EUROLAB Laboratory Services

TEST/INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

5190243IB02

2021092466

Report No:	2021092466
Applicant:	**EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞ. TAAH. TİC. A.Ş.** Saray Mah. Gıdacılar Cad. No:18 Kahramankazan / ANKARA - Turkey
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Sample Accepted on :	30.08.2021
Report Date:	24.09.2021
Total number of pages:	6 (pg)
Sample ID :	**Gloves / Eldiven** Lot 1: 100150 Lot 2: 100155 Lot 3: 100170

	TEST	METHOD	Specimen	RESULT
*	**Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection**	**EN 2859-1**	**Gloves**	**PASS**

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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 2859-1 Sampling Procedures For Inspection By Attributes – Part 1: Sampling Schemes Indexed By Acceptance Quality Limit (AQL) For Lot-By-Lot Inspection

Scope

The purpose of this standard is to use the economic and psychological pressure that arises from the rejection of an inspection lot to get a supplier to maintain an average quality level of the process that is at least as good as the specified acceptable quality limit The customer's upper risk limit ensures that the occasional bad inspection lot is accepted.

General

AQL is an industry standard. It is a statistical sampling process for evaluating quality. According to the International Standards Organization (ISO) (2859-1), AQL is "the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling". Process average is the typical percentage gloves in the lots/batches sampled of defective.

Procedure

AQL is a pass/fail where a predetermined sample size of a manufactured lot is tested following the sampling plan and protocols established by the various international standards or more stringent standards set by manufacturers to ensure stricter and higher quality is delivered to the customer.

The sampling plan is an inspection procedure of a sample size that is used to determine acceptance or rejection criteria from an inspection batch or lot.

First the manufacturer will need to know the size of the lot being manufactured; this is the amount of gloves produced without any conditions changing in a single run. Based on the lot size, the standards will determine the sampling ich is the number of gloves inspection, which randomly selected to be tested. The gloves tested, according with Statistical Quality Control, have all been through 'identical' processing and are truly representative of the total lot or batch. In this test, the gloves are filled with 1000 ml of water, bound or sealed at the cuff and hung upside down for two minutes and checked for leaks under sustained pressure. This is the recognised test method for global glove standards.

Requirements	
Glove Type	**AQL**
Examination gloves	1.5-2.5
The lower the AQL, the lower the chance of finding a defect in the batch of gloves and the higher the quality of the product.	

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<table>
<tr><th>Specimen</th><th>Characteristics</th><th>Requirements</th><th>Acceptable Quality Level (AQL)</th><th>Result</th></tr>
<tr><td rowspan="5">Gloves</td><td>Dimentions</td><td>
<table>
<tr><th>Description</th><th>Size</th><th>Standard</th></tr>
<tr><td>Length (mm)</td><td>All Sizes</td><td>Min 240</td></tr>
<tr><td rowspan="5">Palm width (mm)</td><td>Xs</td><td>76 ± 3</td></tr>
<tr><td>S</td><td>84 ± 3</td></tr>
<tr><td>M</td><td>94 ± 3</td></tr>
<tr><td>L</td><td>105 ± 3</td></tr>
<tr><td>XL</td><td>113 ± 3</td></tr>
<tr><td>Thickness (mm)</td><td>All Sizes</td><td>Finger: 0.05 ± 0.05
(Typical value: 0.11-0.14)

Palm: 0.05 ± 0.05
(Typical value: 0.10-0.12)</td></tr>
</table>
(See table 1)</td><td>1.5</td><td>PASS</td></tr>
<tr><td>Physical Properties</td><td>
<table>
<tr><th rowspan="2">Description</th><th colspan="2">Standard</th></tr>
<tr><th>Before Aging</th><th>After Aging</th></tr>
<tr><td>Elongation at Break %</td><td>Min 650</td><td>Min 500</td></tr>
<tr><td>Tensile Strength</td><td>Min 18</td><td>Min 14</td></tr>
</table>
(See table 2)</td><td>1.5</td><td>PASS</td></tr>
<tr><td>Freedom From Holes (Air Pump Test)</td><td>The sample sizes allowable number of non-conforming gloves in the samples shall be determined in accordance to sampling plane ISO 2859-1 single normal using inpection and acceptable quality level as stated in section II: performance requirements.
(See table 3)</td><td>1.5</td><td>PASS</td></tr>
<tr><td>Visual Defects</td><td>The sample size and allowable number of non-conforming gloves in the sampels for both major and minor defects shall be determined in accordance to sampling plane ISO 2859-1 single normal using inspection and acceptable quality level as stated in section II performance requirements.
(See table 3)</td><td>2.5-4</td><td>PASS</td></tr>
<tr><td>Packaging Defects</td><td>The Sample size and allowable number of non-conforming in the sample for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859- 1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirement (Gloves Counting = 100 pcs by weight per Dispenser).</td><td>4</td><td>PASS</td></tr>
<tr><td>Powder Free Residue</td><td>Maximum 2 mg per glove.
(See table 4)</td><td>--</td><td>PASS</td></tr>
</table>

