UNIVERSAL

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CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 643

Electrostatic Protective Clothing against Infective Agents;
Type 5-B - Providing Protection to the Full Body against Airborne Solid Particulates
Type 6-B - Offering Limited Protective Performance against Liquid Chemicals

HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LİMİTED ŞİRKETİ

Yenimahalle Mahallesi 3126. Sokak No:19/A Atakum SAMSUN / TURKEY

are tested and evaluated according to

EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, EN 1149-5:2018

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation. The details of essential requirement compliance is given in technical report numbered KKD-2163-644

Product Definition

Brand Name: HANIMAĞA, **Model:** HNM 5

Resistance to penetration by contaminated liquids under hydrostatic pressure: Class 2
Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids: Class 1
Resistance to penetration by contaminated liquid aerosols: Class 1
Resistance to penetration by contaminated solid particles: Class 3

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **29/04/2020** and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

DECLARATION OF CONFORMITY

HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LTD ŞTİ

Yenimahalle Mahallesi 3126 Sokak No:19A Atakum / SAMSUN

PRODUCT CATAGORY Tulum / Coverall

PRODUCT LIST PROTECTIVE CLOTHING

CLASSIFICATION Class I

We here with declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EEC for Medical Device Directive.

GENERAL APPLICABLE DIRECTIVES

Medical Devices Directive Council directive 93/42/EEC with amended directive 2007/47/EEC concerning medical devices.

STANDARTS

EN 14126 EN 13982-1 EN 13034 EN 1149 EN 1073-2 EN 1149-1 EN 1149-5

Sertifika No / Certificate No : 1207

İlk Yayın Tarihi / Release date : 14.03.2020

Sertifikanın Yenilendiği Tarih / Validity of Certificate : 14.03.2020

Yeniden Belgelendirme Tarihi / Re-Certification Date : 14.03.2021

Sertifikanın geçerlilik durumu aşagıdaki url den incelenebilir.
The validity status of the certificate can be examined from the following url.

http://www.kalibrisanje.com/s/1207.html

This Document has been prepared based on EUROLAB 2020031309 Technical File Information.

CE

Tarih
Date
14.03.2020

Sertifika Müdürü
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KALİBRİSANJE İSO YÖNETİM SİSTEMLERİ ®

212 909 29 01 212 909 29 01

REGULATION 2016/425

EU Type-Examination

HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LTD ŞTİ

Yenimahalle Mahallesi 3126 Sokak No:19A Atakum / SAMSUN

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

This certificate remains property of KALİBRİSANJE ISO MANAGEMENT SYSTEMS to whom it must be returned request

Certificate No:	1195
Release date :	April 17, 2020
Validity of Certificate:	April 17, 2020
Re-Certification Date:	April 16, 2021

The validity status of the certificate can be examined from the following url.

http://www.kalibrisanje.com/s/1195.html

Date

April 17, 2020

Authorised By

www.kalibrisanje.com

info@kalibrisanje.com

KALİBRİSANJE ISO MANAGEMENT SYSTEMS ®

212 909 34 50 212 909 34 53

REGULATION 2016/425

EU Type-Examination

HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LTD ŞTİ

Issue 1

PPE Product

Hanımağa branded, high visibility protective coveral with a collar, which is manufactured using fluorescent white %100 PP Spunbond Nonwoven fabric and retroreflective tape with sewn seams and has a front entry zipper closure with a flap cover. The coverall has elastication at the cuffs, ankles & back of the waist. One band of retroreflective tape encircles the torso horizontally with vertical retroreflective bands joining the torso band from front to back over each shoulder and two horizantal bands encircling each arm and leg. The coverall is available in four nominal sizes.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to be in accordance with the requirements of Council Directive 89/686/EEC. When examined the PPE satisfied the requirements of the relevant harmonized standards:

EN ISO 13982-1:2004 + A1:2010 (Chemical protective clothing providing protection to the full body against airborne solid particulates (Type 5));
EN 13034:2005 + A1:2009 (Type 6: Limited life, full body chemical protective clothing offering limited protection against liquid chemicals);
EN 14126:2003 (Protective clothing against infective agents) for the performance classification:5-B & 6-B;
EN 1149-5:2008 (Protective clothing – Electrostatic properties) for electrostatic dissipative protective clothing with a surface resistance of ≤ 2.5 x 109 Ω on the internal (White) surface of the garment.
In addition with one exception the PPE satisfied the requirements of EN 1073-2:2002 (Non – ventilated protective clohing against particulate raioactive contamination) for a performance classification of TIL class1. The exception is that clause 4.2 still required resistance to ignition, whereas the same requirement has been removed from the Type 5 & 6 standards in revisions; İf any resistance to heat & flame is now required, testing & certification to the appropriate product standard is necessary. Hence the resistance to ignition was not tested on this coverall.

Additionally the following selected requirements for EN ISO 20471:2013 (High visibility clothing) for a **Class 3** design classification (both relevant clauses 4.1 & 4.2.5), background material (clause 5.1.1 only, as the garment should not be re-used) & retroreflective tape (6 all relevant clauses).

The manufacturer's information notice (Hanımağa), in English, has been inspected and found to have addressed all of the relevant requirements of the standards. However, the detailed content of the information notice is the responsibility of the manufacturer, as are translations in to other languages.
This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 11 of the Directive are implemented and maintained while the is in production.

Issue 2

Hanımağa, %100 PP Spunbond Nonwoven, February 16, 2021

Certificate No: 1195

This Document has been prepared based on SY21Technical File Information.

EN 13795-1:2019

Surgical clothing and drapes. Requirements and test methods

CERRAHİ GİYSİLER VE ÖRTÜLER. GEREKSİNİMLER VE TEST YÖNTEMLERİ

HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LTD ŞTİ

Yenimahalle Mahallesi 3126 Sokak No:19A Atakum / SAMSUN

Brand Name :(Standard Performance) are tested according to the following initial type tests by the manufacturer For the assessment of conformity , the following documents were also reviewed : Laboratory test results for Microbial Penetration (wet / dry) , Bioburden , Bursting and Tensile Strengths (wet / dry)

KBJ 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 belween 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 1 , § 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 levels and other relevant information given in EN ISO 15223-1 : 2016 and EN 1041 : 2008 + A1 : 2013 . It is considered to be suitable lo 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 .

Sertifika No / Certificate No : 1208

İlk Yayın Tarihi / Release date : 15.05.2020

Sertifikanın Yenilendiği Tarih / Validity of Certificate : 15.05.2020

Yeniden Belgelendirme Tarihi / Re-Certification Date : 15.05.2021

Bu sertifikanın geçerliliği gözetim denetimlerinin başarıyla gerçekleştirlmesine bağlıdır.

The validity of this certificate depends on the success of the surveillance audits.

Sertifikanın geçerlilik durumu aşagıdaki url den incelenebilir.

