

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 : CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210

OMH Code : 48172-81, 48173-81, 48174-81, 48175-81, 48176-81, 48177-81, 48178-81, 48179-81

Batches : SM412226X to SM415226X

Total Cases per Lot : 3,213

Date of Manufacture : May-24

Expiration Date : 2027-04-30

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 :	1975	1975	1975	286	143	143	143
AQL Level :	1.0	2.5	4.0	4.0	4.0	4.0	4.0
Failures Allowed per AQL :	30	71	109	22	11	11	11
Failures :	5	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
Averages:					39.15	613	9.02

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 :	852	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	27.283	4.166	1.929	3.102	2.738	2.311	1.735	14.033
Inspection Result :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

Trace Element Results	
Units :	Zinc
	Zn
µg/g glove	6.33
Inspection Result :	Accept

Test Method : IEST-RP-CC005.4

Endotoxin Test Data

Test Result :	0.3741	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 :

Q.S. 14 JUN 2024

(QA Sr. Manager)