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RESULT

Table 1

Sample No	Size	Length (mm)	Width (mm)	Thickness (mm)	
				Fingertip	Palm
Lot 1 : 100150					
1	L	270	108	0.07	0.06
2		271	109	0.10	0.05
3		265	108	0.11	0.10
4		264	109	0.06	0.08
Lot 2: 100155					
5	L	273	105	0.14	0.06
6		261	109	0.12	0.08
7		272	109	0.09	0.06
8		272	110	0.05	0.07
Lot 3: 100170					
9	L	271	108	0.09	0.07
10		273	108	0.10	0.06
11		274	108	0.09	0.07
12		276	107	0.08	0.05

Table 2

Sample No	Size	Before Aging		After Aging	
		Tensile Strength (MPa)	Elongation (%)	Tensile Strength (MPa)	Elongation (%)
Lot 1 : 100150					
1	L	18.3	522	18.1	504
2		18.1	503	18.0	501
3		18.7	528	18.6	517
4		18.1	505	18.1	504
Lot 2: 100155					
5	L	18.2	508	18.1	503
6		19.1	536	18.9	529
7		19.3	542	19.0	531
8		19.8	551	19.6	543
Lot 3: 100170					
9	L	19.5	545	19.4	541
10		19.2	540	19.0	534
11		18.8	534	18.5	514
12		19.7	549	19.5	536

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Table 3

Size	Holes			Visual defect						Result
				Major defect, AQL 2.5			Minor defects, AQL 4.0			
	Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	Sample Size (pcs)	Acceptance (pcs)	Defects (pcs)	
Lot 1 : 100150										
L	50	7	-	50	10	-	50	14	-	PASS
Lot 2: 100155										
L	50	7	-	50	10	-	50	14	-	PASS
Lot 3: 100170										
L	50	7	-	50	10	-	50	14	-	PASS

Table 4

Size	mg/Glove	Result
Lot 1 : 100150		
L	0.1 mg	PASS
Lot 2: 100155		
L	0.1 mg	PASS
Lot 3: 100170		
L	0.1 mg	PASS

IMAGE

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	Lot 1: 100150 Lot 2: 100155 Lot 3: 100170

	TEST	METHOD	Specimen	RESULT
*	**Standard Test Method for Rubber—Deterioration in an Air Oven**	**ASTM D 573**	**Gloves**	See table

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ASTM D 573 : Standard Test Method for Rubber—Deterioration in an Air Oven

Scope

This test method covers a procedure to determine the influence of elevated temperature on the physical properties of vulcanized rubber.

Procedure

- Place the specimens for aging in the oven after it has been preheated to the operating temperature.

- The operating temperature may be any elevated standard temperature as shown in Practice D1349, as agreed upon.

- Start the aging interval at the time the specimens are placed in the oven and continue for a measured time interval.

- Use aging intervals such that the deterioration will not be so great as to prevent determination of the final physical properties.

- At the termination of the aging interval, remove the specimens from the oven, cool to room temperature on a flat surface, and allow them to rest not less than 16 h nor more than 96 h before determination of the physical properties.

