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TEST REPORT

2021EP0504

DATE OF RECEPTION
10/11/2020

DATE TESTS
Starting: 10/11/2020
Ending: 10/02/2021

APPLICANT

MAE GİYİM SAN TİC LTD. ŞTİ
KAYABASI MAH. KAYASEHİR BULVARI PARK
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Att. Emel Konuklu

IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCES
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

TESTS CARRIED OUT

- ERGONOMICS.
- SIZING.
- DETERMINATION OF PH VALUE.
- DETERMINATION OF FORBIDDEN AZO COLORANTS (CANCEROGENIC ARYLAMINES).
- SPECIFIC DESIGN REQUIREMENTS.
- SEAM STRENGTH RESISTANCE.
- DETERMINATION OF THE ABRASION RESISTANCE OF FABRICS.
- DETERMINATION OF TEAR RESISTANCE.
- DETERMINATION OF BREAKING STRENGTH AND ELONGATION.
- PUNCTURE RESISTANCE.
- DETERMINATION OF FLEX CRACKING AND CRACK GROWTH.
- THICKNESS.
- THICKNESS*.
- MASS PER UNIT AREA*.
- RESISTANCE TO PENETRATION BY LIQUIDS UNDER PRESSURE*.
- RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD.
- RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING PHI-X174.
- RESISTANCE TO WET BACTERIAL PENETRATION.
- TEST METHOD FOR RESISTANCE TO DRY BACTERIAL BARRIER PENETRATION.

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SAMPLE DESCRIPTION

PHOTOGRAPHY

Numero de muestras analizadas

2

Reference [1]

D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

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RESULTS

ERGONOMICS

STANDARD
EN ISO 13688:2013

REFERENCE
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

TEST DATE
01/12/2020

REMARK
The ergonomics verification has been performed by physical dimensions commensurate with the size found.

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RESULTS

SIZING

Standard
EN ISO 13688:2013 Apdo. 6

Test uncertainty
The test uncertainty is ±1% of the measurand's value, for a coverage value of K=2 (95%)

Size
XL

Reference	D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	
Bust girth (cm)	**Arm height (cm)**	**Total height (cm)**
140,0	64,0	122,0

Start and finish test date
02/12/2020 - 02/12/2020

RESULTS

DETERMINATION OF PH VALUE

Standard
EN ISO 3071:2006
Determination date
20/11/2020
Extractor solution
A - H_2O
pH Extractor solution
6,40
Temperature
20.5 ºC

Reference	pH	Uncertainty
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	7.40	± 5 %
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389-B	7,10	± 5 %

REQUISITE
In accordance with Standard EN ISO 13688:2013, the pH value shall be greater than 3.5, and less than 9.5.

PASS

RESULTS

DETERMINATION OF FORBIDDEN AZO COLORANTS (CANCEROGENIC ARYLAMINES)

Standard
UNE-EN 14362-1:2017
Test Methods
GC/MSD
Apparatus
Gas Chromatograph 7890A
Uncertainty
± 9 mg/Kg
Detectors
Mass Spectrometer 5975C

Reference	Results
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389 (WHITE FABRIC WITH COATING)	< 30* mg/Kg
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389-B (BLUE FABRIC)	< 30* mg/Kg
*For all forbidden azo dyes listed below.	
The textile products subject to control are according to the Standard EN ISO 13688:2013 on the use of Azo Colorants which release carcinogenic amines listed in the Standard Test	

PASS

Forbidden Azo dyes
4-Aminodiphenyl, Benzidine, 4-Chlor-o-toluidine, 2-Naphthylamine, o-Aminoazotoluene, 2-Amino-4-nitrotoluene, p-Chloraniline, 2,4-Diaminoanisole, 4,4'-Diaminodiphenylmethane, 3,3'-Dichlorobenzidine, 3,3'-Dimethoxybenzidine, ,3,3'-Dimethylbenzidine, 3,3'-Dimethyl-4,4'-diaminodiphenylmethane, p-Cresidine, 4,4'-Methylene-bis-2-chloraniline, 4,4'-Oxydianiline, 4,4'-Thiodianiline, o-Toluidine, 2,4- Toluylenediamine, 2,4,5-Trimethylaniline, o-Anisidine, 4-Aminoazobenzene