The validity status of the certificate can be examined from the following url.

http://www.kalibrisanje.com/s/1208.html

Tarih
Date
15.05.2020

Sertifika Müdürü
Certificate Manager

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KALİBRİSANJE ISO YÖNETİM SİSTEMLERİ ®

212 909 29 01 212 909 29 01

ISO 9001:2015

Quality Management System

HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LTD ŞTİ

Yenimahalle Mahallesi 3126 Sokak No:19A Atakum / SAMSUN

Scope; DISPOSABLE OVERALLS nonsterile, RUBBER MASKS nonsterile, LETEKS GLOVES nonsterile, PATIENT GOWN DISPOSABLE LONG SLEEVE PATIENT GOWN DISPOSABLE SHORT SLEEVE, BOXING SHIRT DISPOSABLE, Reinforced Surgical Gown DISPOSABLE SURGICAL GOWN DISPOSABLE, COLONOSCOPY TROUSERS, COLONOSCOPY SHORTS, the Angio SHORTS, UNDERWEAR DISPOSABLE, CESET BAG, STRETCH COVER SINGLE USE, MAMMOGRAPHY APRON, SINGLE USE, SURGICAL SETS SINGLE USE, WATERPROOF SINGLE USE, SINGLE COVER SINGLE USE, WATER KOMPRESS SINGLE USE, SINGLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE 45 USE, WRAP PAPER, SINGLE USE SLIPPER, SINGLE USE LINENS SET, SINGLE USE BED SHEET, SINGLE USE PILLOW CASE, SINGLE USE LINENS, PATIENT WASHING SLEEVE, SLEEVE, SLEEVE, SLEEVE, SLEEVE AND SLEEVE. APRON GROUPS, PATIENT WASHING SHEET DISPOSABLE, ALEZ, GREEN FABRIC, STERILE AND NONSTERILE COVER AND APRON GROUPS Manufacturing and Sales

With this certificate, it has been determined that the company named meets the requirements of the independent audited standard.

Certificate No: 1157

Release date : 04.02.2020

Validity of Certificate: 04.02.2020

Re-Certification Date: 04.02.2021

The validity of this certificate depends on the success of the surveillance audits.
The validity status of the certificate can be examined from the following url.

http://www.kalibrisanje.com/s/1157i.html

Date

04.02.2020

Certificate Manager

www.kalibrisanje.com

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KALİBRİSANJE ISO MANAGEMENT SYSTEMS ®

212 909 34 50 212 909 34 53

ISO 13485:2016

Medical Devices — Quality Management Systems

HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LTD ŞTİ

Yenimahalle Mahallesi 3126 Sokak No:19A Atakum / SAMSUN

Scope; DISPOSABLE OVERALLS nonsterile, RUBBER MASKS nonsterile, LETEKS GLOVES nonsterile, PATIENT GOWN DISPOSABLE LONG SLEEVE PATIENT GOWN DISPOSABLE SHORT SLEEVE, BOXING SHIRT DISPOSABLE, Reinforced Surgical Gown DISPOSABLE SURGICAL GOWN DISPOSABLE, COLONOSCOPY TROUSERS, COLONOSCOPY SHORTS, the Angio SHORTS, UNDERWEAR DISPOSABLE, CESET BAG, STRETCH COVER SINGLE USE, MAMMOGRAPHY APRON, SINGLE USE, SURGICAL SETS SINGLE USE, WATERPROOF SINGLE USE, SINGLE COVER SINGLE USE, WATER KOMPRESS SINGLE USE, SINGLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE WATER HANDLE 45 USE, WRAP PAPER, SINGLE USE SLIPPER, SINGLE USE LINENS SET, SINGLE USE BED SHEET, SINGLE USE PILLOW CASE, SINGLE USE LINENS, PATIENT WASHING SLEEVE, SLEEVE, SLEEVE, SLEEVE, SLEEVE AND SLEEVE. APRON GROUPS, PATIENT WASHING SHEET DISPOSABLE, ALEZ, GREEN FABRIC, STERILE AND NONSTERILE COVER AND APRON GROUPS Manufacturing and Sales

With this certificate, it has been determined that the company named meets the requirements of the independent audited standard.

Certificate No:	1158
Release date :	04.02.2020
Validity of Certificate:	04.02.2020
Re-Certification Date:	04.02.2021

The validity of this certificate depends on the success of the surveillance audits.
The validity status of the certificate can be examined from the following url.

http://www.kalibrisanje.com/s/1158i.html

Date

04.02.2020

Certificate Manager

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KALİBRİSANJE ISO MANAGEMENT SYSTEMS ®

212 909 34 50 212 909 34 53

Certificate of Registration
2020

This is to certify that the registration of

HANIMAGA MEDIKAL URUNLERI TICARET LIMITED SIRKETI

3126. SK. NO: 19/A SAMSUN

TURKEY- 55200

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by Hanimaga Medikal Urunleri Ticaret Limited Sirketi

Owner/Operator Number	**10073349**
Date of Registration	**May 8, 2020**
Date of Expiration	**December 31, 2020**
US Agent	**Liberty Management Group Ltd.**
Device Listing Numbers	**See Annex**
Certificate Number	**3005080120**

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

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LMG LIBERTY MANAGEMENT GROUP LTD.

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Manoj Zacharias

President

Liberty Management Group LTD.

Dated: May 11, 2020

Certificate of Registration
2020

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D400633	OEA	Non-Surgical Isolation gown- HANIMAGA GOWN
D400632	FXO	Suit, Surgical - HANIMAGA OVERALL COVERALL

EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

5190243IB02

2020031309

Report No:	2020031309
Applicant:	**HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LİMİTED ŞİRKETİ**
Applicant Address:	Yenimahalle Mah. 3126 Sk. NO:19 A Atakum / SAMSUN
Contact Person:	SİBEL YOLCUBAŞI
Contact Telephone:	0555 590 46 76
Contact e-mail:	sibelyolcubasi@gmail.com
Sample Accepted on:	02.03.2020
Report Date:	13.03.2020
Total number of pages:	15 (Pg)

Sample ID: **DISPOSABLE EN 14126 (TYPE 5/6) Standard coverall**

	TEST	METHOD	RESULT
	PROTECTIVE CLOTHING — PERFORMANCE REQUIREMENTS AND TESTS METHODS FOR PROTECTIVE CLOTHING AGAINST INFECTIVE AGENTS	**EN 14126**	**PASS**

Seal

Customer Representative
Hasan KUTLU

Laboratory Manager
Hava SARIAYDIN

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

Environment

The requirements and standards apply to equipment intended for use in

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

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EN 14126 - PROTECTIVE CLOTHING — PERFORMANCE REQUIREMENTS AND TESTS METHODS FOR PROTECTIVE CLOTHING AGAINST INFECTIVE AGENTS

Scope

This European Standard specifies requirements and test methods for re-usable and limited use protective clothing providing protection against infective agents.

Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this standard.

Materials Requirements

If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protective clothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing.

If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to the number of cleaning/reprocessing cycles indicated.

Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h in an atmosphere of (20 ± 2) °C and (65 ± 5) % relative humidity before testing. Tests shall be carried out in the same atmosphere or within 5 min of removing the sample from the conditioning atmosphere.

Mechanical and Flammability Requirements

The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.

Fabric Physical Test according to EN 14325		
Test Method	Result	EN Class
Abrasion Resistance EN530 Method 2	450	4 of 6
Flex ISO 7854 Method B	12000	4 of 6
Tear Resistance EN ISO 9073-4 (MD)	50 N	3 of 6
Tear Resistance EN ISO 9073-4 (CD)	46 N	
Tensile Strength ISO 13934-1 (MD)	230 N	3 of 6
Tensile Strength ISO 13934-1 (CD)	210 N	
Puncture Resistance EN 863	117 N	4 of 6
EN 25978 Resistance to Blocking	No blocking	

Resistance to flame	
Flame exposure	EN Class
specimen stops for 1 s in the flame	2 of 6

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Chemical Requirements

If protection against chemicals is claimed, the materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.

