EUROLAB
Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

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Sample ID: LAMINATED BREATHABLE FABRIC AND COVERALL

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

Seal

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Environment

The requirements and standards apply to equipment intended for use in

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

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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	1760	5 of 6
Flex ISO 7854 Method B	56000	6 of 6
Tear Resistance EN ISO 9073-4 (MD)	128 N	5 of 6
Tear Resistance EN ISO 9073-4 (CD)	112 N	
Tensile Strength ISO 13934-1 (MD)	960 N	5 of 6
Tensile Strength ISO 13934-1 (CD)	892 N	
Puncture Resistance EN 863	276 N	6 of 6
EN 25978 Resistance to Blocking	No blocking	

Resistance to flame	
Flame exposure	EN Class
specimen stops for 5 s in the flame	3 of 3

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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	492 min	6 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	466 min	570 min	487 min
EN Class	5 of 6	6 of 6	6 of 6

Classification of repellency to liquids	
Repellency index	EN Class
% 92	6 of 6

Classification of resistance to penetration by liquids	
Repellency index	EN Class
% 0,86	6 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
24 kPa	6 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
63 min	5 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
7	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
0,92	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 conditioning 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
367 N	5

- **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 movements 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

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.

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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

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

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- **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

Conditioning and testing are carried out at normal room temperature.