REQUISITE
In accordance with standard EN ISO 13688:2013, by detecting Azo colorants the limited stablished is not detected by standard EN 14362-1

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RESULTS

SPECIFIC DESIGN REQUIREMENTS

REFERENCE

D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

STANDARD

EN 340:2003 and EN ISO 13688:2013

DESIGN REQUIREMENTS

The protection clothing design makes easy its correct placement and wearing staying with no movement during the use period intended.	**PASS**
The design of the protective clothing applies elements from other protective or equipment clothing, which are used to create a comprehensive protective outfit.	**PASS**
The clothing has no rough, sharp or hard surfaces or edges that could damage or irritate the user.	**PASS**
The clothing is not enough narrow for causing flow blood restriction.	**PASS**
The clothing is not enough loose and heavy for interfering the user's movement.	**PASS**

Remark
N/A: Not applicable

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RESULTS

SPECIFIC DESIGN REQUIREMENTS

REFERENCE

D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

STANDARD

EN 14126:2003/AC, point 4.3

DESIGN REQUIREMENTS

Protective clothing against infective agents meets the requirements that apply of the Standard ISO 13688:2013	**PASS**
Protective clothing against infective agents meets the requirements specified in the appropriate chemical protection Standard	**PASS**
The garment allows the user to move freely, in as much comfort as possible, in accordance with the protection the garment provides.	**PASS**

Remark
N/A: Not applicable

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RESULTS

SPECIFIC DESIGN REQUIREMENTS

REFERENCE:

D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

STANDARD

EN 13034:2005+A1:2009, point 5.1

DESIGN REQUIREMENTS

The type 6 chemical protection clothing meets the relevant requirements of the Standard EN 340:2003	**PASS**
The garment allows the user to move freely, in as much comfort as possible, in accordance with the protection the garment provides.	**PASS**
There are no special characteristics about the clothing where liquid chemical products can be collected and retained on the material surface (the pockets are protected)	**PASS**

Remark
N/A: Not applicable

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RESULTS

SEAM STRENGTH RESISTANCE

Standard
EN ISO 13935-2:2014
Apparatus
INSTRON Dynamometer

Conditioning date	23/11/2020	**Test date**	24/11/2020

Gauge length
100 mm
Atmosphere for conditioning testing

Temperature	(20±2) ºC	**Relative humidity**	(65±4) %

Number of specimens

Tested	5	Rejected	0

The break of the seam is produced for:
Torn fabric in clamps

Previous treatment
Null
Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Average resistance (N)		C.V.(%)
40,72		
43,72		
45,24	**43,32**	3,84
43,91		
43,02		

Remarks
The relative expanded uncertainty of Seams resistance is ± 6% assay value of the measured, for a probability of coverage of 95%.
The test procedure described in the two versions of the Standard (EN ISO 13935-2:1999 and EN ISO 13935-2:2014) is the same.

REQUISITE ACCORDING TO STANDARD EN 14126:2003/AC:2004; EN ISO 13982-1:2004/A1:2010; EN 14605:2005+A1:2009; EN 13034:2005+A1:2009

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
>30N	> 50N	> 75N	> 125N	> 300N	> 500N

PERFORMANCE LEVEL 1

///

RESULTS

DETERMINATION OF THE ABRASION RESISTANCE OF FABRICS

Standard
EN 530:2010 Method 2
Apparatus
Martindale Abrasion Tester

Conditioning date 23/11/2020 **Test date** 22/12/2020
Atmosphere for conditioning testing
Temperature (20±2) ºC **Relative humidity** (65±4) %
Testing conditions
Rubbing against abradant paper 00
Testing pressure
9kPa
End point
Two thread broken
Technical characteristics of the sample
Not indicated by the client
Previous treatment
Null

Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Specimens	Nº of cycles (n)
1	1500 < n < 2000
2	1500 < n < 2000
3	1500 < n < 2000
4	1500 < n < 2000

Remarks
The end test is performed by visual inspection.
The number of cycles corresponding to the rupture of the specimen.
The performance level is among the most unfavorable value of the pieces tested

