455 - Metal Detectable Disposable Nitrile

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Detectamet are happy to announce a new product to the market, metal detectable nitrile gloves. This product offers a long lasting, low tear rate, metal detectable glove solution, for use within any industry but aimed at the food and pharmaceutical. These gloves have met and exceeded the requirements to be EU & FDA food contact approved. Full testing documentation is available upon request.

This Declaration of Compliance Statement document is appropriate for the following products:

Product Code	Product Description	Product Sizing:
455-A265	Metal Detectable Nitrile Gloves: Medium	Length 243 mm (9.56"). Width 85 mm (3.34").
455-A265	Metal Detectable Nitrile Gloves: Large	Length 244 mm (9.60"). Width 95 mm (3.74").
455-A265	Metal Detectable Nitrile Gloves: Extra Large	Length 245 mm (9.64"). Width 105 mm (4.13").

1.1 – Type

Metal Detectable Nitrile Disposable Glove, Powder Free, online Single Chlorinated, Non-sterile.

1.2 - Material

100% Synthetic Nitrile Latex.

1.3 - Colour

Blue.

1.4 - Design and Feature

Ambidextrous, finger textured, beaded cuff.

1.5 - Powder

No powder lubricant added.

1.6 - Storage Condition

The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.

1.7 - Shelf Life

The gloves shall have shelf life of 3 years from the date of manufacture with the above storage condition.

1.8 - Size Marking

The size of gloves shall be marked in the check box on every carton with black ink

1.9 – Application

Metal detectable nitrile gloves can be detected using metal detector which are commonly used in food & beverages industries to detect fragments of metal presence and becoming as an indicator for contaminated batches.

1.10 - PFAS

These gloves do not contain any perfluoroalkyl and polyfluoroalkyl substances (PFAS)

Section 2: Performance Requirements

Sampling Plan: ISO 2859 Single Normal

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
2.1	Dimensions	S2	4.0	ASTM D6319-19
2.2	Physical Properties	S2	4.0	ASTM D6319-19
2.3	Freedom from Holes Air Pump Test	GI	4.0	In house practice
2.4 i ii	Visual Defects: Major Visual Minor Visual	GI	2.5 4.0	In house practice
2.5 i ii iii	Packaging Defects: i) Regulatory ii) Visual iii) Critical incl. Gloves Counting	GI GI S2	** 4.0 4.0	In house practice
2.6	Powder Free Residue	N=5	N/A	ASTM D6319-19 ASTM D6124-06 (2017)
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

Section 3: Performance Specification

3.1 Dimensions

Description	Size	Standard (mm)
Length, mm	All Sizes	Min 240
Palm Width, mm	M L XL	94 +/- 3 105 +/- 3 113 +/- 3
Thickness, mm *Single wall	All Sizes	Finger: 0.11 +/- 0.02 (4 ± 0.1 MIL) Typical value: 0.12 to 0.13 Palm: 0.07 +/- 0.02 (2.75 ± 0.1 MIL) Typical value: 0.07 to 0.09

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break, %	Min 500 Typical value: 500 to 600	Min 400 Typical value: 400 to 550
Tensile Strength, MPa	Min 14 Typical value: 14 to 18	Min 14 Typical value: 14 to 18

3.3 Freedom from Holes

The sample size and allowable number of non-conforming gloves in the samples shall be determined in accordance with Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Defects
The sample size and allowable number of non-conforming gloves in the samples for both major and minor defects shall be determined in accordance with Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.5 Packaging Defects
The Sample size and allowable number of non-conforming in the samples 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 Requirements, Gloves Counting = 100 pcs by count per Dispenser.

3.6 Powder Free Residue
Maximum 2mg per glove.

Section 4: Certificate of Analysis

The following is a report on the analysis of two (2) samples per size. The sample was tested in accordance with the test method(s) stipulated.

Product: Glove

Test Parameter: Migration using 50% Ethanol and 3% Acetic Acid

Method: Overall Migration Test (EU No. 10/2011)

Factory: F9

Glove Sample	Simulant	
	50% Ethanol (mg/dm3)	3% Acetic Acid (mg/dm3)
Blue MDG CW40 (M Size)	7.74	9.10
EU No. 10/2011 Overall Migration Standard	≤ 10 mg/dm3	≤ 10 mg/dm3

Remark:

1) The glove sample passes the overall migration test by using both 50% ethanol and 3% acetic acid.

Test Report

1. Freedom from Holes and Visual Defects

Size	Holes			Visual Defect, Inspection Level: G1						Result
	Inspection Level: G1, AQL 4.0			Major Defects, 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	
S	200	14	7	200	10	6	200	14	7	Pass
M	200	14	7	200	10	4	200	14	5	Pass
L	200	14	8	200	10	5	200	14	6	Pass

2. Dimensions

Inspection Level: S2, AQL 4.0 Result: Pass
Acceptance: 1

Sample No.	Size	Length, mm	Width, mm	Thickness single wall, mm	
				Fingertip	Palm
1	S	244	86	0.13	0.08
2		243	87	0.12	0.09
3		245	85	0.12	0.08
4		245	86	0.13	0.08
5	M	244	98	0.13	0.09
6		245	96	0.13	0.07
7		245	96	0.12	0.08
8		248	97	0.12	0.07
9	L	246	105	0.13	0.09
10		244	106	0.11	0.08
11		245	106	0.12	0.08
12		246	107	0.12	0.07
13		246	106	0.13	0.09

ASTM D6319 – 19 Requirment

Size	Length, mm	Width, mm	Thickness, mm
XS	≥220	70 ± 10	Finger and palm Single wall Min0.05
S		80 ± 10	
M	≥230	95 ± 10	
L		110 ± 10	
XL		120 ± 10	
XXL		130± 10	

3. Physical Properties

Inspection Level: S2, AQL 4.0 Result: Pass
Acceptance: 1

Sample No.	Size	Before Aging		After Accelerated Aging	
		Tensile Strength, Mpa	Elongation, %	Tensile Strength, Mpa	Elongation, %
1	S	18.2	620	16.2	482
2		16.5	580	15.6	489
3		18.5	625	16.2	465
4		17.8	620	16.0	472
5	M	19.8	618	16.2	485
6		18.8	665	15.8	536
7		19.4	680	16.2	528
8		18.5	645	15.2	532
9	L	16.8	650	16.5	528
10		19.8	636	15.4	550
11		17.5	623	15.8	532
12		16.8	668	15.5	508
13		17.6	683	15.2	520

ASTM D6319 – 19 Requirement

Before Aging		After Accelerated Aging	
Tensile	Elongation	Tensile	Elongation
Min 14 MPa	Min 500%	Min 14 MPa	Min 400%

4. Powder Residue

Sampling size, N = 5
Requirment: Max 2 mg/glove

Size	Mg / glove	Result
S	0.8	Pass
M	1.0	Pass
L	1.2	Pass

Conclusion: We hereby certify that the above consignment of goods were determined to meet the acceptable limit of the specifications as referring to the findings of randomly selected samples.

Helen Morrison
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