

Halyard



## Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323290

pure<sup>11</sup>-Nr.: 1105211, Marke: Halyard

### Eigenschaften

- Steril
- Marke: Halyard
- Handschuhtyp: Dünnsfilm
- Länge in cm: 30,5 cm
- Chemikalienbeständigkeit - Typ: Typ C
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Zytostatikageeignet
- Lebensmittelkonformität
- Silikonfrei
- Vulkanisationsbeschleunigerfrei
- Verpackungsform: paarweise verpackt
- Antistatisch
- AQL (Acceptable Quality Level)-Wert: 0,65
- Länge in Inches: 12 In
- Latexfrei
- Materialzusammensetzung: Reinmaterial
- Oberflächenbeschaffenheit: glatt

### Empfohlene

### Reinraumklassen

ISO 3|4|5|6|7|8|9

GMP A/B|C|D



- Reißfestigkeit EN 455-2 ASTM in MPa: 20-30
- Schutz vor Blut und Körpersekreten ISO 16604:2004
- Passform Hand: handspezifisch
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,16 mm

### **Material**

- Nitril

### **Verpackung**

- 200PAAR

## Produktvarianten

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**pure<sup>11</sup>-Nr.: 1105211WH9, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323290**

Farbe: Weiß; Größe: 9 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1105211WH10, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323210**

Farbe: Weiß; Größe: 10 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1105211WH6, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323260**

Farbe: Weiß; Größe: 6 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1105211WH6\_5, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323265**

Farbe: Weiß; Größe: 6,5 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1105211WH7, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323270**

Farbe: Weiß; Größe: 7 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1105211WH7\_5, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323275**

Farbe: Weiß; Größe: 7,5 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1105211WH8, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323280**

Farbe: Weiß; Größe: 8 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1105211WH8\_5, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN323285**

Farbe: Weiß; Größe: 8,5 / VE: 200PAAR

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# HALYARD\* **PUREZERO\*** HG3 WHITE STERILE CLEANROOM GLOVES

DATA PACK



For the Cleanroom Environment  
For Industrial Use Only

# HALYARD\* **PUREZERO\*** HG3 WHITE STERILE CLEANROOM GLOVES DATA PACK

Some documents depicted here are FOR EXAMPLE ONLY. For specific documents related to lot numbers, please visit [www.halyardhealth.com/information](http://www.halyardhealth.com/information), or ask your Distributor or HALYARD\* Representative.

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# TECHNICAL DATA SHEET

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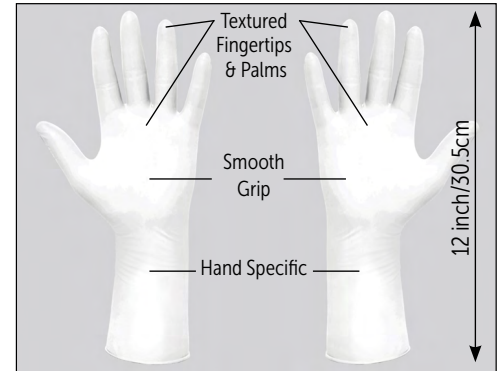
# TECHNICAL DATA SHEET

 Meets  
 USP <797>  
 Guidelines.

 Meets  
 USP <800>  
 Guidelines.

## Description

HALYARD\* **PUREZERO\*** HG3 White Sterile Nitrile Cleanroom Gloves are designed for critical cleanroom environments such as pharmaceutical and biotechnology cleanroom manufacturing as well as sterile compounding cleanroom applications. These hand specific gloves are clean processed (washed repeatedly in deionized water) to ensure consistent control of low particles, extractables and endotoxin levels, and are recommended for use in ISO Class 3 or higher and Grade A/B cleanrooms. Because HALYARD\* **PUREZERO\*** HG3 Sterile Cleanroom Gloves are made with an **accelerator-free**<sup>1</sup> nitrile polymer, there is a reduced risk of allergies and skin irritation associated with accelerator chemicals in other nitrile gloves.



Manufactured at OUR OWN  
 Safeskin Facility in Thailand.

## Cleanliness Properties

|                                         |                                |               |
|-----------------------------------------|--------------------------------|---------------|
| Max Particle Count (>0.5 µm)            | <950 Particles/cm <sup>2</sup> | IEST RP-CC005 |
| <b>Max Endotoxin Level</b>              | <20 EU                         |               |
| <b>Ionic Content (Extractable ions)</b> | <b>Max Level (ug/g)</b>        | IEST RP-CC005 |
| Calcium                                 | 50                             |               |
| Chloride                                | 35                             |               |
| Magnesium                               | 5                              |               |
| Nitrate                                 | 20                             |               |
| Potassium                               | 5                              |               |
| Sodium                                  | 10                             |               |
| Sulfate                                 | 10                             |               |
| Zinc                                    | 7                              |               |
| Ammonium                                | 5                              |               |

## Physical Properties

|                                  |                  |
|----------------------------------|------------------|
| AQL                              | 0.65             |
| Sterile                          | ✓                |
| Hand Specific Pairs              | ✓                |
| Smooth Grip                      | ✓                |
| Textured Fingertips and Palms    | ✓                |
| Accelerator-Free <sup>1</sup>    | ✓                |
| Latex-Free                       | ✓                |
| Powder-Free                      | ✓                |
| Silicone-Free                    | ✓                |
| Contains No Nickel               | ✓                |
| Static Dissipative in Use        | ✓                |
| Tensile Strength <sup>2</sup>    | 35 MPa (Target)  |
| Ultimate Elongation <sup>2</sup> | 600%             |
| Sterility Assurance Level (SAL)  | 10 <sup>-6</sup> |
| Shelf Life                       | 3 Years          |

# TECHNICAL DATA SHEET

## Glove Dimensions

|                                  | 6.0                  | 6.5                  | 7.0                  | 7.5                  | 8.0                  | 8.5                  | 9.0                  | 10.0                 |
|----------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <b>Glove Length (inch/cm)</b>    | 12"/30.5             | 12"/30.5             | 12"/30.5             | 12"/30.5             | 12"/30.5             | 12"/30.5             | 12"/30.5             | 12"/30.5             |
| <b>Width of Palm (mm)</b>        | 80                   | 87                   | 94                   | 98                   | 109                  | 114                  | 120                  | 128                  |
| <b>Middle finger length (mm)</b> | 70.8                 | 72.4                 | 80.6                 | 83.9                 | 86.0                 | 90.1                 | 92.7                 | 96.2                 |
| <b>Finger Tip Thickness</b>      | 0.16 mm<br>(6.3 mil) | 0.16 mm<br>(6.3 mil) | 0.16 mm<br>(6.3 mil) | 0.16 mm<br>(6.3 mil) | 0.16 mm<br>(6.3 mil) | 0.16 mm<br>(6.3 mil) | 0.16 mm<br>(6.3 mil) | 0.16 mm<br>(6.3 mil) |
| <b>Palm Thickness</b>            | 0.13 mm<br>(5.1 mil) | 0.13 mm<br>(5.1 mil) | 0.13 mm<br>(5.1 mil) | 0.13 mm<br>(5.1 mil) | 0.13 mm<br>(5.1 mil) | 0.13 mm<br>(5.1 mil) | 0.13 mm<br>(5.1 mil) | 0.13 mm<br>(5.1 mil) |
| <b>Cuff Thickness</b>            | 0.10 mm<br>(3.9 mil) | 0.10 mm<br>(3.9 mil) | 0.10 mm<br>(3.9 mil) | 0.10 mm<br>(3.9 mil) | 0.10 mm<br>(3.9 mil) | 0.10 mm<br>(3.9 mil) | 0.10 mm<br>(3.9 mil) | 0.10 mm<br>(3.9 mil) |

## Packaging Data

Triple layer packaging (poly pouch and poly bag plus case liner)

200 hand specific pairs per case: 2 gloves/poly wallet & pouch x 20 sealed pouches per bag x 10 PE bags per lined carton

Packaged in ISO Class 5 Cleanroom

The PUREZERO\* HG3 Sterile Nitrile Cleanroom glove sterile pouch is made from PET/PE film pouch and is Plastic Recycling Number/Category 7.

## Quality & Regulatory Standards

Compliant to these regulatory standards:

ISO 9001  
ISO 13485  
ISO 14001

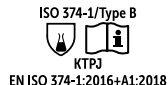
Compliant to these food handling regulatory standards:

FDA 21 CFR 177-2600  
FDA 21 CFR 180.22  
Commission Regulation (EU) No 10/2011

CE 2797 PPE Category III according to Regulation (EU) 2016/425 EEC  
EN 16523-1:2015+A1:2018

EN ISO 374-2:2019  
EN ISO 374-4:2019  
EN ISO 374-5:2016 Bacteria, Fungi, and Virus Protection  
EN ISO 374-1:2016+A1:2018/Type B  
EN ISO 21420:2020 Dexterity Classification: Level 5  
Compliant with the REACH regulation  
RoHS 2011/65/EU Annex II  
Static Dissipative in Use  
Tested per ANSI/ESD SP 15.1  
Meets USP <800> Guidelines  
Meets USP <797> Guidelines

**CE 2797**  
(PPE Cat. III)



## Additional Glove Information

Recommended for use in ISO Class 3 or higher and Grade A/B cleanrooms.

Tested against 29 chemicals, 14 chemotherapy drugs and Fentanyl.

Made in Thailand

Declaration of Conformity (DoC), Certificates of Analysis (COA) and Certificates of Processing (COP) for every production lot available online at [halyardhealth.com/information](http://halyardhealth.com/information)

## Storage Instructions

HALYARD\* PUREZERO\* Nitrile Gloves shall be stored in conditions where the product is kept dry (away from moisture), away from direct sunlight, away from sources of heat, and away from radioactive sources.

## Ordering Information

**HALYARD\* PUREZERO\* HG3 WHITE STERILE NITRILE GLOVES, HAND SPECIFIC, SMOOTH GRIP, TEXTURED FINGERTIPS AND PALMS**

| Size | Code      | Size | Code      |
|------|-----------|------|-----------|
| 6.0  | CLN323260 | 8.0  | CLN323280 |
| 6.5  | CLN323265 | 8.5  | CLN323285 |
| 7.0  | CLN323270 | 9.0  | CLN323290 |
| 7.5  | CLN323275 | 10.0 | CLN323210 |

For additional information or samples, contact your local distributor or visit [www.purezerogloves.com](http://www.purezerogloves.com)

1 Not formulated with these commonly used vulcanizing chemicals: Sulfur, Thiurams, Thiazoles, Guanidines and Carbamates.

2 Tested per ASTM D412

This fact sheet has been created using the most recent information. In the interest of continuous improvement, the characteristics of the products may change without prior notice.