>>>

RESULTS

REQUISITE ACCORDING STANDARD EN 13034:2005+A1:2009

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
> 10 cycles	> 100 cycles	> 500 cycles	> 1000 cycles	> 1500 cycles	> 2000 cycles

PERFORMANCE LEVEL 5

REQUISITE ACCORDING STANDARD EN 14605:2005+A1:2009

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
> 10 cycles	> 100 cycles	> 500 cycles	> 1000 cycles	> 1500 cycles	> 2000 cycles

PERFORMANCE LEVEL 5

REQUISITE ACCORDING STANDARD EN 13982-1:2004/A1:2010

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
> 10 cycles	> 100 cycles	> 500 cycles	> 1000 cycles	> 1500 cycles	> 2000 cycles

PERFORMANCE LEVEL 5

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RESULTS

DETERMINATION OF TEAR RESISTANCE

Standard
EN ISO 9073-4:1997

Apparatus
INSTRON Dynamometer

Conditioning date 21/01/2021 **Test date** 27/01/2021

Atmosphere for conditioning testing
Temperature (20±2) ºC **Relative humidity** (65±2) %

Nº of specimens
Tested 5 for each direction **Rejected** 0

The calculation of averages has been made
For electronic device

Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Tear	Average load (N)	C.V. (%)
Lengthwise	50.42 47.49 49.73 49.77 53.26 47.95	4.62
Crosswise	19.98 20.19 23.42 23.65 24.89 29.79	17.01

REQUISITE ACCORDING TO STANDARD EN 14605:2005+A1:2009

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
>10N	> 20N	> 40N	> 60N	> 100N	> 150N

PERFORMANCE LEVEL 1

///

RESULTS

DETERMINATION OF BREAKING STRENGTH AND ELONGATION

Standard

EN ISO 13934-1:2013

Apparatus

INSTRON Dynamometer

Conditioning date 23/11/2020 **Test date** 04/01/2021

Atmosphere for conditioning testing

Temperature (20±2) ºC **Relative humidity** (65±4) %

Gauge length

Lengthwise 200 mm. **Crosswise** 200 mm.

Test velocity

Lengthwise 100 mm/min **Crosswise** 100 mm/min

Pretension

Lengthwise 2 N **Crosswise** 2 N

Nº of specimens

Tested 5 for each direction **Rejected** 0

State of the specimens Conditioned

Reference

D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Direction	Maximum average load (N)	C.V. (%)	Average elongation (%)	C.V. (%)
Lengthwise	93 95 82 **89** 86 88	6	45 50 35 **42** 39.5 42	13.5
Crosswise	33 33 34 **33** 32 34	3	33 36 33.5 **32.5** 30 31	7.4

Remark

The relative expanded uncertainty of Tensile strength resistance is ±5% assay value of the measured, for a probability of coverage of 95%.

The test procedure described in the two versions of the Standard (EN ISO 13934-1:1999 and EN ISO 13934-1:2013) is the same.

REQUISITE ACCORDING TO STANDARD EN 14126:2003/AC:2004; EN 13034:2005+A1:2009; EN 14605:2005+A1:2009

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
>30N	> 60N	> 100N	> 250N	> 500N	> 1000N

PERFORMANCE LEVEL 1

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RESULTS

PUNCTURE RESISTANCE

Standard
EN 863:1995
Apparatus
INSTRON Dynamometer

Conditioning date 19/11/2020 **Test date** 24/11/2020
Atmosphere for conditioning testing
Temperature (20±2) ºC **Relative humidity** (65±5) %
Type of fabric
Coated fabric
Previous treatment
Null

Reference	Maximum force (N)	Average resistance (N)
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	6,35 7,32 5,95 6,90 6,85	6,67

Remark
The relative expanded uncertainty of puncture resistance is ±11% assay value of the measured, for a probability of coverage of 95%.

