

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 : 48172-00, 48173-00, 48174-00, 48175-00, 48176-00, 48177-00, 48178-00, 48179-00

Batches : SM203226X to SM205926X
SM203226V to SM205926V

Total Cases per Lot : 2,661
Date of Manufacture : Feb-22
Expiration Date : 2027-01-30

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 :	2955	2457	2334	519	285	285	285
AQL Level :	1.0	2.5	4.0	4.0	4.0	4.0	4.0
Failures Allowed per AQL :	39	87	125	35	18	18	18
Failures :	0	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
Averages:					35.00	591	7.88

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 ²	Inspection Result
#/cm ² :	541	948	838	Accept

Particulate Level (≥0.5 microns) #/cm²

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	25.869	15.927	3.307	3.882	1.773	2.344	1.663	32.850
Inspection Result :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

Trace Element Results

Units :	Zinc
	Zn
µg/g glove	3.18
Inspection Result :	Accept

Test Method : IEST-RP-CC005.4

Endotoxin Test Data

Test Result :	BD	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 ISO11737 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 :

 10 May 2022

(QA Sr. Manager)