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## 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 : 48192-82, 48193-82, 48194-82, 48195-82, 48196-82, 48197-82, 48198-82, 48199-82

Batches : SM503225X to SM505925X

Total Cases per Lot : 532

Date of Manufacture : Feb-25

Expiration Date : 2028-01-30

### Physical Test Data

|                            | Watertight | Visual Defects |            | Dimensions | Tensile (MPa) |           | Median Force at Break (N) |
|----------------------------|------------|----------------|------------|------------|---------------|-----------|---------------------------|
|                            |            | Minor          | Negligible |            | Pre Aging     | Pre Aging | Pre Aging                 |
| Sample Size :              | 330        | 330            | 330        | 91         | 39            | 39        | 39                        |
| AQL Level :                | 0.65       | 2.5            | 4.0        | 4.0        | 4.0           | 4.0       | 4.0                       |
| Failures Allowed per AQL : | 2          | 13             | 19         | 7          | 3             | 3         | 3                         |
| Failures :                 | 0          | 0              | 0          | 0          | 0             | 0         | 0                         |
| Inspection Results :       | Accept     | Accept         | Accept     | Accept     | Accept        | Accept    | Accept                    |
| Averages:                  |            |                |            |            | 41.19         | 590       | 14.63                     |

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 <sup>2</sup> | Inspection Result |
|----------------------------------------------------|---------------------------------|-------------------|
| #/cm <sup>2</sup> :                                | 852                             | 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          | 28.183          | 4.575                        | 2.105                         | 3.607           | 1.980                        | 1.533          | 1.129            | 16.688           |
| Inspection Result : | Accept          | Accept                       | Accept                        | Accept          | Accept                       | Accept         | Accept           | Accept           |

| Trace Element Results |        |
|-----------------------|--------|
| Units :               | Zinc   |
|                       | Zn     |
| µg/g glove            | 6.29   |
| Inspection Result :   | Accept |

Test Method : IEST-RP-CC005.4

### Endotoxin Test Data

|                 |        |                         |
|-----------------|--------|-------------------------|
| Test Result :   | 0.4169 | 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 :

*GK* 12 Mar 2025

( QA Sr. Manager )

FORM-28014/8

## STERIS: Certificate Of Processing

Prepared For                      SAFESKIN MEDICAL & SCIENTIFIC (THAILAND) LTD (10230)  
Gamma Process Run ID        3023-5024A

| <u>Product Code</u>                                        | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|------------------------------------------------------------|-------------------|-----------------|------------|
| HALYARD*PUREZERO*HG3 STERILE<br>WHITE NITRILE GLOVES-PAIRS | N/A               | 69              | Case       |
| Validation Reference Number: 0.0969 Rev01                  |                   |                 |            |

Processing Run Start Date 02-Apr-2025 11:27 PM

Processing Run End Date 03-Apr-2025 9:06 AM

|                            |             |                           |      |
|----------------------------|-------------|---------------------------|------|
| Specified Dose Range (kGy) | 25.0 - 50.0 | Calculated Min Dose (kGy) | 26.7 |
| Reference Dose Range (kGy) | 30.0 - 45.6 | Calculated Max Dose (kGy) | 38.0 |

PO Number: 4027025838

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Other Information

Refer Attachment 1

### Signature Manifest

Reviewed and E-Signed By: **Nursyuhada Shoib (Quality Analyst)**

Date/Time E-signed 03-Apr-2025 5:56 PM

Document Content Revision 1

Operating facility is in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485, ISO 9001 current version and is in alignment with EN/ISO 11137 current version.

### Processing Location

Synergy Sterilisation (M) Sdn Bhd  
Plot 203, Kuala Ketil Industrial Park  
09300 Kuala Ketil  
Kedah Malaysia  
Phone: (60)44152111

Document ID: 81293



Applied Sterilization Technologies

## Attachment 1

Run ID Process :3023-5024A

HALYARD\* PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs

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

OMH Code : 48192-82, 48193-82, 48194-82, 48195-82, 48196-82, 48197-82, 48198-82, 48199-82

| Catalog Number(s)  | Lot No./Batch No. | Quantity |
|--------------------|-------------------|----------|
| CLN323275 48195-82 | NIL/SM506225X     | 51       |
| CLN323290 48198-82 | NIL/SM506225X     | 18       |

# PACKAGE LABELS

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## 7

200 

- |    |                                            |
|----|--------------------------------------------|
| FR | Gants stériles en nitrile blancs HG3       |
| DE | HG3 Sterile Nitrhandschuhe, weiß           |
| BE | Стерилни бели нитрилни рукавици HG3        |
| ES | Gautes de nitrilo estériles blancos HG3    |
| CN | Стерилни бјеле нитронове рукавице HG3      |
| DA | HG3 Sterile hvide nitrilhandsker           |
| EL | HG3 sterilised valged nitrilkinidok        |
| ET | HG3 leuka smootsepuuõlevärviga viltplaatid |
| FI | Guanti in nitrile sterili bianchi HG3      |
| SV | HG3 sterili, haitti nitrila cimdi          |
| HR | HG3 sterilnos baltos nitrilines pištines   |
| LT | HG3 sterilios bijele nitrilines rukavice   |
| HU | HG3 sterili fehér nitrilessztyű            |

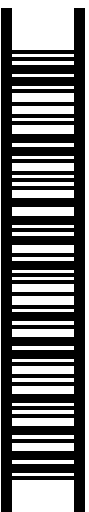
Product of Thailand

|                                                                                                                      |                                                                                                                        |                                                                                                             |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <p>ISO 374-3:2016</p> <p> VIRUS</p> | <p>ISO 374-1/Type 8</p> <p> RT/PA</p> | <p>EN 421:2010</p> <p></p> |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|

104819483

REF

# CLN323270



## 7

200 

- |      |          |            |             |                   |                   |
|------|----------|------------|-------------|-------------------|-------------------|
| (49) | HG3      | Ingwanti   | tan-Nitritl | Bojod             | Sterili           |
| (50) | HG3      | Witte      | steriele    | nitritl           | handschoenen      |
| (51) | HG3      | steriele   | hüte        | nitritlhansker    |                   |
| (52) | HG3      | Sterylene  | biäle       | rekäweise         | nitrylowe         |
| (53) | lunas    | de         | nitritlo    | brancas           | HG3 esterilizadas |
| (54) | Mänuş    | din        | nitritl     | albe              | sterile           |
| (55) | HG3      | Стерильные | белые       | нитритловые       | перчатки          |
| (56) | Sterilné | biele      | nitritlové  | rukavice          | HG3               |
| (57) | HG3      | Sterilne   | bele        | rukavice          | iz nitritla       |
| (58) | HG3      | sterilitil | valkoiset   | nitrittilkäsinnet |                   |
| (59) | HG3      | Sterilia   | vita        | nitritrihandskal  |                   |
| (60) | ビュラセロ    | HG3        | ホフクト        | 滅菌ニト              | リルゾローア            |
| (61) | HG3      | 흰색         | 니트릴 장갑      |                   |                   |
| (62) | HG3      | 先白色丁膈手套    |             |                   |                   |

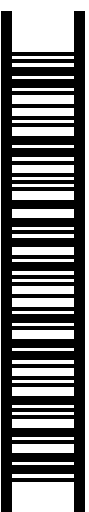
Product of Thailand

|                                                                                     |                                                                                     |                                                                                     |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| ISO 374-1:2016                                                                      | ISO 374-1:Type 8                                                                    | EN 421:2010                                                                         |
|  |  |  |
| VIRUS                                                                               | KIT                                                                                 |                                                                                     |
| ISO 374-1 Level 3 G1                                                                | EN ISO 374-1:2016+A1:2018                                                           |                                                                                     |

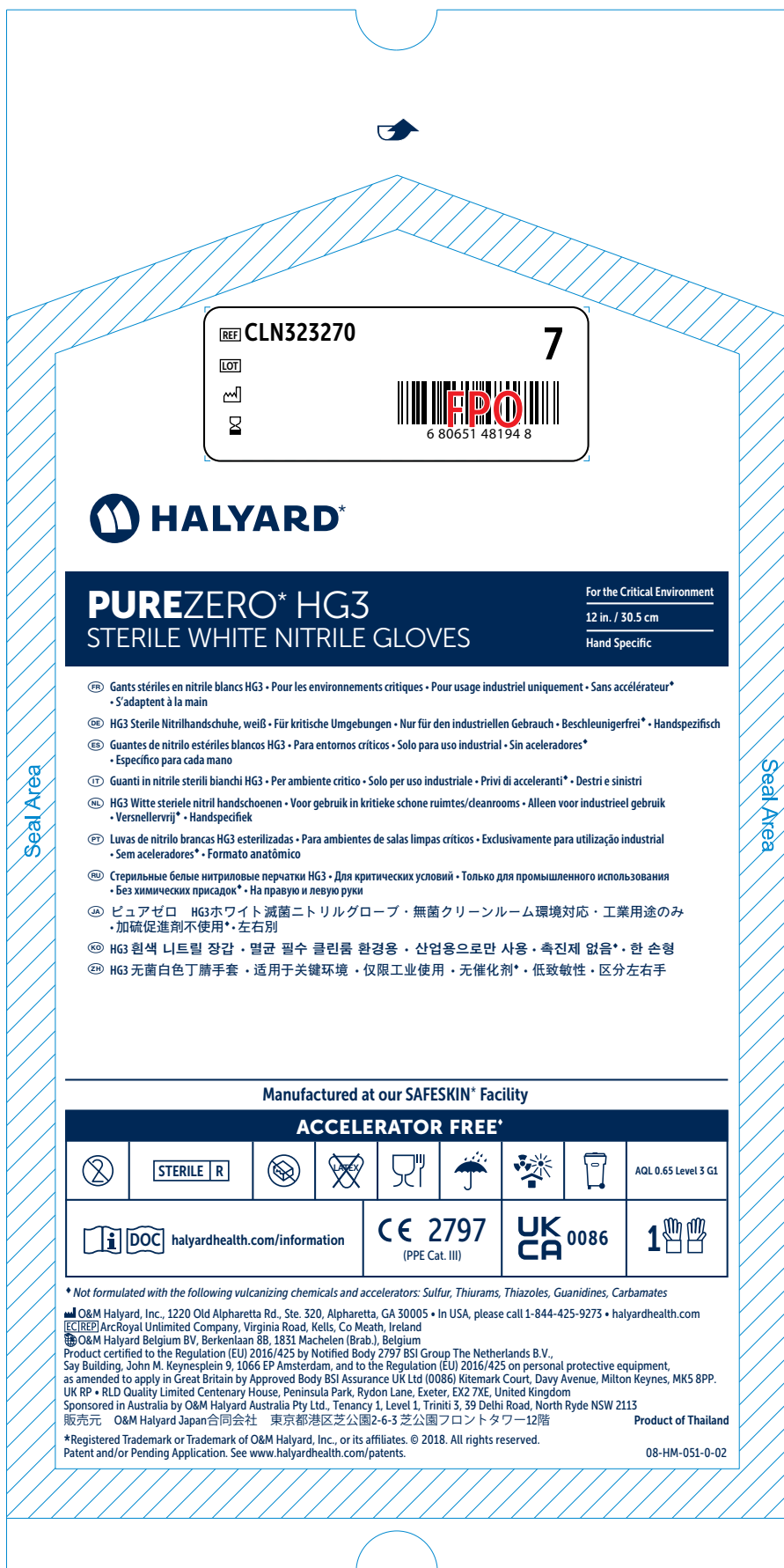
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## REFERENCES