>>>

RESULTS

REQUISITE ACCORDING TO STANDARD EN 13034:2005+A1:2009

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
>5N	> 10N	> 50N	> 100N	> 150N	> 250N

PERFORMANCE LEVEL 1

REQUISITE ACCORDING TO STANDARD EN 14605:2005+A1:2009

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
>5N	> 10N	> 50N	> 100N	> 150N	> 250N

PERFORMANCE LEVEL 1

REQUISITE ACCORDING TO STANDARD EN 13982-1:2004/A1:2010

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
>5N	> 10N	> 50N	> 100N	> 150N	> 250N

PERFORMANCE LEVEL 1

REQUISITE ACCORDING TO STANDARD EN 14126:2003/AC:2004

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
>5N	> 10N	> 50N	> 100N	> 150N	> 250N

PERFORMANCE LEVEL 1

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RESULTS

RESISTANCE OF MATERIALS TO PENETRATION BY LIQUID

Standard
EN ISO 6530:2005, EN 13034:2005+A1:2009

Atmosphere for conditioning and testing
Temperature (20±2) ºC **Relative Humidity (RH)** (65±5) %

Flow
10 ml in 10 s

Mass per unit area approximate of the sample tested
Does not provided by the customer

Pre-treatment
As received

Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Measurement uncertainty

Test liquid	Penetration index (%)[1]	Repellency index (%)[1]
Sulphuric Acid 30%	±0.3	±0.3
Sodium Hydroxide 10%	±1.1	±1.1
O-Xylene	±5.0	±7.8
1-Butanol	±5.8	±5.4

[1] On the measured value

Material tested
No-woven fabric, white colour

Test date
08/01/2021

>>>

RESULTS

1. Test liquid Sulphuric Acid 30%
Trade name SCHARLAU (Ref: AC20791000)
Boiling point 336.85 ºC
Evaporative losses prevision None

Direction	Specimen	Penetration index (%)		Repellency index (%)		Absorption index (%)	
Warp	1	0.0		98.6		1.4	
	2	0.0	0.0	99.0	98.6	1.0	1.4
	3	0.0		98.6		1.4	
Weft	1	0.0		99.3		0.7	
	2	0.0	0.0	98.8	98.7	1.2	1.3
	3	0.0		98.7		1.3	

CLASSIFICATION ACCORDING TO EN 14325:2004
Class according to repellency index: **3**
Class according to penetration index: **3**

2. Test liquid Sodium Hydroxide 10 %
Trade name MERCK (Ref: 1055881000)
Boiling point 1390 ºC
Evaporative losses prevision None

Direction	Specimen	Penetration index (%)		Repellency index (%)		Absorption index (%)	
Warp	1	0.0		98.0		2.0	
	2	0.0	0.0	98.7	98.0	1.3	2.0
	3	0.0		98.0		2.0	
Weft	1	0.0		98.4		1.6	
	2	0.0	0.0	98.7	98.3	1.3	1.7
	3	0.0		98.3		1.7	

CLASSIFICATION ACCORDING TO EN 14325:2004
Class according to repellency index: **3**
Class according to penetration index: **3**

>>>

RESULTS

3. Test liquid O-Xylene
Trade name SCHARLAU (Ref: XI00252500)
Boiling point 139 ºC
Evaporative losses prevision None

Direction	Specimen	Penetration index (%)		Repellency index (%)		Absorption index (%)	
Warp	1	0.0	0.0	96.9	95.8	3.1	4.2
	2	0.0		95.9		4.1	
	3	0.0		95.8		4.2	
Weft	1	0.0	0.0	96.2	95.1	3.8	4.9
	2	0.0		96.1		3.9	
	3	0.0		95.1		4.9	

CLASSIFICATION ACCORDING TO EN 14325:2004
Class according to repellency index: **3**
Class according to penetration index: **3**

4. Test liquid 1-Butanol
Trade name SCHARLAU (Ref: AL01732500)
Boiling point 117.88 ºC
Evaporative losses prevision None

Direction	Specimen	Penetration index (%)		Repellency index (%)		Absorption index (%)	
Warp	1	0.0	0.0	96.9	96.4	3.1	3.6
	2	0.0		96.8		3.2	
	3	0.0		96.4		3.6	
Weft	1	0.0	0.0	96.9	96.6	3.1	3.4
	2	0.0		96.6		3.4	
	3	0.0		96.7		3.3	

CLASSIFICATION ACCORDING TO EN 14325:2004
Class according to repellency index: **3**
Class according to penetration index: **3**

>>>

RESULTS

Classification of the repellency to the liquids according to standard EN 14325:2004