Fabric Chemical Test according to EN 14325		
Test Method	Normalised Breakthrough Time -Result	EN Class
Classification of permeation resistance by breakthrough time	126 min	4 of 6

	Classification of permeation resistance by cumulative permeation		
	Chemical skin/dermal toxicity based cumulative permeated mass (in µg/cm²) , classification based to time to reach cumulative permeated mass		
	Very Toxic	**Toxic**	**Other Chemicals**
	Cumulative Mass 20 µg/cm²	**Cumulative Mass 75 µg/cm²**	**Cumulative Mass 150 µg/cm²**
Results	72min	207 min	215 min
EN Class	3 of 6	4 of 6	4 of 6

Classification of repellency to liquids	
Repellency index	EN Class
% 86	2 of 6

Classification of resistance to penetration by liquids	
Repellency index	EN Class
% 6	2 of 6

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Performance Requirements Against Penetration By Infective Agents

- **Resistance To Penetration By Contaminated Liquids Under Hydrostatic Pressure**

They are tested according to ISO / FDIS 16603 and ISO / FDIS 16604, the material is classified according to the performance levels achieved in the bacteriophage test (ISO / FDIS 16604).

Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604)	
Hydrostatic pressure at which the material passes the test	EN Class
5 kPa	3 of 6

- **Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.**

Tested according to Annex A.

Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids	
Breakthrough time, *t* min	EN Class
52 min	4 of 6

- **Resistance to penetration by contaminated liquid aerosols**

It is tested according to ISO / DIS 22611, and the results of the sample are classified according to their performance levels.

Classification of resistance to penetration by contaminated liquid aerosols	
Penetration ratio (log)	EN Class
6	3

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- **Resistance to penetration by contaminated solid particles.**

Tested in accordance with ISO / DIS 22612, sample results are classified according to performance levels.

Classification of resistance to penetration by contaminated solid particles	
Penetration (log cfu)	EN Class
1	3

Performance requirements for seams, joins and assemblages

Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN 14325

Unless otherwise specified in the product standard, all samples are conditioned for at least 24 hours at (20 ± 2)°C and (65 ± 5) relative humidity. Experiments are not examined within 5 minutes after detailing from the onditioning atmosphere, unless otherwise specified in the test method standard.

- **Seam strength**

Three samples of each type of sewing construction are tested and the arithmetic mean of each set of three samples is calculated. For classification purposes, the seam strength is reported regardless of where the sample is broken, ie regardless of whether the test sample containing the seam is broken in the material or seam.

Performance is classified according to sewing levels.

Classification of seam strength	
Seam strength	EN Class
50 N	1

- **Whole suit requirements**

The materials and design used shall not cause skin irritation nor have any adverse effect to health.

The suit should be as light and as flexible as possible in order to ensure the comfort of the wearer, not to hinder .ovements and still provide at the same time effective protection.

Types of protective clothing against infective agents	
Type 5	prEN ISO 13982-1
Type 6	prEN 13034

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Test method for resistance to wet bacterial barrier penetration

This test describes a method of testing together with the relevant equipment for it includes the resistance of a material to the penetration of bacteria in a liquid.

A test sample is placed on a capless agar plate on a rotating disc. A piece of donor material and a piece of HD polyethylene film about 10 µm thick is placed on the test sample and the samples are fixed using a double steel ring.

An abrasion resistant finger is placed on top of the donor material to exert a specified force on the donor and test specimen to bring them into contact with the agar. The finger is applied to the material by a pivoted lever moved by an excenter cam in such a way that it moves over the entire surface of the plate within 15 minutes. The assemblage of materials is stretched by the weight of the steel ring so that only a small area of the test specimen is brought into contact with the agar surface at a time. Due to the combined effect of rubbing and liquid migration bacteria may spread from the donor material through the test specimen down to the agar surface.

After 15 minutes of testing, the agar plate is replaced and the test repeated. Within five periods of 15 minutes each, tests are performed with the same pair of donor material and test specimen. In that way the test allows for an estimation of the penetration over time.

Finally the bacterial contamination on the test specimen is estimated using the same technique.

The agar plates are incubated to visualise the bacterial colonies, which are then enumerated.

The results are processed in accumulated form to characterize the barrier capability and penetration kinetics of the material.

Turntable

The turntable consists of three parts:

- the motor compartment;
- the agar plate holder;
- the finger holder arm.

The motor compartment contains an electric motor, electric switches and transmission to two outgoing spindles, one for the agar plate holder and one for an excenter operating the finger holder arm. The rotation of the motor spindle is transmitted to the outgoing spindles by means of gear wheels and gear belts in two steps both 11:36 and arranged so that plate holder rotates with (60 ±1) min-1 and the excenter with 5,60 min-1. A main electric switch breaks the power supply to the apparatus whereas a clock switch (tolerance 15 min ± 5 s) allows the test to be carried out for a predetermined time.

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The agar plate holder is mounted on the outgoing plate holder spindle. It has a recess on its top surface that has the same diameter as the agar plate to be used in the test.

The finger holder arm is mounted in an rotatable pivot protruding from the top surface of the motor component in such way that it is level when the finger at its end rests on the agar dish surface of. The length of arm is 462 mm and it is carried in the pivot in a ball bearing at a distance of (256 ± 0,5) mm from the centre of the finger.

The arm carries a weight of (250 ± 0,5) g that may be slid along it to adjust the downward force from the finger to the agar. A loop is attached to the upper edge of the arm at the centre of the finger. It makes it possible to attach a dynamometer when adjusting the downward force. The arm has, at its end, a shaft pointing towards the agar plate holder. It serves the purpose to hold a finger such that it can be removed for disinfection and then fitted again.

The finger shall be made from polished to R_a= 0,2 µm. The end of the finger being in contact with the test material shall be semi-spherical with a radius of 11 mm. The finger has a hole in its top surface so that it can be fitted to the shaft on holder arm. The finger is removable and shall be disinfected between tests.

A force of (3 ± 0,02) N exerted by the finger on the materials is measured by e. g. a dynamometer attached to the lever or by balance placed on the turntable.

Steel Ring

A double steel ring weighing (800 ± 1) g is used to fasten the test material and donor. The inner diameter is large enough to let the agar plate holder pass through it so that the ring can hang freely outside it.

Sets of 6 agar plates

The set of 6 petri dishes, 14 cm diameter, is filled with nutrient agar, to (3 ± 0,2) mm from the brim. The agar plates shall be prepared the day before the test is performed and be stored over water so that weight loss is minimized.

Carrier material

The carrier material is a wettable, solvent-cast polyurethane film on the paper carrier that has the following properties:

- thickness: 30 µm
- elongation at maximum load
- (350 ± 50) % in the machine direction
- (400 ± 75) % in the cross direction

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Cut pieces of 25 cm x 25 cm from the carrier. Put each piece between sheets of cardboard, and then in a sterilizer bag. Sterilize by steam.

Staphylococcus aureus suspension

S. aureus strain, ATCC 29213, is cultured 18 to 24 h at (36 ± 1) °C on tryptic soy agar.

From this, 2 or 3 colonies are suspended in 3 ml tryptic soy broth, and cultured 18 to 24 h at (36 ± 1) °C.

A viable count is performed on the final suspension.

Preparation of donor

Open a sterilizer bag and extract the polyurethane film. Place the carrier material on a clean tray, wettable pu side up.

For ease of handling fix the carrier to the tray using double sided adhesive tape in the corners. An area corresponding to the lid of the agar plate is marked on the carrier material.

1,0 ml of the *S. aureus* suspencion is disturbuted over this area of the carrier material. The donor is then dried at 56 °C for approx 30 min. The *S. aureus* suspension is further spread on the polymer film during the drying using a disinfected glass spreader to ensure an even spread.

The donor shall be used the same day as it prepared.

Covering film

Five pieces, 25 cm x 25 cm, of approx 10 µ HD polyethylene film with a density of (950 ± 2) kg/m^3 and a MFR (190°C , 5 kg) of 0,27 g/10 min.

Test samples

Five pieces of 25 cm x 25 cm or 25 cm diameter are cut randomly from the material to be tested under aseptic conditions.