# CLN323270

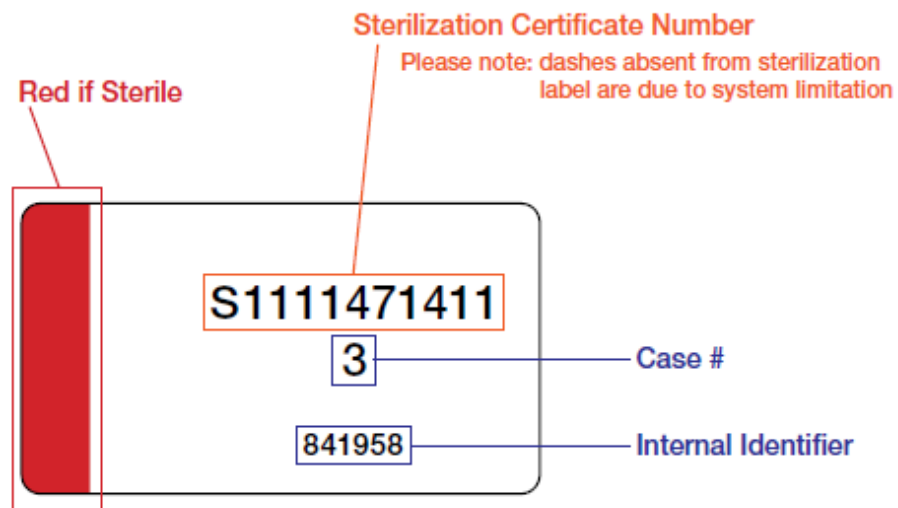


## POUCH LABEL



# STERILIZATION/IRRADIATION LABEL

## Irradiation Label Format – HALYARD\* PUREZERO\* HG3 Sterile Nitrile Gloves



# PACKAGING CERTIFICATES

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## TIP CORPORATION SDN BHD

Lot 2288, Jalan P4/8, Bandar Teknologi Kajang,  
Semenyih, 43500 Selangor, Malaysia.  
Tel: +603-8723 7889  
E-mail: sales@tipcorp.com Website: www.tipcorp.com  
SST No: W24-1808-21017734



Reg. No: 198901010228  
(187530-A)

FORM QC-21

### LPC Test Report

Item: C/R EASY PEEL-PRT Lot No: K34514(Outgoing A)  
Testing Date: 26.10.2020 Size: 152.4 X 304.8 X 0.07MM  
Customer: SAFESKIN Method: BY HAND  
Machine: BS-5

#### Blank Particle Counts (Cumulative)

|            | Blank Cts 1 | Blank Cts 2 | Blank Cts 3 | Average Blank (A)    |
|------------|-------------|-------------|-------------|----------------------|
|            | Counts      | Counts      | Counts      | Counts               |
| 0.5 micron | 2.0         | 4.0         | 3.0         | 3.0                  |
| 1.0 micron | 0.0         | 0.0         | 0.0         | 0.0                  |
| 2.0 micron | 0.0         | 0.0         | 0.0         | 0.0                  |
| 5.0 micron | 0.0         | 0.0         | 0.0         | 0.0                  |
|            |             |             |             | 0.0 Total counts 3.0 |

#### W Sample Particle Counts (Cumulative)

|            | Washed Cts 1 | Washed Cts 2 | Washed Cts 3 | Average Washed (B)    |
|------------|--------------|--------------|--------------|-----------------------|
|            | Counts       | Counts       | Counts       | Counts                |
| 0.5 micron | 16.0         | 13.0         | 10.0         | 13.0                  |
| 1.0 micron | 3.0          | 4.0          | 2.0          | 3.0                   |
| 2.0 micron | 0.0          | 1.0          | 0.0          | 0.3                   |
| 5.0 micron | 0.0          | 0.0          | 0.0          | 0.0                   |
|            |              |              |              | 0.3 Total counts 16.3 |

#### (C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

|            |      |
|------------|------|
| 0.5 micron | 10.0 |
| 1.0 micron | 3.0  |
| 2.0 micron | 0.3  |
| 5.0 micron | 0.0  |

#### (D) Total Vol. for Washed Sample

Washed Volume (ml) 400 ml

#### (E) Sampling size

5 ml

#### (F) Total Area of Plastic

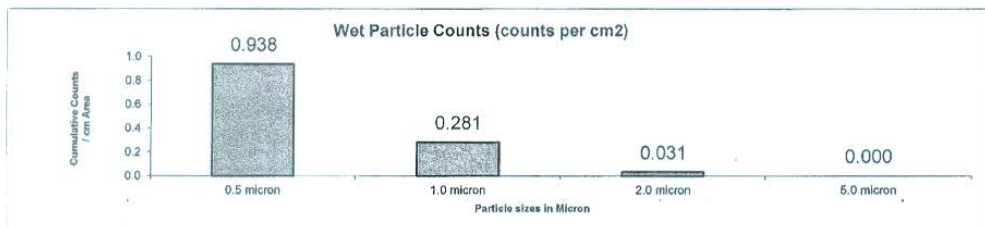
Total Washed Area 853 cm<sup>2</sup>

#### (G) Particle counts per ml (G = C / E)

|            |       |
|------------|-------|
| 0.5 micron | 2.000 |
| 1.0 micron | 0.600 |
| 2.0 micron | 0.067 |
| 5.0 micron | 0.000 |

#### (H) Total Wet Part Cts / cm<sup>2</sup> (H = G X D / F)

|            |       |
|------------|-------|
| 0.5 micron | 0.938 |
| 1.0 micron | 0.281 |
| 2.0 micron | 0.031 |
| 5.0 micron | 0.000 |



Cts/cm2

Total Particle (≥0.5): 1.250

SPEC: ≥ 0.5u <100 COUNTS/CM<sup>2</sup>

Tested By: SUHAIDA

Date: 26.10.2020

Verified By: RUDY

Date: 26.10.2020





## TIP CORPORATION SDN BHD

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SST No: W24-1808-21017734

Reg. No: 198901010228  
(187530-A)



FORM QC-21

### LPC Test Report

Item: C/R EASY PEEL-PRT Lot No: K34514(Outgoing B)  
Testing Date: 26.10.2020 Size: 152.4 X 304.8 X 0.07MM  
Customer: SAFESKIN Method: BY HAND  
Blank Particle Counts (Cumulative) Machine: BS-5

|            | Blank Cts 1<br>Counts | Blank Cts 2<br>Counts | Blank Cts 3<br>Counts | Average Blank ( A )<br>Counts |
|------------|-----------------------|-----------------------|-----------------------|-------------------------------|
| 0.5 micron | 5.0                   | 2.0                   | 4.0                   | 3.7                           |
| 1.0 micron | 0.0                   | 0.0                   | 0.0                   | 0.0                           |
| 2.0 micron | 0.0                   | 0.0                   | 0.0                   | 0.0                           |
| 5.0 micron | 0.0                   | 0.0                   | 0.0                   | 0.0                           |
|            |                       |                       |                       | 0.0 Total counts 3.7          |

#### h Sample Particle Counts (Cumulative)

|            | Washed Cts 1<br>Counts | Washed Cts 2<br>Counts | Washed Cts 3<br>Counts | Average Washed ( B )<br>Counts |
|------------|------------------------|------------------------|------------------------|--------------------------------|
| 0.5 micron | 19.0                   | 15.0                   | 17.0                   | 17.0                           |
| 1.0 micron | 4.0                    | 3.0                    | 2.0                    | 3.0                            |
| 2.0 micron | 1.0                    | 1.0                    | 1.0                    | 1.0                            |
| 5.0 micron | 1.0                    | 1.0                    | 0.0                    | 0.7                            |
|            |                        |                        |                        | 1.0 Total counts 21.7          |

#### (C) Wet Particle Counts

Ave. Washed - Ave. Blank ( C = B - A )

|            |      |
|------------|------|
| 0.5 micron | 13.3 |
| 1.0 micron | 3.0  |
| 2.0 micron | 1.0  |
| 5.0 micron | 0.7  |