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Result

Before Test Value				After Test Value			
Elognation	Tensile Strength	Hardness (Shore A)	Visual Inspection	Elognation	Tensile Strength	Hardness (Shore A)	Visual Inspection
Lot 1: 100150							
522	18.3	73	-	504	18.1	71.5	NP
503	18.1	73	-	501	18.0	71	NP
528	18.7	73	-	517	18.6	71.5	NP
505	18.1	73	-	504	18.0	71.5	NP
Lot 2: 100155							
508	18.2	73	-	503	18.1	71	NP
536	19.1	73	-	529	18.9	71	NP
542	19.3	73	-	531	19.0	71.5	NP
551	19.8	73	-	543	19.6	71	NP
Lot 3: 100170							
545	19.5	73	-	541	19.4	71	NP
540	19.2	73	-	534	19.0	71.5	NP
534	18.8	73	-	514	18.5	71	NP
549	19.7	73	-	536	19.5	71	NP

NP: There was no problem in the sample examined after the test.

Calculation Value			
Elognation	Tensile Strength	Hardness (Shore A)	Visual Inspection
Lot 1: 100150			
%3.4	%1.1	%2.1	NP
%0.4	%0.6	%2.7	NP
%2.1	%0.5	%2.1	NP
%0.2	%0.6	%2.1	NP
Avg: %1.5	**Avg:** %0.7	**Avg:** %2.3	**Avg:** NP
Lot 2: 100155			
%1.0	%0.5	%2.7	NP
%1.3	%1.0	%2.7	NP
%2.0	%1.6	%2.1	NP
%1.5	%1.0	%2.7	NP
Avg: %1.5	**Avg:** %1	**Avg:** %2.6	**Avg:** NP

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Lot 3: 100170			
%0.7	%0.5	%2.7	NP
%1.1	%1.0	%2.1	NP
%3.7	%1.6	%2.7	NP
%2.4	%1.0	%2.7	NP
Avg: %2.0	**Avg:** %1	**Avg:** %2.6	**Avg:** NP

IMAGE

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	TEST	METHOD	Specimen	RESULT
*	**Standard Practice for Rubber—Measurement of Dimensions**	**ASTM D 3767**	**Gloves**	See table

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ASTM D 3767 : Standard Practice for Rubber—Measurement of Dimensions

Scope

This practice is intended for use in determining the geometrical dimensions of rubber products and specimens for physical tests. This practice describes procedures for determining length, width, thickness, diameter, and circumference.

Conditioning

Unless otherwise specified in the detail specifications or test method, geometrical measurements shall be made after conditioning test specimens for 24 h at 23 ± 5°C.

Procedure

If the test specimen is so thin that it will not support itself edgewise, it may be mounted in a slit cut in a cork or other mounting device. Place the ruled glass disk on the cut surface of the cross section with the ruled surface in contact with the test specimen. Read the thickness, if in the field of view, directly from the rulings on the disk to the nearest 0.005 mm. If the thickness is such that it does not all lie within the field of view, move the test specimen by means of the mechanical stage until the complete section thickness passes through the field. Count the rulings on the disk passed over during the movement and record the distance to the nearest 0.005 mm. When the scale is used in the eyepiece, place the ruled glass disk or ocular micrometer in the ocular and calibrate by placing a graduated scale on the stage. Place the test specimen on the stage with the surface to be measured perpendicular to the optical axis of the microscope so as to expose the full thickness. Focus the microscope on the test specimen and determine the thickness by counting the divisions of the ruled disk in the eyepiece that cover the distance from one edge of the test specimen to the other. Record the distance to the nearest 0.005 mm. Equally space four measurements over the test specimen.

Parameter \ Sample	Lot 1: 100150	Lot 2: 100155	Lot 3: 100170
Length	270 mm	273 mm	271 mm
	271 mm	261 mm	273 mm
	265 mm	272 mm	274 mm
Width	108 mm	105 mm	108 mm
	109 mm	109 mm	108 mm
	108 mm	109 mm	108 mm
Thickness	0.06 mm	0.06 mm	0.07 mm
	0.05 mm	0.08 mm	0.06 mm
	0.10 mm	0.06 mm	0.07 mm

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	TEST	METHOD	Specimen	RESULT
*	**Standard Test Method for Detection of Holes in Medical Gloves**	**ASTM D 5151**	**Gloves**	**PASS**

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ASTM D 5151 : Standard Test Method for Detection of Holes in Medical Gloves

Scope

- This test method covers the detection of holes in medical gloves.
- This test method is limited to the detection of holes that allow water leakage under the conditions of the test.

Procedure

- Ensure that the exterior of the glove remains dry.