Nutrient media

- **Tryptic soy agar**

  Tryptone 15 g

  Papaic digest of soybean meal 5 g

  Sodium chloride 5 g

  Agar 17 g

  Dest. water 1000 ml

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Suspend dry ingredients in water and heat while swirling to dissolve and mix. Sterilize at 121°C for 15 minutes, swirl thoroughly and dispense.

- **Tryptic soy broth**

  Tryptone 17 g

  Papaic digest soybean meal 3 g

  Dextrose 2,5 g

  Sodium chloride 5 g

  Dipotassium phosphate 2,5 g

  Dest. water 1000 ml

- **Peptone water**

  Peptone 10 g

  Sodium chloride 5 g

  Polysorbate 80 1 g

  Dest. water 1000 ml

- **Nutrient agar**

  Beef extract 3 g

  Peptone 5 g

  Sodium chloride 8 g

  Agar 17 g

  Dest. Water 1000 ml

Test method

Conditioning

onditioning and testing are carried out at normal room temperature.

Procedure

Specimen preparation

Adjust the weight on the lever so that the force from the finger on the agar plate is (3 ± 0,02) N.

Place agar plate 1 on the turntable.

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To standardize the material stretching force, use the following technique. Use a circular weight consisting of an outer and an inner ring (total weight (800 ± 1) g)

Put the inner ring and a cylindrical body approx. 9 cm in diameter and 4 cm high in its centre onto a horizontal sterile working surface. Use suitable means such as double sided adhesive tape on the outside of the ring to increase friction.

Put a test specimen on the ring and the donor, contaminated side down, removed from the paper and a piece of HD polyethylene on top of it. Now push the outer ring down firmly so that the materials are securely held between the two rings.

Test sequence (specimen 1)

The assemblage can now be lifted with the materials slightly slack and placed on the lidless first agar plate with the steel ring hanging freely outside the rotating disk. Apply the finger to the donor material just inside the brim and in such a way that the test specimen comes into contact with the agar surface. Start running the test as described with a finger force of 3 N and for 15 minutes.

Remove the steel ring with the donor-test piece combination immediately when the 15 minute period has elapsed.

Remove plate 1 from the rotating disk and put the lid on it. Immediately put plate 2 on the rotating disk and the ring with the materials on it.

Repeat the above for plates 2 to 5, using the same material assemblage.

Finally remove and discard the donor, turn the test specimen upside down, cover with the HD polyethylene film and run the sixth plate for 15 minutes.

If liquid has accumulated on the agar surface dry the plate(s) in a clean bench and incubate the agar plates (1 to 6) with their lids on in a thermostat at (36 ± 1) °C for 48 h.

Count the colonies of S. aureus on each plate. Disregard the count in the area of 15 mm radius around the inner of the plate. The plate count shall not exceed 1000. If a colony count exceeds 1000, a new S. aureus suspension with a lower concentration (but still in the fixed range) shall be made and that replicate shall be repeated.

The remaining examples

The remaining 5 test samples are also tested as described above. A freshly prepared donor is used with each test sample.

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Calculation of results

Calculate the expected plate for penetration (EPP) as follows,:

EPP = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)

where:

CUM1 = X1/T

CUM2 = (X2 + X1)/T

CUM3 = (X3 + X2 + X1)/T

CUM4 = (X4 + X3 + X2 + X1)/T

CUM5 = (X5 + X4 + X3 + X2 + X1)/T

T = Z + X1 + X2 + X3 + X4 + X5

X1, X2, X3, X4 and X5 are the numbers of colonies on the five plates from one of five specimens.

Z is the plate count from the inverted test specimen.

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RESULTS

Specimen 1

	X1	X2	X3	X4	X5
Colony Count	616	664	574	615	642

T	3116

CUM1	CUM2	CUM3	CUM4	CUM5
0,1977	0,4108	0,5950	0,7924	0,9984

EPP	3,0057

Specimen 2

	X1	X2	X3	X4	X5
Colony Count	697	612	584	613	597

T	3108

CUM1	CUM2	CUM3	CUM4	CUM5
0,2243	0,4212	0,6091	0,8063	0,9984

EPP	2,9407

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Specimen 3

	X1	X2	X3	X4	X5
Colony Count	578	601	598	672	637

T	3091

CUM1	CUM2	CUM3	CUM4	CUM5
0,1870	0,3814	0,5750	0,7923	0,9984

EPP	3,0659

Specimen 4

	X1	X2	X3	X4	X5
Colony Count	615	634	576	594	663

T	3088

CUM1	CUM2	CUM3	CUM4	CUM5
0,1995	0,4048	0,5913	0,7837	0,9984

EPP	3,0223

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Specimen 5

	X1	X2	X3	X4	X5
Colony Count	624	617	589	574	562

T	2971

CUM1	CUM2	CUM3	CUM4	CUM5
0,2100	0,4177	0,6160	0,8091	0,9984

EPP	2,9488

AVERAGE RESULTS

	X1	X2	X3	X4	X5
Colony Count	622,2	620,6	617,2	616,4	593,2

T	3074,8

CUM1	CUM2	CUM3	CUM4	CUM5
0,2051	0,4072	0,5974	0,7947	0,9984

EPP	2,9967

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Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye, İstanbul / TÜRKEY

TEST REPORT

Report Date:27.04.2020
Report Number: 04-2020-T-070

CLIENT and SAMPLE INFORMATION

TEST OWENER	HANIMAĞA MEDİKAL ÜRÜNLERİ TİCARET LTD. ŞTİ.		
ADDRESS	YENİMAHALLE MAH. 3126 SOK. NO:19 ATAKUM/SAMSUN		
SAMPLE DESCRIPTION	The device is a white material, one piece coverall incorporating elasticated cuffs, ankles, waist and hood. There is a double action zip at the front of the suit which runs from crotch to the neck and is covered during use by a flap which is sealed onto the suit material by means of integral double side adhesive tape		
BRAND NAME – MODEL	HANIMAĞA – HNM 5		
CASE NUMBER: Sample Numbers:	PPE-1962		
SAMPLE RECEIVE DATE	04.04.2020	TESTING START DATE	05.04.2020
DISINFECTION INSTRUCTION *If applicable*	Not given, single use only		
NUMBER OF SAMPLES:	20	SAMPLE IDs:	1 - 20

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

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Suat KAÇMAZ
Director

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TEST SCOPE

Referring Product Standard	Test Standard	Test Name
EN 13034:	EN ISO 12947-2	Abrasion Resistance
	EN ISO 9073-4	Trapezoidal Tear Resistance
	EN ISO 13934-1	Tensile Strength
	EN 863	Puncture Resistance
	EN ISO 6530	Repellency to Liquids
	EN ISO 6530	Resistance to Penetration by Liquids
	Modified EN ISO 17491-4	Resistance to Penetration By Liquids In The Form Of A Light Spray (Mist Test)
	EN ISO 13935-2	Seam Strength
EN ISO 13982-1 (Additional Tests Only)	EN ISO 7854, Method B	Compression-Folding Flex Cracking Resistance
	EN ISO 13982-2	Inward Leakage of Aerosols of Solid Particles
EN 14126 (Additional Tests Only)	ISO 16603	Resistance to penetration by contaminated liquids under hydrostatic pressure
	ISO 16604	Penetration by blood and other body fluids-born pathogens. Phi-X174 bacteriophage
	EN ISO 22610	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids
	EN ISO 22612	Resistance to penetration by contaminated solid particles
EN 1149-5	EN 1149-1	Electrostatic Property - Surface Resistivity
	EN 1149-3	Electrostatic Property - Measurement of Charge Decay

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SECTION 1
EN 13034:2005+A1:2009 Protective clothing against liquid chemicals (Type 6)

1. SECTION SUMMARY

TEST STANDARD	TEST NAME	RESULT	EVALUATION
EN ISO 12947-2	Abrasion Resistance	P	Class 4
EN ISO 9073-4	Trapezoidal Tear Resistance	P	Class 2
EN ISO 13934-1	Tensile Strength	P	Class 1
EN 863	Puncture Resistance	P	Class 2
EN ISO 6530	Repellency to Liquids	P	Class 3
EN ISO 6530	Resistance to Penetration by Liquids	P	Class 1
Modified EN ISO 17491-4	Resistance to Penetration By Liquids In The Form Of A Light Spray (Mist Test)	P	-
EN ISO 13935-2	Seam Strength	P	Class 4

2. TEST RESULTS and EVALUATION

2.1 ABRASION RESISTANCE

Test Reference: EN 13034/A1:2009 Clause 4.1 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN ISO 12947-2 Annex-B

Martindale Test Machine (47.5±2 rpm) with Lissajous Figure.