#### (D) Total Vol. for Washed Sample

Washed Volume ( ml ) 400 ml

#### (E) Sampling size

5 ml

#### (F) Total Area of Plastic

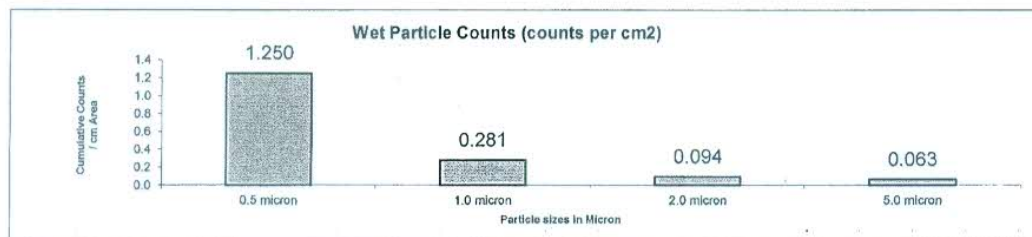
Total Washed Area 853 cm<sup>2</sup>

#### (G) Particle counts per ml ( G = C / E )

|            |       |
|------------|-------|
| 0.5 micron | 2.667 |
| 1.0 micron | 0.600 |
| 2.0 micron | 0.200 |
| 5.0 micron | 0.133 |

#### (H) Total Wet Part Cts / cm<sup>2</sup> ( H = G X D / F )

|            |       |
|------------|-------|
| 0.5 micron | 1.250 |
| 1.0 micron | 0.281 |
| 2.0 micron | 0.094 |
| 5.0 micron | 0.063 |



Cts/cm2

Total Particle (≥0.5): 1.688

SPEC: ≥ 0.5u <100 COUNTS/CM<sup>2</sup>

Tested By: SUHAIDA

Date: 26.10.2020

Verified By: RUDY

Date: 26.10.2020





## TIP CORPORATION SDN BHD

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Reg. No: 198901010228  
(187530-A)



FORM QC-21

### LPC Test Report

Item: C/R EASY PEEL-PRT

Testing Date: 26.10.2020

Customer: SAFESKIN

Blank Particle Counts (Cumulative)

Lot No: K34514(Outgoing C)

Size: 152.4 X 304.8 X 0.07MM

Method: BY HAND

Machine: BS-5

|            | Blank Cts 1 | Blank Cts 2 | Blank Cts 3 |
|------------|-------------|-------------|-------------|
|            | Counts      | Counts      | Counts      |
| 0.5 micron | 4.0         | 3.0         | 3.0         |
| 1.0 micron | 0.0         | 0.0         | 0.0         |
| 2.0 micron | 0.0         | 0.0         | 0.0         |
| 5.0 micron | 0.0         | 0.0         | 0.0         |

Average Blank (A)

Counts

3.3

0.0

0.0 Total counts 3.3

0.0

### Washed Sample Particle Counts (Cumulative)

|            | Washed Cts 1 | Washed Cts 2 | Washed Cts 3 |
|------------|--------------|--------------|--------------|
|            | Counts       | Counts       | Counts       |
| 0.5 micron | 20.0         | 11.0         | 18.0         |
| 1.0 micron | 8.0          | 3.0          | 3.0          |
| 2.0 micron | 3.0          | 1.0          | 0.0          |
| 5.0 micron | 0.0          | 0.0          | 0.0          |

Average Washed (B)

Counts

16.3

4.7

1.3 Total counts 22.3

0.0

### (C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

|            |      |
|------------|------|
| 0.5 micron | 13.0 |
| 1.0 micron | 4.7  |
| 2.0 micron | 1.3  |
| 5.0 micron | 0.0  |

### (D) Total Vol. for Washed Sample

Washed Volume (ml) 400 ml

### (E) Sampling size

5 ml

### (F) Total Area of Plastic

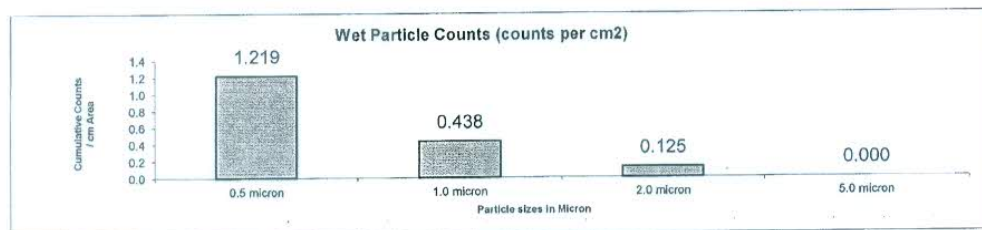
Total Washed Area 853 cm<sup>2</sup>

### (G) Particle counts per ml (G = C / E)

|            |       |
|------------|-------|
| 0.5 micron | 2.600 |
| 1.0 micron | 0.933 |
| 2.0 micron | 0.267 |
| 5.0 micron | 0.000 |

### (H) Total Wet Part Cts / cm<sup>2</sup> (H = G X D / F)

|            |       |
|------------|-------|
| 0.5 micron | 1.219 |
| 1.0 micron | 0.438 |
| 2.0 micron | 0.125 |
| 5.0 micron | 0.000 |



Cts/cm2

Total Particle (≥0.5) : 1.782

SPEC: ≥ 0.5u ≤100 COUNTS/CM<sup>2</sup>

Tested By: SUHAIDA

Date: 26.10.2020

Verified By: RUDY

Date: 26.10.2020





## TIP CORPORATION SDN BHD

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Reg. No: 198901010228  
(187530-A)



FORM QC-21

### LPC Test Report

Item: C/R LDPE WALLET

Lot No: K55532

Testing Date: 09.11.2020

Size: 220X340X0.06MM

Customer: SAFESKIN

Method: BY HAND

#### Blank Particle Counts (Cumulative)

KCCS-17

|            | Blank Cts 1 | Blank Cts 2 | Blank Cts 3 | Average Blank (A) |
|------------|-------------|-------------|-------------|-------------------|
|            | Counts      | Counts      | Counts      | Counts            |
| 0.5 micron | 1.0         | 0.0         | 1.0         | 0.7               |
| 1.0 micron | 0.0         | 0.0         | 0.0         | 0.0               |
| 2.0 micron | 0.0         | 0.0         | 0.0         | 0.0               |
| 0.5 micron | 0.0         | 0.0         | 0.0         | 0.0               |
|            |             |             |             | 0.0 Total counts  |
|            |             |             |             | 0.7               |

#### Washed Sample Particle Counts (Cumulative)

|            | Washed Cts 1 | Washed Cts 2 | Washed Cts 3 | Average Washed (B) |
|------------|--------------|--------------|--------------|--------------------|
|            | Counts       | Counts       | Counts       | Counts             |
| 0.5 micron | 60.0         | 58.0         | 52.0         | 56.7               |
| 1.0 micron | 13.0         | 21.0         | 18.0         | 17.3               |
| 2.0 micron | 4.0          | 5.0          | 6.0          | 5.0                |
| 0.5 micron | 2.0          | 0.0          | 3.0          | 1.7                |
|            |              |              |              | 1.7 Total counts   |
|            |              |              |              | 80.7               |

#### (C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

|            |      |
|------------|------|
| 0.5 micron | 56.0 |
| 1.0 micron | 17.3 |
| 2.0 micron | 5.0  |
| 0.5 micron | 1.7  |

#### (D) Total Vol. for Washed Sample

Washed Volume (ml) 400 ml

(E) Sampling size 5 ml

#### (F) Total Area of Plastic

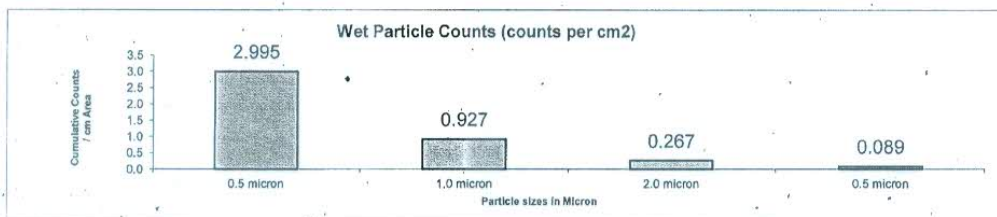
Total Washed Area 1496 cm<sup>2</sup>

#### (G) Particle counts per ml (G = C / E)

|            |        |
|------------|--------|
| 0.5 micron | 11.200 |
| 1.0 micron | 3.467  |
| 2.0 micron | 1.000  |
| 0.5 micron | 0.333  |

#### (H) Total Wet Part Cts / cm<sup>2</sup> (H = G X D / F)

|            |       |
|------------|-------|
| 0.5 micron | 2.995 |
| 1.0 micron | 0.927 |
| 2.0 micron | 0.267 |
| 0.5 micron | 0.089 |



Cts/cm2

Total Particle (≥0.5): 4.278

SPEC: ≥ 0.5u ≤ 100 COUNTS/CM<sup>2</sup>

Tested By: SUHAIDA

Verified By: RUDY

Date: 09.11.2020

Date: 09.11.2020





## TIP CORPORATION SDN BHD

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Reg. No: 198901010228  
(187530-A)



ISO 9001:2015 CERT. NO. AR 1941

ISO 14001:2015 CERT. NO. ER 0499

FORM QC-21

### LPC Test Report

Item: C/R LDPE WALLET

Lot No: K55753

Testing Date: 09.11.2020

Size: 220X340X0.06MM

Customer: SAFESKIN

Method: BY HAND

#### Blank Particle Counts (Cumulative)

|            | Blank Cts 1<br>Counts | Blank Cts 2<br>Counts | Blank Ct 3<br>Counts | Average Blank (A)<br>Counts |     |
|------------|-----------------------|-----------------------|----------------------|-----------------------------|-----|
| 0.5 micron | 6.0                   | 0.0                   | 1.0                  | 2.3                         |     |
| 1.0 micron | 2.0                   | 0.0                   | 0.0                  | 0.7                         |     |
| 2.0 micron | 0.0                   | 0.0                   | 0.0                  | 0.0                         |     |
| 5.0 micron | 0.0                   | 0.0                   | 0.0                  | 0.0                         |     |
|            |                       |                       |                      | 0.0 Total counts            | 3.0 |

#### Washed Sample Particle Counts (Cumulative)

|            | Washed Cts 1<br>Counts | Washed Cts 2<br>Counts | Washed Cts 3<br>Counts | Average Washed (B)<br>Counts |      |
|------------|------------------------|------------------------|------------------------|------------------------------|------|
| 0.5 micron | 56.0                   | 45.0                   | 72.0                   | 57.7                         |      |
| 1.0 micron | 16.0                   | 23.0                   | 32.0                   | 23.7                         |      |
| 2.0 micron | 4.0                    | 6.0                    | 9.0                    | 6.3                          |      |
| 5.0 micron | 2.0                    | 0.0                    | 2.0                    | 1.3                          |      |
|            |                        |                        |                        | 1.3 Total counts             | 89.0 |