- Mount the mandrel in a vertical position using appropriate stands, clamps, and hangers. Affix the glove to the mandrel by stretching the cuff of the glove around the mandrel. A maximum 40 mm of glove cuff should fit over the bottom end of the mandrel. Use the securing device, as necessary, to hold the glove in place. The remainder of the glove should hang freely from the mandrel when filled with water.

- Pour a minimum of 1000 cm^3 of water having a room temperature of 15 to 30°C into the top of the mandrel. The water shall pass freely into the glove.

- Visually inspect the glove for immediate water leakage. Let the glove hang for 2 min and again inspect for water leakage.

Interpretation of Results

-Any glove that shows a droplet, stream, or other type of water leakage shall be considered to have failed the test.

- Water leakage above the junction of the glove cuff and mandrel is not a test failure. If this leakage occurs, remove and dry the outside of the glove and retest.

Result

Specimen No	Lot 1: 100150	Lot 2: 100155	Lot 3: 100170
#1	No holes	No holes	No holes
#2	No holes	No holes	No holes
#3	No holes	No holes	No holes
#4	No holes	No holes	No holes
#5	No holes	No holes	No holes

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*	**Standard Test Method for Residual Powder on Medical Gloves**	**ASTM D 6124**	**Gloves**	**PASS**

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ASTM D 6124 : Standard Test Method for Residual Powder on Medical Gloves

Scope

- This test method covers the determination of average powder or filter-retained mass found on a sample of medical gloves as described in the introduction.
- The average powder mass per glove is reported in milligrams.

Filter Preparation:

- Use a 47 mm, 2.7 µm pore size glass microfiber filter and a suction filtration apparatus.

- Insert the filter disk in the filtration apparatus. Apply suction and wash the filter disk with three successive 50 mL portions of deionized or distilled water. Continue suction to remove all traces of water and discard the washings. Remove the filter from the filtration apparatus and transfer it to a rinsed and dried glass petri dish or equivalent. Dry in an oven at 100 ± 5°C for 1 h. Store the dried filter in a desiccator prior to use. Before use, pre-weigh the dried filter, weighing immediately after removal from the desiccator.

Sample Selection and Test:

- Randomly select five gloves from each lot to be evaluated.

- Place 500 mL of deionized or distilled water into a 1000 mL flask. Water used in this procedure should be at 20 to 25°C.

- Place a glove into the beaker/flask with 1 to 3 cm of the cuff area stretched over the lip. Hold a portion of the cuff away from the lip to vent air from the beaker/flask and add 250 mL of deionized or distilled water to the inside of the glove, making certain the upper cuff is rinsed as the water is poured. Additional water may be used if coverage on the glove exterior is insufficient, or as needed for vacant space within the glove. However, space must be adequate to allow agitation.

- Cap the flask with a rubber stopper or other secure cover and agitate for 30 s on a mechanical shaker with a minimum side-to-side or rotational speed of 1.7 Hz (100 cycles/min).

- Remove the cap and pour the water from the inside of the glove into a 600 mL glass beaker.

- Pour the water from the 600 mL glass beaker and the beaker/flask through the suction filtration unit containing the weighed filter.

- Rinse the 600 mL glass beaker with 250 mL of deionized or distilled water. Successively add the rinse water to the beaker/flask and into the suction filtration unit containing the weighed filter.

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- Rinse the beaker/flask, cap, filter housing and any other portions of the test apparatus that may contain residual powder to ensure all powder extract is filtered.

- Continue suction to remove all traces of water and discard the washings. Remove the filter from the filtration apparatus and transfer it to a rinsed and dried glass petri dish or equivalent. Dry in an oven at 100 ± 5°C for 1 h. Cool in a desiccator for 30 min prior to weighing. Weigh immediately after removal from the desiccator.

