

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 White Nitrile Gloves - Pairs

Catalog Numbers : CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323285, CLN323290, CLN323210

OMH Code : 48192-80, 48193-80, 48194-80, 48195-80, 48196-80, 48197-80, 48198-80, 48199-80

Batches : SM221325X to SM224325X

Total Cases per Lot : 254

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 :	125	125	125	39	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	3	1	1	1
Failures :	0	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
Averages:					36.60	571	12.50

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 :	437	542	485	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	27.359	8.366	3.769	4.258	1.229	1.219	0.938	20.037
Inspection Result :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

Trace Element Results

Units :	Zinc
	Zn
µg/g glove	2.55
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 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 :

GA, 14 Sept 2022

(QA Sr. Manager)