#### (C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

|            |      |
|------------|------|
| 0.5 micron | 55.3 |
| 1.0 micron | 23.0 |
| 2.0 micron | 6.3  |
| 5.0 micron | 1.3  |

#### (D) Total Vol. for Washed Sample

Washed Volume (ml) 400 ml

(E) Sampling size 5 ml

#### (F) Total Area of Plastic

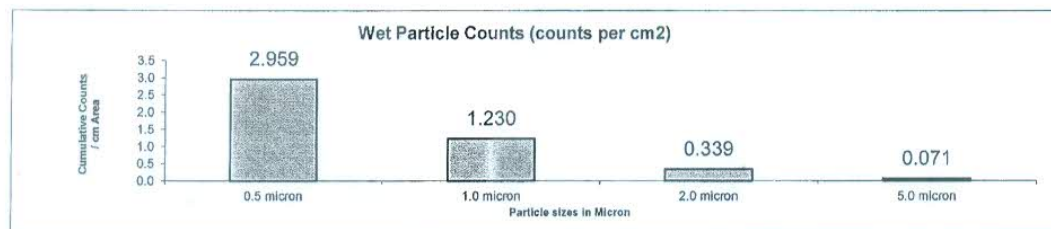
Total Washed Area 1496 cm<sup>2</sup>

#### (G) Particle counts per ml (G = C / E)

|            |        |
|------------|--------|
| micron     | 11.067 |
| 1.0 micron | 4.600  |
| 2.0 micron | 1.267  |
| 5.0 micron | 0.267  |

#### (H) Total Wet Part Cts / cm<sup>2</sup> (H = G X D / F)

|            |       |
|------------|-------|
| 0.5 micron | 2.959 |
| 1.0 micron | 1.230 |
| 2.0 micron | 0.339 |
| 5.0 micron | 0.071 |



Cts/cm2

Total Particle (≥0.5) : 4.599

SPEC: ≥ 0.5u ≤100 COUNTS/CM<sup>2</sup>

Tested By: SUHAIDA

Date: 09.11.2020

Verified By: RUDY

Date: 09.11.2020





## TIP CORPORATION SDN BHD

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Reg. No. 198901010228  
(187530-A)



MS ISO 9001:2015 CERT NO. AT 1941

MS ISO 14001:2015 CERT NO. ET 0499

FORM QC-21

### LPC Test Report

Item: C/R LDPE WALLET

Lot No: K55752

Testing Date: 09.11.2020

Size: 220X340X0.06MM

Customer: SAFESKIN

Method: BY HAND

#### Blank Particle Counts (Cumulative)

KCCS-17

|            | Blank Cts 1<br>Counts | Blank Cts 2<br>Counts | Blank Ct 3<br>Counts | Average Blank (A)<br>Counts |
|------------|-----------------------|-----------------------|----------------------|-----------------------------|
| 0.5 micron | 9.0                   | 6.0                   | 5.0                  | 6.7                         |
| 1.0 micron | 0.0                   | 0.0                   | 1.0                  | 0.3                         |
| 2.0 micron | 0.0                   | 0.0                   | 0.0                  | 0.0                         |
| 5.0 micron | 0.0                   | 0.0                   | 0.0                  | 0.0                         |
|            |                       |                       |                      | 0.0 Total counts            |
|            |                       |                       |                      | 7.0                         |

#### Washed Sample Particle Counts (Cumulative)

|            | Washed Cts 1<br>Counts | Washed Cts 2<br>Counts | Washed Cts 3<br>Counts | Average Washed (B)<br>Counts |
|------------|------------------------|------------------------|------------------------|------------------------------|
| 0.5 micron | 65.0                   | 96.0                   | 98.0                   | 86.3                         |
| 1.0 micron | 22.0                   | 25.0                   | 28.0                   | 25.0                         |
| 2.0 micron | 8.0                    | 6.0                    | 6.0                    | 6.7                          |
| 5.0 micron | 2.0                    | 3.0                    | 0.0                    | 1.7                          |
|            |                        |                        |                        | 1.7 Total counts             |
|            |                        |                        |                        | 119.7                        |

#### (C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

|            |      |
|------------|------|
| 0.5 micron | 79.7 |
| 1.0 micron | 24.7 |
| 2.0 micron | 6.7  |
| 5.0 micron | 1.7  |

#### (D) Total Vol. for Washed Sample

Washed Volume (ml) 400 ml

#### (E) Sampling size

5 ml

#### (F) Total Area of Plastic

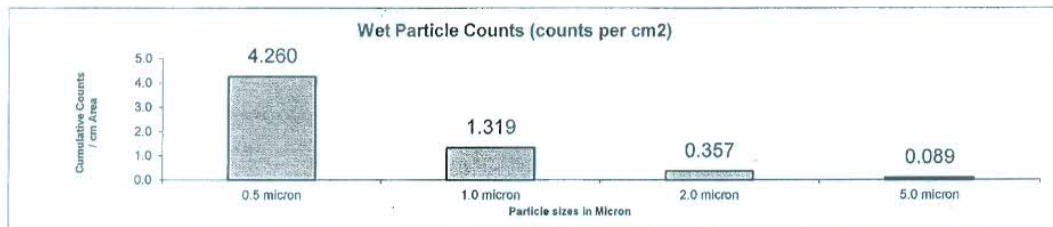
Total Washed Area 1496 cm<sup>2</sup>

#### (G) Particle counts per ml (G = C / E)

|            |        |
|------------|--------|
| 0.5 micron | 15.933 |
| 1.0 micron | 4.933  |
| 2.0 micron | 1.333  |
| 5.0 micron | 0.333  |

#### (H) Total Wet Part Cts / cm<sup>2</sup> (H = G X D / F)

|            |       |
|------------|-------|
| 0.5 micron | 4.260 |
| 1.0 micron | 1.319 |
| 2.0 micron | 0.357 |
| 5.0 micron | 0.089 |



Cts/cm<sup>2</sup>

Total Particle (≥0.5):

6.025

SPEC: ≥ 0.5u <100 COUNTS/CM<sup>2</sup>

Tested By: SUHAIDA

Date: 09.11.2020

Verified By: RUDY

Date: 09.11.2020





**TIP CORPORATION SDN BHD** Reg No: 19890101022H (187530-A)  
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FORM QC-21

## LPC Test Report

Item: C/R LDPE WALLET Lot No: K55751  
 Testing Date: 09.11.2020 Size: 18"X0.06MM(18"X18")  
 Customer: SAFESKIN Method: BY SHAKER  
 Machine: KL-2

### Blank Particle Counts (Cumulative)

|            | Blank Cts 1 | Blank Cts 2 | Blank Cts 3 | Average Blank (A) |
|------------|-------------|-------------|-------------|-------------------|
|            | Counts      | Counts      | Counts      | Counts            |
| 0.5 micron | 2.0         | 1.0         | 0.0         | 1.0               |
| 1.0 micron | 0.0         | 1.0         | 0.0         | 0.3               |
| 2.0 micron | 0.0         | 0.0         | 0.0         | 0.0               |
| 5.0 micron | 0.0         | 0.0         | 0.0         | 0.0               |
|            |             |             |             | 0.0 Total counts  |
|            |             |             |             | 1.3               |

### Wash Sample Particle Counts (Cumulative)

|            | Washed Cts 1 | Washed Cts 2 | Washed Cts 3 | Average Washed (B) |
|------------|--------------|--------------|--------------|--------------------|
|            | Counts       | Counts       | Counts       | Counts             |
| 0.5 micron | 289.0        | 258.0        | 286.0        | 277.7              |
| 1.0 micron | 120.0        | 92.0         | 111.0        | 107.7              |
| 2.0 micron | 39.0         | 51.0         | 33.0         | 41.0               |
| 5.0 micron | 9.0          | 5.0          | 6.0          | 6.7                |
|            |              |              |              | 6.7 Total counts   |
|            |              |              |              | 433.0              |

### (C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

|            |       |
|------------|-------|
| 0.5 micron | 276.7 |
| 1.0 micron | 107.3 |
| 2.0 micron | 41.0  |
| 5.0 micron | 6.7   |

### (D) Total Vol. for Washed Sample

Washed Volume (ml) 1000 ml

### (E) Sampling size

5 ml

### (F) Total Area of Plastic

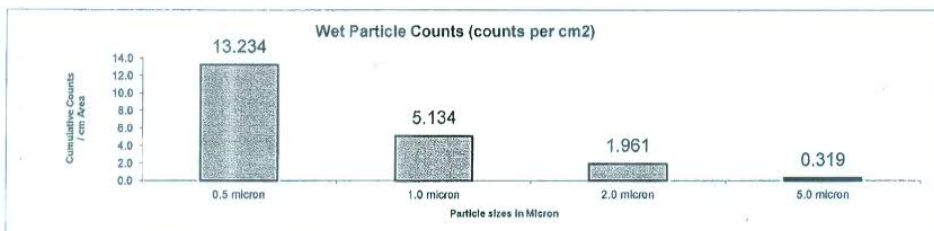
Total Washed Area 4181 cm<sup>2</sup>

### (G) Particle counts per ml (G = C / E)

|            |        |
|------------|--------|
| 0.5 micron | 55.333 |
| 1.0 micron | 21.467 |
| 2.0 micron | 8.200  |
| 5.0 micron | 1.333  |

### (H) Total Wet Part Cts / cm<sup>2</sup> (H = G X D / F)

|            |        |
|------------|--------|
| 0.5 micron | 13.234 |
| 1.0 micron | 5.134  |
| 2.0 micron | 1.961  |
| 5.0 micron | 0.319  |



Cts/cm2

Total Particle (≥0.5) : 20.649

SPEC: ≥ 0.5u ≤30 COUNTS/CM<sup>2</sup>  
 SPEC: ≥ 0.5u ≤10 COUNTS/CM<sup>2</sup>

Tested By : SUHAIDA  
 Date : 09.11.2020

Verified By : RUDY  
 Date : 09.11.2020





## TIP CORPORATION SDN BHD

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Reg. No: 198901010228  
(187530-A)