Class	Repellency index
3	> 95 %
2	> 90 %
1	> 80 %

Classification to the penetration by liquids according to standard EN 14325:2004

Class	Penetration index
3	< 1 %
2	< 5 %
1	< 10 %

ACCORDING TO STANDARD EN 13034:2005+A1:2009	**PASS**

REQUISITES ACCORDING TO STANDARD EN 13034:2005+A1:2009
According to the Standard EN 13034:2005+A1:2009, for liquid repellency a performance level 3 shall be obtained for at least one of the chemicals referred to EN 14325:2004, and for resistance to penetration by liquids a performance level of at least 2 shall be obtained for at least one of the chemicals referred to EN 14325:2004.

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RESULTS

DETERMINATION OF FLEX CRACKING AND CRACK GROWTH

Standard
EN ISO 7854:1997 Method B

Used apparatus
Crumpleflex equipment.

Number of specimens
6

Test temperature
23,0 ºC and 50,0 % RH

Reference	D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	
Specimen	**Direction**	**Flex cycles**
Specimen 1	Warp	>50000
Specimen 2	Warp	>50000
Specimen 3	Warp	>50000
Specimen 4	Weft	>50000
Specimen 5	Weft	>50000
Specimen 6	Weft	>50000

Remark:
According to EN 14126: 2003/AC: 2004, the mechanical requirements must be tested and classified according to EN 14325: 2018 point 4.5.2.1.

PERFORMANCE LEVEL ACCORDING TO STANDARD EN 14325:2018 LEVEL 6

Classification of resistance to flex cracking according to Standard EN 14325: 2018 point 4.5.2.1.

Performance levels	Cycles
6	> 50000
5	> 20000
4	> 8000
3	> 3000
2	> 1250
1	> 500

>>>

RESULTS

Reference	D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	
Specimen	**Direction**	**Flex cycles**
Specimen 1	Warp	>100000
Specimen 2	Warp	>100000
Specimen 3	Warp	>100000
Specimen 4	Weft	>100000
Specimen 5	Weft	>100000
Specimen 6	Weft	>100000

Requirements according to Standard EN ISO 13982-1:2004+A1:2010

According the standard EN ISO 13982-1:2004+A1:2010 The materials of type 5 chemical protective clothing must be tested and classified in accordance with the provisions of EN 14325: 2004 pto. 4.5.

PERFORMANCE LEVEL ACCORDING TO STANDARD EN 14325:2004	LEVEL 6

Requirements according to Standard EN 14605:2005+A1:2019

By the method of cell pressure examine the tightness of the specimens. Should obtain, at least, the level of benefit 1 in the classification according to EN 14605:2005+A1:2009.

PERFORMANCE LEVEL ACCORDING TO STANDARD EN 14605:2005+A1:2009	PASS

Classification of resistance to flex cracking according to Standard EN 14325:2004

Performance levels	Cycles
6	> 100000
5	> 40000
4	> 15000
3	> 5000
2	> 2500
1	> 1000

///

RESULTS

DETERMINATION OF FLEX CRACKING AND CRACK GROWTH

Standard
EN ISO 7854:1997 Method B

Used apparatus
Crumpleflex equipment.

Number of specimens
6

Test temperature
-30 ºC

Reference	D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	
Specimen	**Direction**	**Flex cycles**
Specimen 1	Warp	>4000
Specimen 2	Warp	>4000
Specimen 3	Warp	>4000
Specimen 4	Weft	>4000
Specimen 5	Weft	>4000
Specimen 6	Weft	>4000

Remark:
According to EN 14126: 2003/AC: 2004, the mechanical requirements must be tested and classified according to EN 14325: 2018 point 4.6

PERFORMANCE LEVEL ACCORDING TO STANDARD EN 14325:2018 LEVEL 6

Classification of resistance to flex cracking according to Standard EN 14325: 2018 point 4.6

Performance levels	Cycles
6	> 4000
5	> 2000
4	> 1000
3	> 500
2	> 200
1	> 100

>>>

RESULTS

Reference	D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	
Specimen	**Direction**	**Flex cycles**
Specimen 1	Warp	>4000
Specimen 2	Warp	>4000
Specimen 3	Warp	>4000
Specimen 4	Weft	>4000
Specimen 5	Weft	>4000
Specimen 6	Weft	>4000