Lot 1: 100150	
Sample 1	0.1 mg
Sample 2	0.1 mg
Sample 3	0.3 mg
Sample 4	0.1 mg
Sample 5	0.3 mg
Lot 2: 100155	
Sample 1	0.1 mg
Sample 2	0.2 mg
Sample 3	0.1 mg
Sample 4	0.1 mg
Sample 5	0.1 mg
Lot 3: 100170	
Sample 1	0.1 mg
Sample 2	0.2 mg
Sample 3	0.1 mg
Sample 4	0.3 mg
Sample 5	0.1 mg

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IMAGE

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EUROLAB Laboratory Services

TEST/INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

5190243IB02

2021092471

Report No:	2021092471
Applicant:	**EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞ. TAAH. TİC. A.Ş.** Saray Mah. Gıdacılar Cad. No:18 Kahramankazan / ANKARA - Turkey
Contact Person:	Mine SEVİMLİ
Contact Telephone:	0312 577 2119
Contact e-mail:	minesevimli@enmedglobal.com
Sample Accepted on :	30.08.2021
Report Date:	24.09.2021
Total number of pages:	5 (pg)
Sample ID :	**Gloves / Eldiven**
	Lot 1: 100150 Lot 2: 100155 Lot 3: 100170

	TEST	METHOD	Specimen	RESULT
*	**Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs**	**ASTM D 6978**	**Gloves**	See table

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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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ASTM D 6978 : Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Scope

This practice covers a protocol for the assessment of resistance of medical glove materials to permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact. An assessment is made based on the permeation of nine chemotherapy drugs through the glove material over a certain period of time.

Test Protocol:

- Cut one 5 by 5-cm piece of material from the palm or cuff of each test medical glove, whichever area measured thinnest. Identify the outer side of the sample.

- One test sample shall be obtained from each of the three test medical gloves. As a result, there will be a minimum of 27 test samples obtained when testing against the nine test drugs. The number of test drugs, nine, is a minimum.

- Representative Drugs to be Tested:

See table 1.

-Test Conditions:

The test shall be conducted at 35 ± 2°C and the temperature recorded.

- The outer surface of the glove material shall contact the donor solution of the test drug.

- The collection medium shall be mixed continuously.

- The test duration shall be 4 h, during which an aliquot of an appropriate volume of the collection medium shall be removed at least every 30 min from the collection cell for the measurement of the concentration of the test drug in the collection medium based on drug manufacturer's recommended detection method.

- The collection cell shall be replenished immediately with the same volume of the liquid removed from the collection medium.

Test Termination:

- The test shall be terminated after 4 h.

- The breakthrough shall be deemed to have occurred when the quantitative analysis based on drug manufacturer's recommended detection method, detects a permeation rate of 0.01 $\mu g/cm^2/min$.

- Each test glove material shall be inspected at the end of the test period for physical changes, such as signs of flaking, swelling, disintegration, embrittlement, discoloration, or other physical changes.

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Table 1

Chemotherapy Drugs	Concentration (mg/ml)
Carmustine	3.3
Cyclophosphamide	20.0
Doxorubicin HCl (Adriamycin)	2.0
Etoposite	20.0
Fluorouracil (Adrucil)	50.0
Paclitaxel (Taxol)	6.0
ThioTEPA	10.0
Cisplatin	1.0
Cytarabine	100
Dacarbazine	10.0
Ifosfamide	50.0
Methotrexate	25.0
Mitomycin C	0.5
Mitoxantrone	2.0
Vincristine sulfate	1.0

Sample / Drugs	Lot 1: 100150	Lot 2: 100155	Lot 3: 100170
Carmustine	>480 min	>480 min	>480 min
Cyclophosphamide	>480 min	>480 min	>480 min
Doxorubicin HCl (Adriamycin)	>480 min	>480 min	>480 min
Etoposite	>480 min	>480 min	>480 min
Fluorouracil (Adrucil)	>480 min	>480 min	>480 min
Paclitaxel (Taxol)	>480 min	>480 min	>480 min
ThioTEPA	>480 min	>480 min	>480 min
Cisplatin	>480 min	>480 min	>480 min
Cytarabine	>480 min	>480 min	>480 min
Dacarbazine	>480 min	>480 min	>480 min
Ifosfamide	>480 min	>480 min	>480 min
Methotrexate	>480 min	>480 min	>480 min
Mitomycin C	>480 min	>480 min	>480 min
Mitoxantrone	>480 min	>480 min	>480 min
Vincristine sulfate	>480 min	>480 min	>480 min

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Visual Inspection	Glove samples withstood the drug permeability test for 480 minutes. No visual disturbance was detected in the sample.

