

## CERTIFICATE OF ANALYSIS

**Product Description :** HALYARD\* PUREZERO\* HG3 Sterile Light Blue Nitrile Gloves - Pairs

**Catalog Numbers :** CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210

**OMH Code :** 48172-80, 48173-80, 48174-80, 48175-80, 48176-80, 48177-80, 48178-80, 48179-80

**Batches :** SM221326X to SM224326X

**Total Cases per Lot :** 507

**Date of Manufacture :** Aug-22

**Expiration Date :** 2027-07-30

### Physical Test Data

	Watertight	Visual Defects		Dimensions	Tensile (MPa)	Elongation (%)	Median Force at Break (N)
		Minor	Negligible		Pre Aging	Pre Aging	Pre Aging
Sample Size :	485	485	485	65	52	52	52
AQL Level :	1.0	2.5	4.0	4.0	4.0	4.0	4.0
Failures Allowed per AQL :	7	18	28	5	4	4	4
Failures :	0	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
<b>Averages:</b>					35.85	564	8.31

Test Methods : Water tight test ASTM D 5151, EN 455-1, Elongation and Tensile ASTM D 412, ASTM D 6319, Median Force at Break EN 455-2, Dimension ASTM D 6319, EN 455-2

### Particle Test Data

Particle	Min	Max	Average Particles/cm <sup>2</sup>	Inspection Result
#/cm <sup>2</sup> :	677	947	849	Accept

Particulate Level (≥0.5 microns) #/cm<sup>2</sup>

Test Method : IEST-RP-CC005.4

### Extractable Ion Test Data

	Anions Results				Cations Results			
	Chloride	Nitrate	Sulfate	Sodium	Ammonium	Potassium	Magnesium	Calcium
Units :	Cl <sup>-</sup>	NO <sub>3</sub> <sup>-</sup>	SO <sub>4</sub> <sup>-2</sup>	Na <sup>+</sup>	NH <sub>4</sub> <sup>+</sup>	K <sup>+</sup>	Mg <sup>+2</sup>	Ca <sup>+2</sup>
µg/g glove	12.340	15.537	1.733	3.124	1.732	2.528	1.732	22.034
Inspection Result :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

#### Trace Element Results

Units :	Zinc
	Zn
µg/g glove	2.70
Inspection Result :	Accept

Test Method : IEST-RP-CC005.4

### Endotoxin Test Data

<b>Test Result :</b>	BD	Endotoxin Units/ device
<b>Specification :</b>	≤ 20	Endotoxin Units/ device

Detection Limit is ≤ 0.4 EU/device : BD = Below Detection Limit

Test Method : Limulus Amebocyte Lysate (LAL) Test: Kinetic Turbidimetric Technique

#### Sterility Data

This product conforms to standards for sterility ISO11137 with sterility assurance level (SAL) 10<sup>-6</sup>. A Certificate of Irradiation is also available to assure that the product has received the specified radiation dosage.

Review By :

14 Sept 2022  
 ( QA Sr. Manager )