Requirements according to Standard EN ISO 13982-1:2004+A1:2010

According the standard EN ISO 13982-1:2004+A1:2010 The materials of type 5 chemical protective clothing must be tested and classified in accordance with the provisions of EN 14325: 2004 pto. 4.6

PERFORMANCE LEVEL ACCORDING TO STANDARD EN 14325:2004	**LEVEL 6**

Requirements according to Standard EN 14605:2005+A1:2019

By the method of cell pressure examine the tightness of the specimens. Should obtain, at least, the level of benefit 1 in the classification according to EN 14605:2005+A1:2009.

PERFORMANCE LEVEL ACCORDING TO STANDARD EN 14605:2005+A1:2009	**PASS**

Classification of resistance to flex cracking according to Standard EN 14325:2004 pto. 4.6

Performance levels	Cycles
6	> 4000
5	> 2000
4	> 1000
3	> 500
2	> 200
1	> 100

///

RESULTS

THICKNESS

Standard
EN ISO 2286-3:2017
Apparatus
Thickness meter MESDAN LAB

Conditioning date 19/11/2020 **Test date** 23/11/2020
Atmosphere for conditioning testing
Temperature (20±2) ºC **Relative humidity** (65±5) %
Test pressure
2 kpa ± 0.2 KPa
Type of fabric
Coated fabric
Pressure foot
(50.5 ± 0.2) mm
Nº of specimens
5
Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Minimal thickness (mm)	Average thickness (mm)	Maximum thickness (mm)
0,18	0,22	0,23

///

RESULTS

THICKNESS*

Standard
EN ISO 9073-2:1996. Method A
Apparatus
Thickness meter

Conditioning date	23/11/2020	**Test date**	25/11/2020

Atmosphere for conditioning testing

Temperature	(20±2) ºC	**Relative humidity**	(65±5) %

Test pressure
0.5 kPa
Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389 (SEAMS)

Average thickness	CV (%)
1,25	8,15

RESULTS

MASS PER UNIT AREA*

Standard
ISO 3801:1977, Method 5

Conditioning date 19/11/2020 **Test date** 23/11/2020

Atmosphere for conditioning testing

Temperature (20±2) ºC **Relative humidity** (65±2) %

State of the specimens
Original

Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Mass per unit area (g/m^2)	CV (%)
58,9	4,18

///

RESULTS

MASS PER UNIT AREA*

Standard
ISO 3801:1977, Method 5

Conditioning date 25/11/2020 **Test date** 26/11/2020

Atmosphere for conditioning testing

Temperature (20±2) ºC **Relative humidity** (65±2) %

Type of fabric
Coated fabric

State of the specimens
Original

Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389 (Seams)

Mass per unit area (g/m^2)	CV (%)
73,3	2,78

///

RESULTS

RESISTANCE TO PENETRATION BY LIQUIDS UNDER PRESSURE*

Standard: ISO 13994:2005

Method: A

- 0 kPa for 5 min
- 13.8 kPa for 10 min

Test liquid: Distilled water

Temperature: 22 ºC ± 2 ºC

Test date : 17/12/2020

Reference	Resistance to Penetration
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	PASS
	PASS
	PASS

RESULTS

DETERMINATION OF THE ABRASION RESISTANCE OF FABRICS

Standard
EN ISO 12947-2:2016
Apparatus
Martindale Abrasion Tester
Conditioning date 19/11/2020 **Test date** 04/01/2020
Atmosphere for conditioning and testing according accordance EN ISO 139:2005/A1:2011
Temperature (20±2) ºC **Relative humidity** (65±4) %
Testing conditions
Abrasive paper Trizact Grit A65
Technical characteristics of the sample
Not indicated by the client
Testing pressure
9 kPa
End point
Specimen breakdown
Reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Specimens	No. of cycles in the inspection interval before the end of the test is reached
1	400 < n < 1000
2	400 < n < 1000
3	400 < n < 1000
4	400 < n < 1000
Lowest individual result	**400 < n < 1000**

Remarks

The end test is performed by hydrostatic head end-point determination, according standard EN 14325:2018, point 4.4.2.3.