IMAGE

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2021092473

Report No:	2021092473
Applicant:	**EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞ. TAAH. TİC. A.Ş.** Saray Mah. Gıdacılar Cad. No:18 Kahramankazan / ANKARA - Turkey
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Sample Accepted on:	30.08.2021
Report Date:	24.09.2021
Total number of pages:	6 (Pg)
Sample ID:	**Gloves / Eldiven** Lot 1: 100150 Lot 2: 100155 Lot 3: 100170

	TEST	METHOD	Specimen	RESULT
*	**Nitrile Examination Gloves for Medical Application**	**ASTM D 6319**	**Gloves**	**PASS**

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Scope

This specification covers certain requirements for nitrile rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures. This specification covers nitrile rubber examination gloves that fit either hand, paired gloves, and gloves by size. It also provides for packaged sterile or nonsterile or bulk nonsterile nitrile rubber examination gloves.

Sampling

For referee purposes, gloves shall be sampled from finished product, after sterilization when labeled sterile, and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall conform to those specified in Table 1.

Methods

The following tests shall be conducted to ensure the requirements prescribed in Table 1.

ASTM D 5151 Detection of Holes in Medical Gloves

Reagents

Tap Water—The water used in this test method shall be clean and free from any visible contaminants.

Procedure

Ensure that the exterior of the glove remains dry.

Mount the mandrel in a vertical position using appropriate stands, clamps, and hangers. Affix the glove to the mandrel by stretching the cuff of the glove around the mandrel. A maximum 40 mm of glove cuff should fit over the bottom end of the mandrel. Use the securing device, as necessary, to hold the glove in place. The remainder of the glove should hang freely from the mandrel when filled with water.

Pour a minimum of 1000 cm^3 of water having a room temperature of 15 to 30°C into the top of the mandrel. The water shall pass freely into the glove.

Visually inspect the glove for immediate water leakage. Let the glove hang for 2 min and again inspect for water leakage.

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Physical Dimensions Test

The gloves shall comply with the dimension requirements prescribed in Table 2.

The length shall be expressed in millimetres as measured from the tip of the middle finger to the outside edge of the cuff.

The width of the palm shall be expressed in millimetres as measured at a level between the base of the index finger and the base of the thumb. Values of width per size other than listed shall meet the stated tolerance specified in Table 2.

Characteristics	Related Defects	Inspection Level	AQL
Sterility	Fails sterility	-	N/A
Freedom From Holes	Holes	G-1	2.5
Dimensions	Width, length and thickness	S-2	4.0
Physical Properties	Before aging, after accelerated aging	S-2	4.0
Powder-Free Residue	Exceed max. limits	N=5	N/A
Powder Amount	Exceed recommended max. limits	N=2	N/A

TABLE 1. Performance Requirements

	Size							
Designation	**6**	**$6^{1/2}$**	**7**	**$7^{1/2}$**	**8**	**$8^{1/2}$**	**9**	**Tolerance, mm**
Width by size	75	83	89	95	102	108	114	±6
Width by		X small 70	Small 80	Unisize 85	Medium 95	Large 110	X large 120	±10
Length		220	220	230	230	230	230	min
Thickness, mm **Finger** **Palm**				0.05 0.05				min min

TABLE 2. Dimensions and Tolerances

Physical Requirements Test

Accelerated Aging

Before and after accelerated aging, the gloves shall conform to the physical requirements specified in Table 3.

After being subjected to a temperature of 70 ± 2°C for 166 ± 2 h, the tensile strength and ultimate elongation shall not be less than the values specified in Table 3. This method shall be the conditions for referee tests.

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RESULT

Physical Dimensions	
Designation	$8^{1/2}$
Width by size	108
Width by	Large 110
Length	271
Thickness, mm **Finger** **Palm**	 0.09 0.07
Tolerance	±10 mm

TEST	METHOD	OBSERVATION	RESULT
Freedom from Holes	ASTM D 5151	During test, There was no water leakage after 2 minutes.	PASS
Powder Free Glove Limit	ASTM D 6124	-	0.1 mg

Physical Rquirement Test (ASTM D 412)			
Before aging		After accelerated aging	
Tensile Strength	**Ultimate Elongation**	**Tensile Strength**	**Ultimate Elongation**
> 14 MPa	500 %	> 14 MPa	400 %

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IMAGE

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