FORM QC-21

### LPC Test Report

Item: C/R LDPE WALLET

Lot No: K55749

Testing Date: 09.11.2020

Size: 220X340X0.06MM

Customer: SAFESKIN

Method: BY HAND

#### Blank Particle Counts (Cumulative)

KCCS-17

|            | Blank Cts 1<br>Counts | Blank Cts 2<br>Counts | Blank Ct 3<br>Counts | Average Blank (A)<br>Counts |     |
|------------|-----------------------|-----------------------|----------------------|-----------------------------|-----|
| 0.5 micron | 3.0                   | 3.0                   | 2.0                  | 2.7                         |     |
| 1.0 micron | 0.0                   | 0.0                   | 0.0                  | 0.0                         |     |
| 2.0 micron | 0.0                   | 0.0                   | 0.0                  | 0.0                         |     |
| 0.5 micron | 0.0                   | 0.0                   | 0.0                  | 0.0 Total counts            | 2.7 |

#### Wash Sample Particle Counts (Cumulative)

|            | Washed Cts 1<br>Counts | Washed Cts 2<br>Counts | Washed Cts 3<br>Counts | Average Washed (B)<br>Counts |      |
|------------|------------------------|------------------------|------------------------|------------------------------|------|
| 0.5 micron | 48.0                   | 58.0                   | 72.0                   | 59.3                         |      |
| 1.0 micron | 17.0                   | 18.0                   | 14.0                   | 16.3                         |      |
| 2.0 micron | 9.0                    | 10.0                   | 3.0                    | 7.3                          |      |
| 0.5 micron | 0.0                    | 2.0                    | 0.0                    | 0.7 Total counts             | 83.7 |

#### (C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

|            |      |
|------------|------|
| 0.5 micron | 56.7 |
| 1.0 micron | 16.3 |
| 2.0 micron | 7.3  |
| 0.5 micron | 0.7  |

#### (D) Total Vol. for Washed Sample

Washed Volume (ml) 400 ml

(E) Sampling size 5 ml

#### (F) Total Area of Plastic

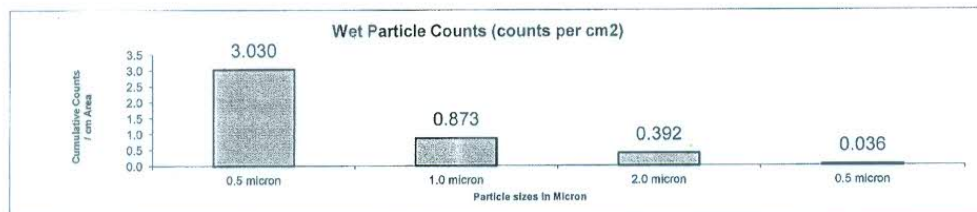
Total Washed Area 1496 cm<sup>2</sup>

#### (G) Particle counts per ml (G = C / E)

|            |        |
|------------|--------|
| 0.5 micron | 11.333 |
| 1.0 micron | 3.267  |
| 2.0 micron | 1.467  |
| 0.5 micron | 0.133  |

#### (H) Total Wet Part Cts / cm<sup>2</sup> (H = G X D / F)

|            |       |
|------------|-------|
| 0.5 micron | 3.030 |
| 1.0 micron | 0.873 |
| 2.0 micron | 0.392 |
| 0.5 micron | 0.036 |



Cts/cm2

Total Particle (≥0.5): 4.332

SPEC: ≥ 0.5u <100 COUNTS/CM<sup>2</sup>

Tested By: SUHAIDA

Verified By: RUDY

Date: 09.11.2020

Date: 09.11.2020



# DOSE MAPPING REPORT

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Safeskin Medical & Scientific (Thailand) Ltd

Please find enclosed with our compliments, the completed process validation report  
in accordance with EN ISO 11137-1:2015 for the products as below:

|                        |                                                                       |
|------------------------|-----------------------------------------------------------------------|
| Product name:          | <b>HALYARD*PUREZERO* HG3 Sterile White Nitrile Gloves -<br/>Pairs</b> |
| The validation ref no: | <b>0.0969      Rev 01</b>                                             |

We would appreciate you quoting the product name as above in your PO/DO/reference documents  
to STERIS, this will aid in identifying your products prior to processing.

Your sincerely,



07 May 2021  
Yow Hueh Koon  
Malaysia Radiation Validation Manager  
STERIS Applied Sterilization Technologies  
Tel: +603 3101 3366  
Email: [huehkoon\\_yow@steris.com](mailto:huehkoon_yow@steris.com)

Customer Acknowledge,

Name :  
Designation :  
(Please sign this section and scan a  
copy to [huehkoon\\_yow@steris.com](mailto:huehkoon_yow@steris.com))

**DOSE MAPPING REPORT**  
**Safeskin Medical & Scientific (Thailand) Ltd**  
**For**  
**HALYARD\*PUREZERO\* HG3**  
**Sterile White Nitrile Gloves - Pairs**

**Validation Report Number : 0.0969 Rev 01**

**Summary of Performance Qualification:**

Customer Name : Safeskin Medical & Scientific (Thailand) Ltd  
 Report Ref. : 0.0969 Rev 01  
 Issue Date : 29.04.2021

Product Description: : HALYARD\*PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs

Type of package: : Corrugated carton

Carton dimension : : 345 mm (L) x 285 mm (W) x 390 mm (H) ( 15 ctns/tote)

Method : ISO/ASTM 52303: 2015 (E)

Reference Standard : EN ISO 11137-1: 2015

Reference Procedure : QWI 24 Rev 12 Dose Mapping

**Dose Specification:**

Minimum dose (kGy) : 25.0

Maximum dose (kGy) : 50.0

| Requirement                   | Minimum specification | Maximum specification |
|-------------------------------|-----------------------|-----------------------|
| Dose at DRef                  | 30.1                  | 45.6                  |
| Dwell time(s)                 | 137                   | 202                   |
| Number of Xs                  | 36                    | 53                    |
| Correction Factor (Rmin/Rmax) | 0.832                 | 1.096                 |

**Conclusion**

The delivered dose in the product presentation illustrated on page 4 and 5 achieves the requested dose specification of minimum and maximum specification. In order to meet this specification during routine processing the recorded dose at Dref must be as above specification. This incorporates an estimation of uncertainty associated with the measurement system.

**Authorisation**

|             | Position                              | Signature                                                                            | Date        |
|-------------|---------------------------------------|--------------------------------------------------------------------------------------|-------------|
| Prepared by | Malaysia Radiation Validation Manager |  | 06 May 2021 |
| Reviewed by | Operation Management or designee      |  | 07/05/2021  |
| Approved by | QA Management or designee             |  | 07/05/2021  |

**Note:**

It is the responsibility of the Customer to routinely provide product in the presentation and orientation outlined in this report. This performance qualification validates the delivery of radiation doses only. Validation of the sterilisation effect and radiation induced material effects, if any, are not addressed by this qualification.

## Performance Qualification STERIS Kuala Ketil

Applied Sterilization Technologies

Validation Ref : 0.0969 Rev 01

Product description: **HALYARD\*PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs**

Qualification data is obtained by placing 4034 PW Red dosimeters in a defined pattern throughout a STERIS tote loaded with product.

The performance qualification is conducted in triplicate with the dosimeters placed throughout the product to assess both the dose distribution and determine the variability of the absorbed dose measurements, when processed under the same processing conditions.

Following processing the relationship between  $D_{ref} / D_{min}$  and  $D_{ref} / D_{max}$  are calculated to determine an acceptable  $D_{ref}$  processing range.

$D_{ref}$  processing range is calculated by multiplying the  $R_{min}$  by the Customer minimum specification and the  $R_{max}$  by the customer maximum specification .

During routine processing if the  $D_{ref}$  value falls within this range then processing is deemed as meeting the required specification:

$D_{ref}$  Minimum = Expected value of  $R_{min}$  x Minimum Dose Required

$D_{ref}$  Maximum = Expected value of  $R_{max}$  x Maximum Dose Required

### Uncertainty

The specification for  $D_{ref}$  incorporates an estimation of the uncertainty associated with the measurement system. Uncertainty has been calculated using the method outlined in ASTM 52303:2015 (E). This method provides a confidence level of 95%

### Definitions

|           |                             |
|-----------|-----------------------------|
| $D_{ref}$ | - Reference Dose            |
| $D_{min}$ | - Minimum Dose              |
| $D_{max}$ | - Maximum Dose              |
| $R_{min}$ | - $D_{ref} / D_{min}$ ratio |
| $R_{max}$ | - $D_{ref} / D_{max}$ ratio |
| CV%       | - Coefficient of Variance   |
| C060      | - Cobalt 60                 |

**Performance Qualification STERIS Kuala Ketil**

Applied Sterilization Technologies

Validation Ref : 0.0969 Rev 01

**Product:** HALYARD\*PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs

**LOW DENSITY**

Analysis for the Calculation of Release Specification Incorporating Uncertainties