REQUISITE ACCORDING STANDARD EN 14126:2003

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
> 10 cycles	> 40 cycles	> 100 cycles	> 400 cycles	> 1000 cycles	> 2000 cycles

PERFORMANCE LEVEL 4

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RESULTS

WATER PENETRATION RESISTANCE. TEST UNDER HYDROSTATIC PRESSURE

Standard
EN 20811:1992 (Obsolete)
Apparatus
Hydrostatic Head Tester
Atmosphere for conditioning and testing
Temperature (20±2) ºC **Relative humidity** (65±4) %
Water temperature
20 ºC
Rate of increase of water pressure
10 cm H_2O/min ((980±50)Pa/min)
Surface exposed
External side
After abrasion test
According to standard EN 14325:2018 pto. 4.4.

Reference	Specimen	Pressure (mm/H_2O)
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	1 2 3 4	>200 >200 >200 >200

Remark
The edition of the standard used, does not correspond to the latest version released.

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RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD

Standard: ISO 16603:2004 Procedure: C

Principle:

A specimen is subjected to a body fluid stimulant (synthetic blood) for a specified time and pressure sequence. A visual observation is made to determine when, or if, penetration occurs. Any evidence of synthetic blood penetration constitutes failure. Results are reported as PASS / FAIL.
In the method, the specimen is inserted in the penetration cell with the normal outside surface of the textile towards the cell reservoir which is further filled with synthetic blood. The other face is in contact with retaining screen (which ensures a good bearing of the textile during the pressure application).

The pressure application procedure is the following:

- 0 KPa for 5 min
- 1,75 KPa for 5 min
- 3,5 KPa for 5 min
- 7 KPa for 5 min
- 14 KPa for 5 min
- 20 KPa for 5 min

Test date: 17/12/2020

Environmental condition: 22 ºC and 40 % H.R

Tested side: External side

Pretreatment: ---

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY SYNTHETIC BLOOD

Results:

Reference of the sample	D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389		
Results	**Replicate 1**	**Replicate 2**	**Replicate 3**
0 KPa for 5 min	PASS	PASS	PASS
1,75 KPa for 5 min	PASS	PASS	PASS
3,5 KPa for 5 min	PASS	PASS	PASS
7 KPa for 5 min	PASS	PASS	PASS
14 KPa for 5 min	PASS	PASS	PASS
20 KPa for 5 min	PASS	PASS	PASS
Retaining screen specifications	Not used		

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING Phi-X174

Standard: ISO 16604:2004.

Procedure: C.

Principle:

In the method, the material is placed in the test cell. The good side of the test material is directly in contact with a suspension of bacteriophage (phi-X174) After assembly, the cell is placed in the apparatus as defined in the standard and the corresponding pressure is applied:

- 5 minutes in contact without pressure application.
- 5 minutes at 20 kPa.

End of test, the sample surface that has not been in contact with the bacteriophage suspension is clarified. The rinsing liquid is then placed on an agar plate which has previously been inoculated with *Escherichia coli* (used as host bacteria of bacteriophage).The plates are incubated for 24 hours at 37 ° C, the presence of colonies on the agar surface means that the bacteriophage has passed through the sample.

Results are expressed in the form: PASS or FAIL test. The detection of only one plaque constitutes a failure of the textile.

Date test: 09/12/2020 – 10/12/2020

Dimension of the test specimens: 7,5 cm x 7,5 cm.

Bacteriophage: Bacteriophage Phi-X174 (ATCC 13706-B1).

Host bacteria of the used of bacteriophage: *Escherichia Coli* (ATCC 13706).

Retaining screen: not use.

Environmental condition: 22 ºC y/and 39 % H.R

Bacteriophage concentration:

- Starting: 3,06 $\cdot 10^8$ (PFU/ml)
- Ending: 2,16 $\cdot 10^8$ (PFU/ml)

Compatibility ratio: 1,04

Pretreatment: ---

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING Phi-X174

Results:

Reference	Test 1	Test 2	Test 3
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389	PASS (-)	PASS (-)	PASS (-)
Negative Control	(-)	(-)	(-)
Positive Control	(+)	(+)	(+)

Remarks:

- Symbols used in the table of results meaning the following:

  (+) = Penetration of bacteriophages.

