

Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla 90120 Thailand

CERTIFICATE OF ANALYSIS

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

Catalog Numbers : CLN923265, CLN923280

OMH Code : 48173-81, 48176-81

Total Cases per Lot : 150

Date of Manufacture : 2024-08-24

Expiration Date : 2027-07-30

Batches : SM423726X

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 :	125	125	125	26	13	13	13
AQL Level :	1.0	2.5	4.0	4.0	4.0	4.0	4.0
Failures Allowed per AQL :	2	5	7	2	1	1	1
Failures :	0	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
Averages:					38.35	612	8.63

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	Total Particles/cm ²	Inspection Result
#/cm ² :	848	Accept
Particulate Level (≥0.5 microns) #/cm ²		

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data

	Anions Results				Cations Results			
	Chloride	Nitrate	Sulfate	Sodium	Ammonium	Potassium	Magnesium	Calcium
Units :	Cl ⁻	NO ₃ ⁻	SO ₄ ⁻²	Na ⁺	NH ₄ ⁺	K ⁺	Mg ⁺²	Ca ⁺²
µg/g glove	20.196	5.322	1.822	2.076	4.619	2.369	1.822	7.846
Inspection Result :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

Trace Element Results

Units :	Zinc Zn
µg/g glove	6.23
Inspection Result :	Accept

Test Method : IEST-RP-CC005.4

Endotoxin Test Data

Test Result :	0.3922	Endotoxin Units/ device
Specification :	≤ 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) 10⁻⁶. A Certificate of Irradiation is also available to assure that the product has received the specified radiation dosage.

Review By : *Janis Ch 13-Sep-24*

(QA Sr. Manager)

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