| Position | PQ1  |       | PQ2  |       | PQ3  |       | Mean | Stdev | CV   | Sum of Squared Differences |
|----------|------|-------|------|-------|------|-------|------|-------|------|----------------------------|
| A11      | 32.3 |       | 32.3 |       | 32.2 |       | 32.3 | 0.06  | 0.19 | 0.01                       |
| A21      | 30.9 |       | 32.2 |       | 31.8 |       | 31.6 | 0.67  | 2.12 | 0.89                       |
| A31      | 30.2 |       | 30.3 |       | 30.8 |       | 30.4 | 0.32  | 1.05 | 0.21                       |
| A41      | 32.5 |       | 33.2 |       | 32.4 |       | 32.7 | 0.44  | 1.35 | 0.38                       |
| A51      | 33.2 |       | 33.0 |       | 33.7 |       | 33.3 | 0.36  | 1.08 | 0.26                       |
| A15      | 33.3 |       | 34.9 |       | 34.7 |       | 34.3 | 0.87  | 2.54 | 1.52                       |
| A25      | 32.3 |       | 33.2 |       | 33.5 |       | 33.0 | 0.62  | 1.88 | 0.78                       |
| A35      | 34.4 |       | 34.7 |       | 34.3 |       | 34.5 | 0.21  | 0.61 | 0.09                       |
| A45      | 34.7 |       | 34.9 |       | 34.8 |       | 34.8 | 0.10  | 0.29 | 0.02                       |
| A55      | 35.6 |       | 35.4 |       | 35.0 |       | 35.3 | 0.31  | 0.88 | 0.19                       |
| A19      | 33.1 |       | 33.4 |       | 35.1 | √-MAX | 33.9 | 1.08  | 3.19 | 2.33                       |
| A29      | 34.2 |       | 35.2 |       | 33.9 |       | 34.4 | 0.68  | 1.98 | 0.93                       |
| A39      | 34.7 |       | 35.7 |       | 34.8 |       | 35.1 | 0.55  | 1.57 | 0.61                       |
| A49      | 36.1 | √-MAX | 35.3 |       | 34.9 |       | 35.4 | 0.61  | 1.72 | 0.75                       |
| A59      | 35.5 |       | 36.1 | √-MAX | 34.2 |       | 35.3 | 0.97  | 2.75 | 1.89                       |
| B11      | 28.6 |       | 28.8 |       | 28.9 |       | 28.8 | 0.15  | 0.52 | 0.05                       |
| B21      | 27.8 | √-MIN | 28.7 | √-MIN | 28.4 | √-MIN | 28.3 | 0.46  | 1.63 | 0.42                       |
| B31      | 28.5 |       | 28.8 |       | 28.4 | √-MIN | 28.6 | 0.21  | 0.73 | 0.09                       |
| B41      | 31.9 |       | 32.0 |       | 32.0 |       | 32.0 | 0.06  | 0.19 | 0.01                       |
| B51      | 32.6 |       | 32.4 |       | 32.8 |       | 32.6 | 0.20  | 0.61 | 0.08                       |
| B15      | 30.4 |       | 31.3 |       | 30.9 |       | 30.9 | 0.45  | 1.46 | 0.41                       |
| B25      | 29.9 |       | 29.8 |       | 30.5 |       | 30.1 | 0.38  | 1.26 | 0.29                       |
| B35      | 29.8 |       | 29.7 |       | 28.8 |       | 29.4 | 0.55  | 1.87 | 0.61                       |
| B45      | 30.2 |       | 30.7 |       | 31.5 |       | 30.8 | 0.66  | 2.14 | 0.86                       |
| B55      | 31.2 |       | 32.2 |       | 31.2 |       | 31.5 | 0.58  | 1.84 | 0.67                       |
| B19      | 30.1 |       | 30.1 |       | 30.9 |       | 30.4 | 0.46  | 1.51 | 0.43                       |
| B29      | 29.3 |       | 29.4 |       | 30.1 |       | 29.6 | 0.44  | 1.49 | 0.38                       |
| B39      | 29.6 |       | 29.3 |       | 28.8 |       | 29.2 | 0.40  | 1.37 | 0.33                       |
| B49      | 32.9 |       | 33.7 |       | 33.2 |       | 33.3 | 0.40  | 1.20 | 0.33                       |
| B59      | 34.4 |       | 33.8 |       | 33.0 |       | 33.7 | 0.70  | 2.08 | 0.99                       |

 Pooled variance ( $s^2_{\text{overall}}$ )

**0.28**

Minimum detectable difference (6)

**0.72**

Mean Minimum dose (DMin)

**28.3 B21**

Mean Maximum dose (DMax)

**35.4 A49**

Expected value of Rmin ( Dref/Dmin )

**1.142 \***

Expected value of Rmax ( Dref/Dmax)

**0.912 \***

| DRef Ratio : |              |
|--------------|--------------|
| 1/Rmin       | <b>0.876</b> |
| 1/Rmax       | <b>1.096</b> |

Remarks: \* incorporates an estimation of the uncertainty

 Customer Spec Min: **25.0** Max: **50.0**

 D reference Min: **28.6** Max: **45.6**

 Dose Uniformity Ratio (DUR): **1.25**

# Performance Qualification STERIS Kuala Ketil

Applied Sterilization Technologies

Validation Ref : 0.0969 Rev 01

**Product:** HALYARD\*PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs

**HIGH DENSITY**

Analysis for the Calculation of Release Specification Incorporating Uncertainties

| Position | PQ1         |       | PQ2         |       | PQ3         |       | Mean        | Stdev | CV   | Sum of Squared Difference |
|----------|-------------|-------|-------------|-------|-------------|-------|-------------|-------|------|---------------------------|
| A11      | 31.5        |       | 32.3        |       | 32.8        |       | 32.2        | 0.66  | 2.05 | 0.86                      |
| A21      | 31.5        |       | 31.7        |       | 31.6        |       | 31.6        | 0.10  | 0.32 | 0.02                      |
| A31      | 29.9        |       | 29.4        |       | 30.2        |       | 29.8        | 0.40  | 1.34 | 0.33                      |
| A41      | 31.7        |       | 31.4        |       | 31.4        |       | 31.5        | 0.17  | 0.54 | 0.06                      |
| A51      | 34.5        |       | 32.9        |       | 32.9        |       | 33.4        | 0.92  | 2.75 | 1.71                      |
| A15      | 34.0        |       | 33.9        |       | 34.2        |       | 34.0        | 0.15  | 0.44 | 0.05                      |
| A25      | 32.3        |       | 31.9        |       | 31.7        |       | 32.0        | 0.31  | 0.97 | 0.19                      |
| A35      | 34.1        |       | 33.7        |       | 34.0        |       | 33.9        | 0.21  | 0.62 | 0.09                      |
| A45      | 34.8        |       | 32.9        |       | 33.7        |       | 33.8        | 0.95  | 2.81 | 1.82                      |
| A55      | 31.8        |       | 33.8        |       | 34.5        |       | 33.4        | 1.40  | 4.19 | 3.93                      |
| A19      | 33.6        |       | 34.1        |       | 33.7        |       | 33.8        | 0.26  | 0.77 | 0.14                      |
| A29      | 33.9        |       | 35.0        |       | 33.9        |       | 34.3        | 0.64  | 1.87 | 0.81                      |
| A39      | <b>35.2</b> | √-MAX | 34.4        |       | 34.8        |       | 34.8        | 0.40  | 1.15 | 0.32                      |
| A49      | 34.5        |       | 34.2        |       | 34.3        |       | 34.3        | 0.15  | 0.44 | 0.05                      |
| A59      | 34.9        |       | <b>35.4</b> | √-MAX | <b>35.1</b> | √-MAX | <b>35.1</b> | 0.25  | 0.71 | 0.13                      |
| B11      | 27.8        |       | 28.6        |       | 28.6        |       | 28.3        | 0.46  | 1.63 | 0.43                      |
| B21      | 27.6        |       | 28.0        |       | 28.1        |       | 27.9        | 0.26  | 0.93 | 0.14                      |
| B31      | <b>26.8</b> | √-MIN | <b>26.7</b> | √-MIN | <b>26.8</b> | √-MIN | <b>26.8</b> | 0.06  | 0.22 | 0.01                      |
| B41      | 31.3        |       | 30.6        |       | 31.3        |       | 31.1        | 0.40  | 1.29 | 0.33                      |
| B51      | 32.9        |       | 32.2        |       | 32.0        |       | 32.4        | 0.47  | 1.45 | 0.45                      |
| B15      | 30.0        |       | 29.7        |       | 30.6        |       | 30.1        | 0.46  | 1.53 | 0.42                      |
| B25      | 28.3        |       | 28.7        |       | 28.7        |       | 28.6        | 0.23  | 0.80 | 0.11                      |
| B35      | 27.4        |       | 27.6        |       | 27.9        |       | 27.6        | 0.25  | 0.91 | 0.13                      |
| B45      | 29.5        |       | 29.0        |       | 30.6        |       | 29.7        | 0.82  | 2.76 | 1.34                      |
| B55      | 31.2        |       | 28.5        |       | 31.7        |       | 30.5        | 1.72  | 5.64 | 5.93                      |
| B19      | 29.9        |       | 31.9        |       | 30.4        |       | 30.7        | 1.04  | 3.39 | 2.17                      |
| B29      | 28.3        |       | 30.8        |       | 28.9        |       | 29.3        | 1.31  | 4.47 | 3.41                      |
| B39      | 28.6        |       | 31.4        |       | 28.4        |       | 29.5        | 1.68  | 5.69 | 5.63                      |
| B49      | 33.3        |       | 32.7        |       | 32.5        |       | 32.8        | 0.42  | 1.28 | 0.35                      |
| B59      | 33.6        |       | 34.3        |       | 33.4        |       | 33.8        | 0.47  | 1.39 | 0.45                      |

Pooled variance ( $s^2_{\text{overall}}$ )

**0.53**

Minimum detectable difference ( $\delta$ )

**0.99**

Mean Minimum dose (DMin)

**26.8 B31**

Mean Maximum dose (DMax)

**35.1 A59**

Expected value of Rmin ( Dref/Dmin )

**1.202 \***

Expected value of Rmax ( Dref/Dmax )

**0.917 \***

| Dref Ratio : |              |
|--------------|--------------|
| 1/Rmin       | <b>0.832</b> |
| 1/Rmax       | <b>1.091</b> |

Remarks: \* incorporates an estimation of the uncertainty

Customer Spec Min: **25.0** Max: **50.0**

D reference Min: **30.1** Max: **45.9**

Dose Uniformity Ratio (DUR): **1.31**

**Performance Qualification STERIS Kuala Ketil**

Applied Sterilization Technologies

**Product Detail**
**Validation Ref : 0.0969 Rev 01**
**Customer Name : Safeskin Medical & Scientific (Thailand) Ltd**
**Issue Date : 29.04.2021**
**Product Description : HALYARD\*PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs**
**Plant Batch No : S12562828-1-1 (HD - high density, size 10.0)  
S12562828-1-2 (LD - low density, size 6.0)**

|                                |                     |              |                           |
|--------------------------------|---------------------|--------------|---------------------------|
| Current Cobalt Loading         | : 4,591,067 Curries | Weight (LD)  | : 6.45 kg                 |
| Standard Plant Dwell Time      | : 146 Sec           | Weight (HD)  | : 8.20 kg                 |
| Actual Dwell Time              | : 146 Sec           | Length       | : 345 mm                  |
| Number of Xs                   | : 38.0              | Width        | : 285 mm                  |
| Value of X                     | : 3.83              | Height       | : 390 mm                  |
| Type of package                | : Corrugated carton | Density (LD) | : 0.168 g/cm <sup>3</sup> |
| Dose Range Specification (kGy) | : 25 Min            | Density (HD) | : 0.214 g/cm <sup>3</sup> |
|                                | 50 Max              | Tote Fit     | : 15 ctn/tote             |