9 kPa pressure, Performed in the conditioned room (20±2°C - 65%±4).

RESULT	EVALUATION (See Table 1)
No Abrasion @ 700 revs	Class 4

Determination of the highest number of abrasion rubs which does not cause damage to the material and which shall be used for the performance classification. The abrasion resistance of sample shall be Classified according to the levels of performance given in Table-1 below.

Table 1: Classification of Abrasion Resistance

Class	Number of Rubs
6	> 2.000
5	> 1.000
4	> 400
3	> 100
2	> 40
1	> 10

Lab A

2.2 TRAPEZOIDAL TEAR RESISTANCE

Test Reference: EN 13034/A1:2009 Clause 4.1 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN ISO 9073-4:2002

Instron 5969 Speed:100 ±10 mm/min, Gauge length: 5cm

The average results are given for width and length direction of five samples. 2 pre-tension applied

Performed in the conditioned room. (20±2°C - 65% ±4)

	RESULT	EVALUATION (See Table 2)
Width	22.20 N	Class 2
Height	31.77 N	

Table 2: Classification of Trapezoidal Tear Resistance

Class	Tear Strength
6	> 150 N
5	> 100 N
4	> 60 N
3	> 40 N
2	> 20 N
1	> 10 N

Lab A

2.3 TENSILE STRENGTH

Test Reference: EN 13034/A1:2009 Clause 4.1 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN ISO 13934-1:2013

Instron 5969 (Load: 50 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 five samples.

Performed in the conditioned room. (20±2°C - 65% ±4)

	RESULT	EVALUATION (See Table 3)
Width	43.38 N	Class 1
Height	75.22 N	

Table 3: Classification of Tensile Strength

Class	Tear Strength
6	> 1000 N
5	> 500 N
4	> 250 N
3	> 100 N
2	> 60 N
1	> 30 N

Lab A

2.4 PUNCTURE RESISTANCE

Test Reference: EN 13034/A1:2009 Clause 4.1 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN 863:1995

SDL ATLAS M229 tester. Test area: 30.5 mm diameter

Rate of increase in volume; 29 cm3/min.

The average results are given of five samples. Performed in the conditioned room. (20±2°C - 65% ±4)

RESULT	EVALUATION (See Table 4)
25.8 N	Class 2

Table 4: Classification of Puncture Resistance

Class	Tear Strength
6	> 250 N
5	> 150 N
4	> 100 N
3	> 50 N
2	> 10 N
1	> 5 N

Lab A

2.5 REPELLENCY TO LIQUIDS

Test Reference: EN 13034/A1:2009 Clause 4.1 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN ISO 6530:2005

When tested in accordance with EN ISO 6530 for repellency to the liquid chemicals given in Table -5, the material shall be classified according to the levels performance in given Table-6 for each chemical tested.

Use those liquids against which protection is required, water is also cenvenient and safe liquid for general screening purposes. Performed in the conditioned room. (20±2°C - 65% ±4)

For each test liquid, cut six test specimens of (360±2) mm by (235±5) mm from the sample.

Chemicals shall be of analytical purity grade. Discharged the test liquid (10 cm^3) within (10±1)s

Table-5 List of reference chemicals for absorption ,penetration and repellency testing

Chemical	Concentration weight %	Temperature of chemical (±2 °C)
Sulfuric Acid (H_2S0_4)	30	20
Sodium Hydroxide (NaOH)	10	20
o-Xylene	Undiluted	20

	RESULT I_R	EVALUATION (See Table 6)
Sulfuric Acid (H_2S0_4)	95.45 %	Class 3
Sodium Hydroxide (NaOH)	96.20 %	Class 3
o-Xylene	90.08 %	Class 3

Table 6: Classification of Repellency to liquids

Class	Repellency Index (I_R)
3	> 90 %
2	> 80 %
1	> 70 %

Lab A

2.6 RESISTANCE TO PENETRATION BY LIQUIDS

Test Reference: EN 13034/A1:2009 Clause 4.1 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN ISO 6530:2005

When tested in accordance with EN ISO 6530 for penetration by the liquid chemicals given in Table 5, the material shall be classified according to the levels of performance given in Table 7 for each chemical tested.

Performed in the conditioned room. (20±2°C - 65% ±4)

For each test liquid, cut six test specimens of (360±2) mm by (235±5) mm from the sample.

Chemicals shall be of analytical purity grade. Discharged the test liquid (10 cm^3) within (10±1)s

	RESULT I_P	EVALUATION (See Table 7)
Sulfuric Acid (H_2S0_4)	0 %	Class 3
Sodium Hydroxide (NaOH)	0 %	Class 3
o-Xylene	5.6 %	Class 1

Table 7: Classification of Repellency to liquids

Class	Repellency Index (I_P)
3	< 1 %
2	< 5 %
1	< 10 %

Lab A

2.7 SEAM STRENGTH – GRAB METHOD

Test Reference: EN 13034/A1:2009 Clause 4.2.2 - EN ISO 13935-2:2014 Seam tensile properties of fabrics and made-up textile articles - Part 2: Determination of maximum force to seam rupture using the grab method

Test Method: EN ISO 13935-2:2014

Jaw Speed: 50±5 mrnlmin, Gauge Length: 100 mm±1 mm.

Seam Type : 301. 100 %Polyester core-spun sewing-thread was used.

5kN. load was applied. The average results are given for width and length direction of five samples.

Performed in the conditioned room. (20±2°C - 65% ±4)

RESULT	Seam Strength (N)	Fail	EVALUATION (See Table 8)
Sleeve	160 N	FTJ	Class 4
Crotch	210 N	FTJ	
Inner side seam	190 N	FTJ	
Front center seam	160 N	FTJ	
Back ceter seam	230 N	FTJ	

Table 8: Classification of Seam Strength

Class	Repellency Index (I_P)
6	> 500 N
5	> 300 N
4	> 125 N
3	> 75 N
2	> 50 N
1	> 30 N

Lab A

2.8 RESISTANCE TO PENETRATION BY LIQUIDS IN THE FORM OF A LIGHT SPRAY (MIST TEST)

Test Reference: EN 13034/A1:2009 Clause 5.2 - EN ISO EN ISO 17491-4 Test methods for clothing providing protection against chemicals - Part 4: Determination of resistance to penetration by a spray of liquid (spray test)

Test Method: EN ISO EN ISO 17491-4

The test method modified as follows for low-level spray testing conditions:

- The four hydraulic nozzles are hollow cone type nozzles, with a spray testing angle of (75±5)° at 3 bar, each nozzle supplying liquid rate of (0,47 ± 0,05) l/min at 300 kPa pressure;
- The liquid used are modified to have a surface tension of (52,5 ± 7,5)10^{-3} N/m in order to form suitable spray droplets; the test apparatus is carried out with test liquid at the same surface tension.

