

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 : SM421426X to SM424426X

Total Cases per Lot : 2,714

Date of Manufacture : Aug-24

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 :              | 2260       | 2260           | 2260       | 585        | 221           | 221            | 221                       |
| AQL Level :                | 1.0        | 2.5            | 4.0        | 4.0        | 4.0           | 4.0            | 4.0                       |
| Failures Allowed per AQL : | 35         | 87             | 127        | 45         | 17            | 17             | 17                        |
| Failures :                 | 0          | 0              | 0          | 0          | 0             | 0              | 0                         |
| Inspection Results :       | Accept     | Accept         | Accept     | Accept     | Accept        | Accept         | Accept                    |
| Averages:                  |            |                |            |            | 40.03         | 588            | 9.78                      |

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                     | Inspection |
|----------------------------------------------------|---------------------------|------------|
| #/cm <sup>2</sup> :                                | Particles/cm <sup>2</sup> | Result     |
|                                                    | 880                       | 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          | 21.428          | 4.440                        | 1.922                         | 2.453           | 2.136                        | 2.269          | 1.626            | 18.854           |
| Inspection Result : | Accept          | Accept                       | Accept                        | Accept          | Accept                       | Accept         | Accept           | Accept           |

### Trace Element Results

|                     | Zinc   |
|---------------------|--------|
| Units :             | Zn     |
| µg/g glove          | 6.41   |
| Inspection Result : | Accept |

Test Method : IEST-RP-CC005.4

### Endotoxin Test Data

|                 |        |                         |
|-----------------|--------|-------------------------|
| Test Result :   | 0.7044 | 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<sup>-6</sup>. A Certificate of Irradiation is also available to assure that the product has received the specified radiation dosage.

Review By :

*Champh A 13-sep-24*

( QA Sr. Manager )