD. NO: 34 A
BATTALGAZİ / MALATYA / TURKEY

DOĞA MİNERAL

Kuruluşunun "TEK KULLANIMLIK CERRAHİ MASKE, TEK KULLANIMLIK YÜZ MASKESİ, TEK KULLANIMLIK CERRAHİ ÖNLÜK, TEK KULLANIMLIK MEDİKAL ÖNLÜK, TEK KULLANIMLIK CERRAHİ ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK ELDİVEN, TEK KULLANIMLIK TULUM, TEK KULLANIMLIK BONE, GALOŞ, SLİKON MASKE, FİLTRELİ SLİKON MASKE, KORUYUCU GÖZLÜK, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, ÜRETİMİ VE SATIŞI" **Kapsamı için**

For scope "*SINGLE USE SURGICAL MASK, SINGLE USE FACE MASK, SINGLE USE SURGICAL GOWNS, SINGLE USE MEDICAL GOWNS, SINGLE USE SURGICAL DRAPE, SINGLE USE INSPECTION COVERS, SINGLE USE GLOVES, SINGLE USE OVERALLS, SINGLE USE BONNET, WAG, SILICON MASK, FILTERED SILICON MASK, PROTECTIVE GLASSES, SINGLE USE STRETCHER COVER, PRODUCTION AND SALES*"

ISO 10002:2018

MÜŞTERİ MEMNUNİYETİ YÖNETİM SİSTEMİ
Customer Satisfaction Management System

Kurduğunu ve uyguladığını belgelemekte ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

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Sertifika Numarası / ***Certificate Number***	**: 20042407**
Sertifika Kodu / ***Certificate Code***	**: DOĞA MİNERAL**
Sertifika Yayın Tarihi / ***Certificate Issue Date***	**: 24.04.2020**
Sertifika Geçerlilik Tarihi / ***Certificate Validity Date***	**: 24.04.2021**
Sertifika Periyodu / ***Certificate Period***	**: 1 Yıl** / ***1 Year***

Certification Manager
Belgelendirme Müdürü

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

20018936-ing-Add
07-20

TEST REPORT
DENEY RAPORU

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	Yukarı Dudullu Mahallesi, KEYAP E2 No:84, 34775 Dudullu Organize Sanayi Bölgesi/Ümraniye/İstanbul
Buyer name:	DOĞA MİNERAL MADENCİLİK ENDÜSTRİYEL İNŞ. TAŞ. PET. Ü.İTH.İH.SAN. VE DIŞ TİC. LTD.ŞTİ.
Contact Person:	SUAT KAÇMAZ
Order No:	-
Article No:	-
Name and identity of test item:	Blue surgical gown
The date of receipt of test item:	12.06.2020
Re-submitted/re-confirmation date:	-
Date of test:	12.06.2020-01.07.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not specified.
Number of pages of the report:	7

Gen.f136-2/03

Seal EKOTEKS TESTED BY TESTEDİLMİŞTİR

Date
01.07.2020

Customer Representative
Servin YURTSEVEN

Head of Testing Laboratory
Sevim A. RAZAK

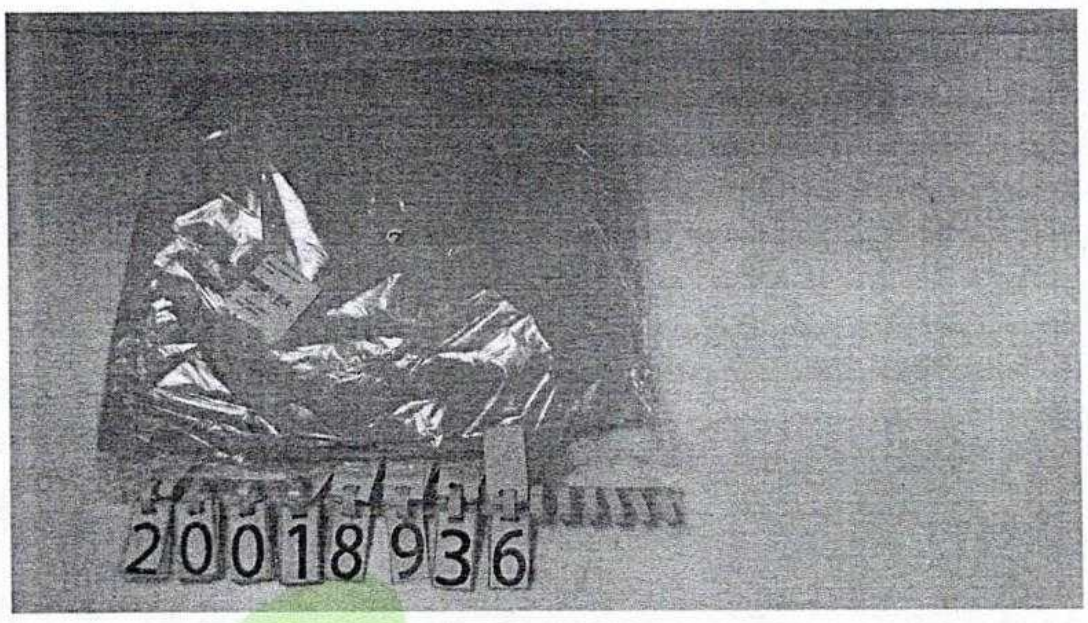
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20018936-ing-Add
07-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry- Bacterial Penetration[1]	P	
PHYSICAL PROPERTIES TESTS		
Tensile Stregth / **Dry**	P	
Tensile Stregth / **Wet**	P	
Bursting Strength / **Dry**	P	
Bursting Strength / **Wet**	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties Critical Sample Group limit values (Table 1)
[1]This report was reissued to add this test result.