The manufacturer claims the product for single use. No cleaning instruction was given, no cleaning conducted. The test subject (OK) carried out the seven movement exercise (as given in EN 13034 Clause 5.2) in advance of the mist test.

Performed in the conditioned room. (20±2°C - 65% ±4)

Undergarments as detailed in ISO 17491-4 and an absorbent suit were worn directly under the test garment.
The device is a white material one piece coverall incorporating elasticated cuffs, ankles, waist and hood. There is a double action zip at the front of the suit which runs from crotch to the neck and is covered during use by a flap which is sealed onto the suit material by means of integral double sided adhesive tape.
The coveralls were taped onto a full face mask, wellington boots and rubber gloves. The wearers were dressed in accordance with the manufacturer's dressing procedures.

Test Results:
In response to the question "does the suit fit", the test subject answered "Yes".
After testing in accordance with the practical movements defined in EN13034 Clause 5.2, the subject could able to do the exercises and no damage was observed on the suit.
Surface tension measurements of the test solution were recorded in the reservoir and at the nozzle before and after testing and these ranged from 50.0 to 51.5Nm-1x10 -3 and 50.6 to 51.3Nm-1 x10-3 respectively.

The temperature measurement in the test chamber before and after testing and these ranged from 19.6 to 20.6°C
A Leakage stain was observed at the right upper waist area on the dosimeter suit of the second suit tested.
No leakage staining was observed on the dosimeter suits of the other two suits tested.

Leakage results in terms of area of leakage stains(s) on the dosimeter suit as a ratio of the calibration stain are shown in the following table;

Suit Number	Calibration of Stain (cm^2) (CS)	Total Lekage Stain (cm^2) (TLS)	Ratio (TLS / CS)	EVALUATION *(Max Allowed Ratio 3)*
1	8,42	0	0	Pass
2	8,42	0	0	Pass
3	8,42	0	0	Pass

Lab C

END of SECTION 1

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SECTION 2
EN 13982-1:2004+A1:2010 **Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates**

1. SECTION SUMMARY

TEST STANDARD	TEST NAME	RESULT	EVALUATION
EN ISO 7854, Method B	Compression-Folding Flex Cracking Resistance	P	-
EN ISO 13982-2	Inward Leakage of Aerosols of Solid Particles	P	-

2. TEST RESULTS and EVALUATION

2.1 FLEX CRACKING RESISTANCE

Test Reference: EN 13982-1/A1:2010 Clause 4.1 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN ISO 7854, Method B

Test Equipment: Flexometer

Test condition: (20 ± 2) °C , (65 ± 5) %RH

Sample size: 105x50mm

No. of sample: 6

No. of cycles: 100000

Mobile disk frequency: (8.3 ± 0.4) Hz compression pulse per minute

Stroke length of mob. disk: (11.7 ± 0.35)mm

Test results:

The test results obtained are given in the tables as follows

Max direction longitudinal	Result
Lowest value after 19.000 cycles	1-2 null
Max direction longitudinal	**Result**
Lowest value after 18.000 cycles	1-2 null

0- any deterioration, 1- slight deterioration, 3- moderated deterioration, 4- severe deterioration

Depth of cracking:

Null-no cracks,

A-surface or finish crack, not exposing the cellular or middle layer

B-cracking into but not right through the middle layer

C-cracking through the base fabric

D-cracking right the material

Lab A

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2.2 INWARD LEAKAGE OF AEROSOLS OF SOLID PARTICLES

Test Reference: EN 13982-1/A1:2010 Clause 4.3.2 - EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Test Method: EN ISO 12947-2 Annex-B

Martindale Test Machine (47.5±2 rpm) with Lissajous Figure.

9 kPa pressure, Performed in the conditioned room (20±2°C - 65%±4).

Test Purpose:

This test method is used to determine the barrier efficiency of chemical protective clothing against aerosols of dry, fine dusts.

Sampling method:

At least 5 test subjects are involved, each testing 2 suits. So at least 10 suits are tested.

The device is a white material one piece hooded coverall incorporating elasticated ankles, waist, hood and wrists.

There is a double action zip at the front of the suit which runs from the crotch to the neck and is covered during use by a flap which is sealed onto the suit material by means of double sided tape.

Testing methods used:

Test agent: Sodium Chloride aerosol

Test conditions:

Temperature and relative humidity measurements were recorded in the test chamber before and after each test and these ranged from 24.5 to 27.4°C and 47.1 to 59.6%, respectively

Test Equipment:

Aerosol Test Chamber.

Test Procedure:

This test is performed using "real people" and is designed to simulate everyday use. The garment is donned according to the manufacturers' instructions, including any protective equipment.

Prior to entering the test chamber the test subject (real person) is asked to repeat the following sequence of movements 3 times at what is termed "normal working speed";

1) Kneel on both knees, lean forward and place both hands on the floor 45cm in front of the knees. Crawl forward on hands and knees over a distance of 3m and crawl backwards again over the same distance

2) Stand with feet shoulder width apart, arms at side. Raise arms until they are parallel to the floor in front of the body. Squat down as far as possible.

3) Kneel on right knee, place left foot on floor with left knee bent 90°, left arm hanging loosely at side. Raise left arm fully overhead. Once they have completed these movements the suit is inspected visually for tears or rips in the fabric, seams, closures or connections to gloves, boots or mask (if any). Any damage is mentioned in the test report, but the test would be discontinued if the damage was significant or hindered the test subjects' movement.

On entering the test chamber the test subject is asked to perform various test exercises in sequence. These are;

1) standing still

2) walking at 5 km/h

3) continuous squatting at a frequency of five squats per minute, between standing up straight and knees completely bent, while keeping both hands during all squats on a grip at a height of 1m (+/-0.05m) above the standing surface.

4) A 3 min rest is allowed (standing still) between the walking and squatting exercises.

Throughout the process various measurements are taken on the concentration of particulates inside and outside of the suit. A calculation is then used to ascertain the inward leakage during each test and the total inward leakage of particles into the suit.

The physical dimensions of the wearers are shown below;

Wearer	Height (cm)	Chest (cm)	Suit size
AN	175	102	L
BV	174	97	L
CT	172	99	L
MF	183	103	XL
AD	176	98	L

Test results: The test results obtained are given in the tables as follows

Result-1) Aerosol Inward leakage (%) individual results

wearer	position	knee	waist	chest	average
AN	stand	0,895	0,764	2,125	1,261
	walk	0,125	1,586	0,964	0,892
	squat	7,256	8,156	12,046	9,153
	average	2,759	3,502	5,045	3,769
AN	stand	0,765	1,254	2,249	1,423
	walk	0,598	0,761	1,456	0,938
	squat	8,200	10,265	9,442	9,302
	average	3,188	4,093	4,382	3,888
BV	stand	2,495	0,752	2,146	1,798
	walk	1,810	0,698	1,548	1,352
	squat	7,549	8,820	14,157	10,175
	average	3,951	3,423	5,950	4,442
BV	stand	1,325	0,981	1,454	1,253
	walk	0,752	0,888	2,029	1,223
	squat	11,940	20,185	7,856	13,327
	average	4,672	7,351	3,780	5,268
CT	stand	0,792	0,852	0,852	0,832
	walk	1,015	0,642	0,761	0,806
	squat	14,054	8,594	9,258	10,635
	average	5,287	3,363	3,624	4,091
CT	stand	1,095	0,814	1,237	1,049
	walk	0,852	0,942	0,861	0,885
	squat	16,910	9,253	10,372	12,178
	average	6,286	3,670	4,157	4,704
MF	stand	0,852	1,254	0,676	0,927
	walk	1,052	0,925	0,794	0,924
	squat	7,430	8,461	11,546	9,146
	average	3,111	3,547	4,339	3,666
MF	stand	1,546	0,859	0,942	1,116
	walk	0,837	1,276	2,543	1,552
	squat	10,589	25,294	18,846	18,243
	average	4,324	9,143	7,444	6,970
AD	stand	0,816	0,924	1,649	1,130
	walk	1,194	2,195	0,946	1,445
	squat	8,591	11,946	10,549	10,362
	average	3,534	5,022	4,381	4,312
AD	stand	1,549	2,849	0,894	1,764
	walk	0,946	1,981	0,855	1,261
	squat	10,494	11,694	8,959	10,382
	average	4,330	5,508	3,569	4,469