  (-) = No penetration of bacteriophages.

- In accordance with the standard EN 14126:2003 point 4.1.4.1, the product should be classify as **CLASS 6** according with the following table:

Table of classification of resistance to penetration of contaminated liquids under hydrostatic pressure.

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[a]

[a] Means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell.

RESULTS

RESISTANCE TO WET BACTERIAL PENETRATION

Standard

EN 14126:2003/AC:2004; EN ISO 22610:2006

Test date

11/12/2020 - 14/12/2020

Verifications of equipment operation performed

-Adjustment of the force of the finger to 3 ± 0,02 N according to point 8.3.
-Verification with carbon paper according to point 10.2.
-Verification with reference material according to point 10.3.

Environmental conditions

- Temperature (ºC): 21
- Relative humidity (%): 38

Distance from the agar surface to the edge of the Petri dish (mm):

3

Size specimens:

25 cm x 25 cm

Carrier material

Material de PU (Schuett-biotec GmbH)

Staphylococcus aureus suspension ATCC 29213 (CECT 794) (cfu/mL)

21,100

Nº tested specimens

5

Pre-treatment

>>>

RESULTS

Sample reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389

Batch nº

Results

Replica	1	2	3	4	5
Test time	**ufc**	**ufc**	**ufc**	**ufc**	**ufc**
15 min	0	0	0	7	0
30 min	1	0	1	8	1
45 min	2	1	2	1	0
1 h	1	0	4	3	0
1h 15min	0	0	1	1	1
Test specimen upside down	288	260	289	234	205
cfu/plate maximum	2	1	4	8	1

Calculated barrier index I_B

Replica	1	2	3	4	5	Average[(2)]
I_B	6,0	6,0	5,9	5,7	6,0	**5,9** ± 0,2

Remarks
- [(2)]Average value (n = 5) ± U (extended uncertainty) for a probability of coverage of 95%

>>>

RESULTS

Remarks
In accordance with the standard EN 14126:2003/AC:2004 point 4.1.4.2, the product should be classified as **CLASS 1** according with the following table:

Table.Classification of resistance to penetration of biological agents by mechanical contact with substances containing contaminated liquids.

Class	Penetration time (t min)
6	t > 75
5	60 < t ≤ 75
4	45 < t ≤ 60
3	30 < t ≤ 45
2	15 < t ≤ 30
1	≤ 15 min

- [(1)]Data provided by the Customer.

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RESULTS

TEST METHOD FOR RESISTANCE TO DRY BACTERIAL BARRIER PENETRATION

Standard

EN ISO 22612:2005

Test date

01/12/2020 - 02/12/2020

Principle

The test is carried out on test pieces fixed each in a container. In each container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at base of each container at a short distance below the test piece.

The apparatus supporting the containers is then brought into vibration by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate. The sedimentation plates are removed and incubated; the numbers of colonies produced are counted.

Equipment

- 9 cm diameter Petri dishes containing TGE agar.
- 50 g of talc (95% < 15µ).
- Purified spores of Bacillus subtilis in a concentration of $8{,}8 \cdot 10^8$ ufc/g talc.
- 12 test pieces 20x20 cm, of reference barrier material.

Pre-treatment

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RESULTS

Sample reference
D-Lab Bioclean Isolation Gown - AAMI Level 3: SG 1389
Batch number[(1)]

Results

Test pieces	log (ufc)
1	0,00
2	0,48
3	0,00
4	0,00
5	0,00
6	0,00
7	0,00
8	0,00
9	0,00
10	0,00
Average	**0,05**

CLASS 3

Remarks
In accordance with the standard EN 14126:2003/AC:2004 point 4.1.4.4, the product should be classify as **CLASS 3** according with the following table:

Table. Classification of the Contaminated solid particles penetration resistance:

Class	Penetration log (ufc)
3	≤ 1
2	1 < log(ufc) ≤ 2
1	2 < log(ufc) ≤ 3

- [(1)]Data provided by the Customer.

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Lucia Martinez
Head of PPE and Ballistics department

Digitally signed by LUCIA MARTINEZ MOLTO - NIF:21651425F
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Reason: Responsable
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