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.



TEST RESULTS

Surgical clothing and drapes - Requirements and test methods – Part 1: Surgical drapes and gowns EN 13795-1 :2019

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018 (*)

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

	RESULTS	**REQUIREMENT**
Microbial cleanliness (cfu/g)	17 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

TEST RESULTS

WET-BACTERIAL PENETRATION

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability) (*)

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	0	R_{CUM1}	0
X_2	0	R_{CUM2}	0
X_3	0	R_{CUM3}	0
X_4	150	R_{CUM4}	0,23
X_5	160	R_{CUM5}	0,48
Z	328		
T	638		

X1 ..... X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

$R_{CUM1} = X1/T$
$R_{CUM2} = (X2 + X1)/T$
$R_{CUM3} = (X3 + X2 + X1)/T$
$R_{CUM4} = (X4 + X3 + X2 + X1)/T$
$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

BARRIER INDEX (I_B)		
	Result	**Expected value (*)**
I_B	5,3	≥2,8

$I_B = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*

TEST RESULTS

Test Method: ISO 22612: 2005 (Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration)

Samples and containers are sterilized. Agar plates are placed in each container. Samples are placed aseptically in the apparatus. The covers are closed. After making a pot in the sample with the piston, the pistons are removed and 0.5 g ± 0.1 g are added to five samples from the powder contaminated with bacteria and the six to the non-contaminated powder. Then all openings are closed with a plastic bag. The device is operated to give 20,800 vibrations per minute. The test time is 30 minutes. After the test is over, all agar plates are incubated at 35 ° C for 24 hours.

Sample amount:	6 pieces 20x20 cm²
Mikroorganism:	*Bacillus subtilis ATCC 9372*
Bacterial concentration (cfu/ml):	$1x10^8$
Incubation conditions:	35°C / 24 hours

RESULTS	
Number of Populationg Bacteria (cfu)	
1	0
2	1
3	1
4	1
5	1
6 (Control)	0
Total	4
Logarithm	0,6

EVALUATION	
Result	**Class (*)**
≤ 1	3

** EN 14126: 2003 Protective Clothing - Performance Properties and Test Methods of Protective Clothing Against Infectious Agents are evaluated according to Table-4.*

Sınıf	**Penetrasyon (log kob)**
3	*≤ 1*
2	1 < log kob ≤ 2
1	2 < log kob ≤ 3

** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*

RESULT	
Result (cfu/g)	**Expected Value**
4 cfu/g	≤300 cfu/g

TEST RESULTS

TENSILE STRENGTH; EN 29073-3:1996 (*)
Instron 5969 (Load: 5 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for width and length direction of four samples
Performed in the conditioned room (20±2°C-65%±4).

Dry ;

	RESULT	REQUIREMENT
Width	61.4 N	≥ 20N (Dry)
Length	145.9 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)
Instron 5969 (Load: 5 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. With wetting samples.
The average results are given for width and length direction of four samples
Performed in the conditioned room (20±2°C-65%±4).

Wet ;

	RESULT	REQUIREMENT
Width	60.9 N	≥ 20N (Wet)
Length	145.2 N	≥ 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	199.4 kPa	≥ 40 kPa (Dry)
Height at Burst*	13.4 mm	

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20018936-ing-Add
07-20

TEST RESULTS

BURSTING STRENGTH;; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	**REQUIREMENT**
Wet ;	172.4kPa	≥ 40 kPa (Wet)
Height at Burst*	12.8mm	

Gen.f136-2/03

2020

CERTIFICATE OF REGISTRATION

This certifies that:

DOGA MINERAL MADDELERI END. INS. TAS. PET. URUN. ITH. IHR. S
B.Huseyin Bey Mah. Cezmi Kartay Cad. Efe Is Merkezi
34 A Battalgazi
Malatya Malatya, TR 44320

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10074216**
Device Classification Name:	**SUIT, SURGICAL**
Product Code:	**FXO**
Regulation Number:	**878.4040**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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David Lemarz
Executive Director
Registrar Corp
Dated: May 25, 2020