Result-2) Total Inward leakage (%) (overall average, all wearers)

position	knee	waist	chest	average
stand	1,213	1,130	1,422	1,255
walk	0,918	1,189	1,276	1,128
squat	10,301	12,267	11,303	11,290
average	4,144	4,862	4,667	4,558

Result-3) Total Inward leakage per test object

wearer	average
AN	3,828
BV	4,855
CT	4,398
MF	5,318
AD	4,391
average	4,558

Assessment of compliance:

EN ISO 13982-1 specifies the requirements and classes of type 5 suits as:

When tested in accordance with EN ISO 13982-2 the type 5 protective clothing shall be characterized by the following parameters:

Ljmn,82/90 : 90

LjmIL 82/90: the inward leakage value (in percent), equal to or superior to 82/90 (91.1%) of all IL values measured (all exercises, all sampling positions, all suits); TILS8/10: the "total inward leakage per suit" value, equal or superior to 80% of all TILS-values. Type 5 chemical protective clothing shall meet at least the following requirements: IL 82/90

For this suit, all of the IL results are less than 30% and all of the TILS are less than 15%. The sample complies with the requirements of EN ISO 13982-1 for inward leakage of aerosol of solid.

Lab C

END of SECTION 2

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SECTION 3

EN 14126:2003/AC:2004

Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

1. SECTION SUMMARY

TEST STANDARD	TEST NAME	RESULT	EVALUATION	
ISO 16603	Resistance to penetration by contaminated liquids under hydrostatic pressure	P	Class 2	See Results
ISO 16604	Penetration by blood and other body fluids-born pathogens. Phi-X174 bacteriophage	P	-	See Results
EN ISO 22610	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids	P	Class 1	See Results
EN ISO 22612	Resistance to penetration by contaminated solid particles	P	Class 3	See Results

2. TEST RESULTS and EVALUATION

2.1 RESISTANCE TO PENETRATION BY CONTAMINATED LIQUIDS UNDER HYDROSTATIC PRESSURE

Test Reference: EN 14126/AC:2004 Clause 4.1.4.1 - ISO 16603:2004 Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood

Test Purpose:

This test method is used to determinate of the resistance of protective clothing materials to penetration by blood and body fluids - test method using synthetic. This a test conducted using synthetic blood, which establishes at what pressure the liquid will pass through the test material.

Sampling method:

3 samples used in this test. Sample size: 75x75mm

Testing methods used:

Time and pressure control: Procedure D used. 5 minutes each samples pressure tested.

Test conditions:

Min. 24hr, temperature of (21 ± 5) °C and a relative humidity of air of (60 ± 10) %.

Test Equipment:

Penetration test cell.

Test Procedure:

ISO 16603 uses synthetic blood in a simple visual penetration test to estimate the pressure at which strike through is likely to occur in ISO 16604. Testing to ISO 16604 can then proceed at this pressure as a starting point.

Test results:

The test results obtained are given in the tables as follows

No. of Sample	Hydrostatic pressure	Result	Evaluation (See Table 9)
1.sample	0 kPa	Pass	Class 1
2.sample	0 kPa	Pass	Class 1
3.sample	0 kPa	Pass	Class 1
1.sample	1.75 kPa	Pass	Class 2

2.sample	1.75 kPa	Pass	Class 2
3.sample	1.75 kPa	Pass	Class 2
1.sample	3.5 kPa	Fail	X
2.sample	3.5 kPa	Fail	X
3.sample	3.5 kPa	Fail	X
1.sample	7 kPa	Fail	X
2.sample	7 kPa	Fail	X
3.sample	7 kPa	Fail	X

*Pass: The sample resist to penetration and synthetic blood doesn't pass through the fabric

*Fail: The sample doesn't resist to penetration and synthetic blood pass through the fabric

Table 9: Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO 16604)

Class	Hydrostatic pressure at which the material passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3,5 kPa
2	1,75 kPa
1	0 kPa

Lab B

2.2 DETERMINATION OF RESISTANCE OF PROTECTIVE CLOTHING MATERIALS TO PENETRATION BY BLOOD-BORNE PATHOGENS

Test Reference: EN 14126/AC:2004 Clause 4.1.4.1 - ISO 16604:2004 Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X 174 bacteriophage

Test Purpose: This test method is used to determinate of the resistance of protective clothing materials to penetration by blood and body fluids - test method using synthetic. This a test conducted using synthetic blood, which establishes at what pressure the liquid will pass through the test material.

Sampling method: 3 samples used in this test. Sample size: 75x75mm

Testing methods used:

Time and pressure control: Procedure D used. 5 minutes each samples pressure tested.

Penetration survey method is Plaque-forming units (PFU)

Name of test microorganism: Bacteriophage Phi-X 174

Test conditions:

Min. 24hr, temperature of (21 ± 5) °C and a relative humidity of air of (60 ± 10) %.

Test Equipment: Penetration test cell.

Test Procedure: It can be clearly seen that only the ISO 16604 test uses a contaminant – a bacteriophage (that is, a virus that parasitises a bacteria by infecting it, in this case Phi X174, selected, according to the standard, for its small size) – that is considerably smaller than the Coronavirus now filling the news. The other tests use bacteria considerably larger than Coronavirus. Thus, ISO 16604 is the only test providing a clear indication of effective resistance to penetration of that size of infectious agent.

It also describes a laboratory test method used to measure the resistance of the materials used in protective clothing to penetration by blood-borne pathogens using a surrogate microbe with continuous liquid contact. Protective clothing either passes or fails depending on whether viral penetration at a specific hydrostatic pressure can be detected.

Test results:

The test results obtained are given in the tables as follows

No. of Sample	Hydrostatic pressure	Result
1.sample	3.5 kPa	Pass
2.sample	3.5 kPa	Pass
3.sample	3.5 kPa	Pass
	Negative control(PE 10μm)	Pass
	Positive control	Fail

***Pass:** The sample resist to penetration and synthetic blood doesn't pass through the fabric

***Fail:** The sample doesn't resist to penetration and synthetic blood pass through the fabric

Pre-test bacteriophage titer: 4.5E+008 PPU/ml

Post-test bacteriophage titer: 4.5E+008 PPU/ml

Lab B

2.3 RESISTANCE TO PENETRATION BY INFECTIVE AGENTS DUE TO MECHANICAL CONTACT WITH SUBSTANCES CONTAINING CONTAMINATED LIQUIDS

Test Reference: EN 14126/AC:2004 Clause 4.1.4.2 – EN ISO 22610:2006 Test method to determine the resistance to wet bacterial penetration

Test Purpose:

This test method is designed to determine a material's resistance to penetration of bacteria in a liquid.

Sampling method:

Five pieces 25 cm x 25 cm or with a diameter of 25 cm shall be randomly cut under aseptic conditions from the material to be tested.

Testing methods used:

Testing time: 5 steps of 15 minutes

S. aureus strain, ATCC 29213, is cultured 18 to 24 h at (36 ± 1) °C on tryptic soy agar.

Culture medium: Nutrient agar

Donor material: Polyurethanic membrane; 30 μm

Distance from agar surface to brim of petri dish: 3mm

Concentration of test suspension: $2.9x10^4$ CFU/ml

Test conditions:

Min. 24hr, temperature of (20 ± 2) °C and a relative humidity of air of (65 ± 5) %.

Test Equipment:

The turntable consists of three parts:

- the motor compartment;
- the agar plate holder;
- the finger holder arm.

Test Procedure:

The material to be tested is put on a lidless agar plate, on a rotating disk on top of the test specimen, a piece of donor material and a piece of approximately 10 μm thick HD polyethylene film of corresponding size is placed and materials are fixed using a double steel ring. An abrasion resistant finger is placed on top of the donor material to exert a specified force on the donor and test specimen to bring them into contact with the agar.

The finger is applied to the material by a pivoted lever moved by an excenter cam in such a way that it moves over the entire surface of the plate within 15 minutes. The assemblage of materials is stretched by the weight of the steel ring so

that only a small area of the test specimen is brought into contact with the agar surface at a time. Due to the combined effect of rubbing and liquid migration bacteria may spread from the donor material through the test specimen down to the agar surface.

After 15 minutes of testing, the agar plate is replaced and the test repeated. Within five periods of 15 minutes each, tests are performed with the same pair of donor material and test specimen. In that way the test allows for an estimation of the penetration over time. Finally the bacterial contamination on the test specimen is estimated using the same technique. The agar plates are incubated to visualise the bacterial colonies, which are then enumerated. The results are processed in accumulated form to characterize the barrier capability and penetration kinetics of the material.

Test results:

The test results obtained are given in the tables as follows

	Interval (Min)	n° colonies 1st sample	n° colonies 2nd sample	n° colonies 3rd sample	n° colonies 4th sample	n° colonies 5th sample	average
Petri dish 1 (X1)	0-15	20	10	15	14	13	14,4
Petri dish 2 (X2)	15-30	23	15	18	22	16	18,8
Petri dish 3 (X3)	30-45	31	20	18	24	22	23
Petri dish 4 (X4)	45-60	31	22	30	25	18	25,2
Petri dish 5 (X5)	60-75	42	53	48	41	37	44,2
Petri dish 6 (ref. Z)		125	150	180	156	140	150,2
T		272	270	309	282	246	275,8
b (EPP)		4,57	5,01	5,00	4,86	4,91	4,87

Legend

b (EPP) = Barrier index

b (EPP) = 6 - (CUM1+CUM2+CUM3+CUM4+CUM5)

where

CUM1 = X1/T

CUM2 = (X2+X1) / T

CUM3 = (X3+X2+X1) / T

CUM4 = (X4+X3+X2+X1) / T

CUM5 = (X5+X4+X3+X2+X1) / T

T = Z + X1 + X2 + X3 + X4 + X5

X1, X2, X3, X4, X5: number of colonies on the five plates from one of five samples

Z = number of colonies from the top side (plate nr. 6 reference)

Item	Unit	Result	Evaluation See Table 10
Breakthrough time	min	T<15	Class 1

Table 10: Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids

Class	Breakthrough time, t, min
6	$t > 75$
5	$60 < t \leq 75$
4	$45 < t \leq 60$
3	$30 < t \leq 45$
2	$15 < t \leq 30$
1	≤ 15 min

Lab B

2.4 Resistance to penetration by contaminated solid particles.

Test Reference: EN 14126/AC:2004 Clause 4.1.4.4 – EN ISO 22612:2005 Test method for resistance to dry microbial penetration

Test Purpose:

This test method is designed to determine a material's resistance to penetration by biologically contaminated powders.

Sampling method:

Ten samples material tested, Sample size: 200x200mm

Testing methods used:

Test time: 30 minutes

Spores of Bacillus subtilis, ATCC 9372, Culture medium: TGE agar

Test conditions:

Min. 24hr, temperature of (20 ± 2) °C and a relative humidity of air of (65 ± 5) %.

Test Equipment:

Vibrating apparatus

Test Procedure:

To measure the barrier against contaminated dust, the test materials is pre- sterilised and then fixed into the test apparatus and dosed with contaminated (Bacillus Subtilis) talcum powder. An agar culture plate is located underneath.

The test apparatus is agitated or shaken. The particles which penetrate the material are cultured and counted after incubation of the agar plate and a non-contaminated test specimen is run as a control. The results (mean values from 10 single results at a given time) are measured in penetration log units

Test results:

The test results obtained are given in the tables as follows

No. of Sample	Unit	Result
1.sample	CFU	17,0
2.sample	CFU	8,0
3.sample	CFU	7,0
4.sample	CFU	10,0
5.sample	CFU	9,0
6.sample	CFU	12,0
7.sample	CFU	16,0
8.sample	CFU	13,0
9.sample	CFU	11,0
10.sample	CFU	12,0
Average	CFU	11,5
No. of Sample	**Unit**	**Result**
1.sample	Log10 CFU	1,2
2.sample	Log10 CFU	0,9
3.sample	Log10 CFU	0,8

4.sample	Log10 CFU	1,0
5.sample	Log10 CFU	1,0
6.sample	Log10 CFU	1,1
7.sample	Log10 CFU	1,2
8.sample	Log10 CFU	1,1
9.sample	Log10 CFU	1,0
10.sample	Log10 CFU	1,1
Average	Log10 CFU	1,0
Talcum Concentration	CFU/g	7.7E+007

Classified as Class 2 See Table 11

Table 11: Classification of resistance to penetration by contaminated solid particles

Class	Penetration (log cfu)
3	≤ 1
2	$1 < \log \text{cfu} \leq 2$
1	$2 < \log \text{cfu} \leq 3$

Lab B

END of SECTION 3

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SECTION 4
EN 1149-5:2018
Electrostatic properties - Part 5: Material performance and design requirements

1. SECTION SUMMARY

TEST STANDARD	TEST NAME	RESULT	EVALUATION
EN 1149-1	Test method for measurement of surface resistivity	P	See Results

2. TEST RESULTS and EVALUATION

2.1 ELECTROSTATIC PROPERTY - SURFACE RESISTIVITY

Test Reference: EN 1149-5:2018 – EN 1149-1 Test method for measurement of surface resistivity

Test procedure:

The sample is placed on an insulating base plate, then placed the group of electrodes on the sample, apply a continuous stream and measure the resistance of the sample

Requirements: Geometric mean of surface resistance shall be less than or equal to $2,5 \times 10^9$ Ω, on at least one surface tested.

Test results:

The test results obtained are given in the tables as follows

Electric Surface Resistance (Ohm)							
Sample 1	Test 1	Test 2	Test 3	Test 4	Test 5	Geometric Mean	Evaluation
1.sample	3,7 10^8Ω	4,6 10^8Ω	3,0 10^8Ω	2,2 10^8Ω	3,2 10^8Ω	3,24 10^8Ω	Pass
3.sample	5,5 10^8Ω	3,4 10^8Ω	3,6 10^8Ω	3,2 10^8Ω	6,7 10^8Ω	4,28 10^8Ω	Pass

Lab C

END of SECTION 4

LABORATORY INFORMATION

Code	Laboratory Name	Competency Explanations
Lab A	EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.	Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-0583-T according to EN ISO/IEC 17025:2017.
Lab B	ÇEVRE ENDÜSTRİYEL ANALİZ LABORATUVAR HİZM. TİC. A.Ş	Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-0363-T according to EN ISO/IEC 17025:2017.
Lab C	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİC. LTD. ŞTİ.	Internal Laboratory Services

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- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

- Rapor Sonu -