**Low Density Dwell Time Control**

| Minimum dwell time to achieve | Minimum dose | Maximum dose |
|-------------------------------|--------------|--------------|
| First tote                    | 131 ✓        | 202 ✓        |
| Second tote                   | 127          | 202 ✓        |
| Third tote                    | 129          | 208          |

**High Density Dwell Time Control**

| Minimum dwell time to achieve | Minimum dose | Maximum dose |
|-------------------------------|--------------|--------------|
| First tote                    | 136          | 207          |
| Second tote                   | 137 ✓        | 206 ✓        |
| Third tote                    | 136          | 208          |

**Reference Procedures:** : QWI 24 Rev 12 Dose Mapping  
**Method** : ISO/ASTM 52303: 2015 (E)  
**Reference Standard** : EN ISO 11137-1: 2015

# Performance Qualification STERIS Kuala Ketil

Applied Sterilization Technologies

Validation Ref : 0.0969 Rev 01

Customer Name : Safeskin Medical & Scientific (Thailand) Ltd

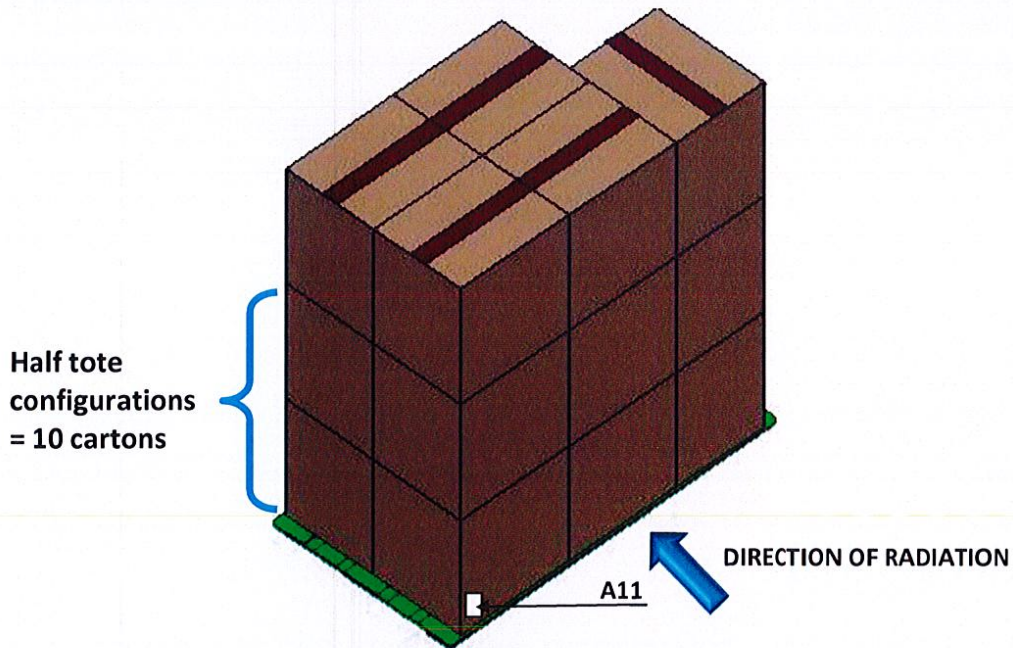
Type of Package : Corrugated carton

Product Description : HALYARD\*PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs

Issue Date : 29.04.2021

This performance qualification relates only to the above product loaded in the configuration outlined below.

Carton dimension : 345 mm (L) x 285 mm (W) x 390 mm (H) ( 15 ctns/tote )



Remark : A11 is the routine process monitoring

| Authorised By:                              | Signature                                                                           | Date        |
|---------------------------------------------|-------------------------------------------------------------------------------------|-------------|
| Radiation Technology Management or designee |  | 06 May 2021 |

**Performance Qualification STERIS Kuala Ketil**

Applied Sterilization Technologies

Validation Ref : 0.0969 Rev 01

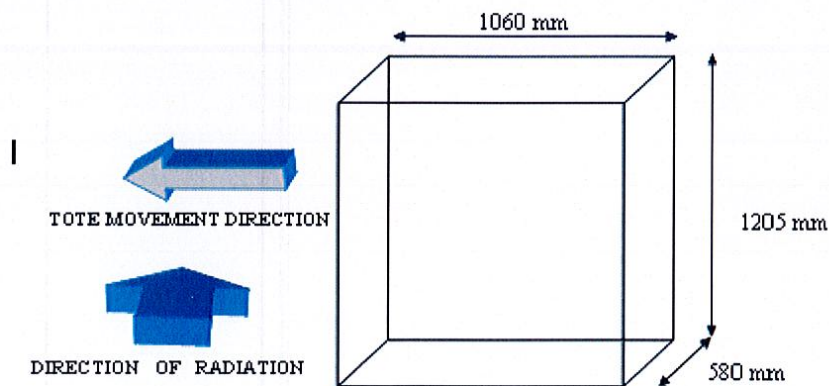
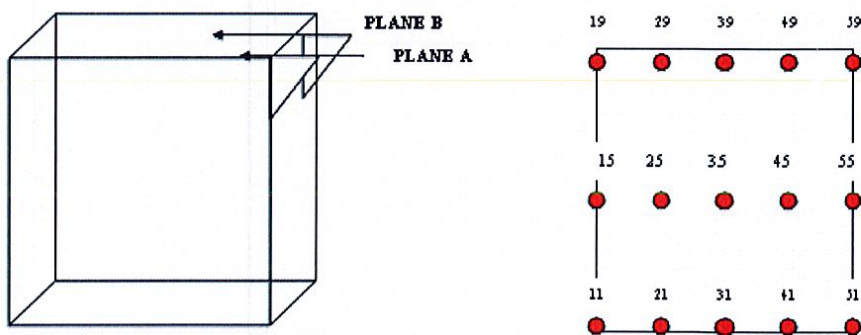
Customer Name : **Safeskin Medical & Scientific (Thailand) Ltd**

Type of Package : **Corrugated carton**

Product Description : **HALYARD\*PUREZERO\* HG3 Sterile White Nitrile Gloves - Pairs**

Issue Date : **29.04.2021**

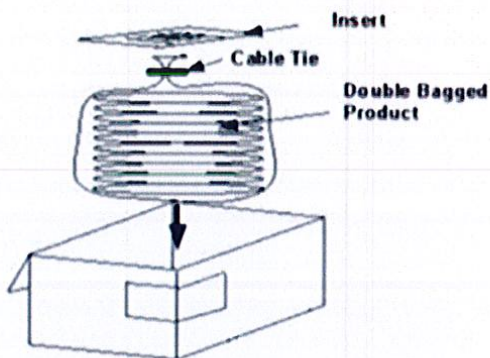
This performance qualification relates only to the above product loaded in the configuration outlined below.

**TOTE CHARACTERISTICS AND ORIENTATION**

**LOCATION OF DOSIMETERS**


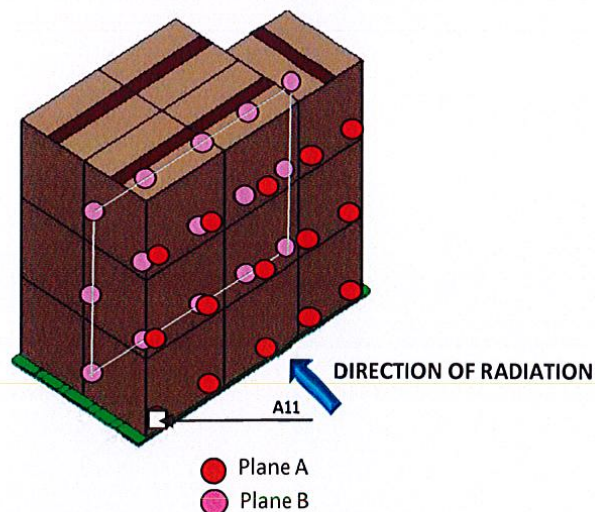
As per our Operational Qualification Report, from latest source loading replenishment, the dose distribution in the front plane (plane A) is the same as in the back plane (plane C).

Customer Name: **Safeskin Medical & Scientific (Thailand) Ltd**

Orientation of product within the package



Dosimeter position



Remark : A11 is the routine process monitoring

| Authorised By:                              | Signature                                                                           | Date        |
|---------------------------------------------|-------------------------------------------------------------------------------------|-------------|
| Radiation Technology Management or designee |  | 06 May 2021 |

# SAFETY DATA SHEET

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## SAFETY DATA SHEET

### HALYARD\* PUREZERO\* HG3 Nitrile Gloves

#### 1. IDENTIFICATION

Product Name: **HALYARD\* PUREZERO\* HG3 Nitrile Gloves**

**Product Number:** Various

|                                                                                       |                                                                                                                                                               |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date Prepared:                                                                        | 6/24/2021                                                                                                                                                     |
| Manufacturer:                                                                         | O&M Halyard, Inc.<br>1 Edison Dr.<br>Alpharetta, Georgia 30005                                                                                                |
| Telephone:<br>MEDICAL EMERGENCY:<br><br>TRANSPORTATION EMERGENCY:<br><br>INFORMATION: | Call 911 or your local Emergency Room or<br>Poison Control Services<br>Chemtrec 1-800-424-9300 or 1-703-527-3887<br>(collect calls accepted)<br>1-844-HALYARD |

**Product Use:** Protective gloves.

#### 2. HAZARDS IDENTIFICATION

**GHS Classification:** Not Hazardous. These products are manufactured articles or articles as this term is defined in the OSHA Hazard Communication Standard (20CFR 1910.1200), EU REACH, Canadian WHMIS, Australia WHS and the GHS. These products are out of the scope of the GHS and no SDS or labeling are required.

**GHS Labeling:** No GHS labeling required.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

| <i>Chemical Name</i>      | <i>CAS-No./<br/>EINECS-No</i> | <i>%</i> | <i>GHS Classification:</i> |
|---------------------------|-------------------------------|----------|----------------------------|
| Non-Hazardous Ingredients | Mixture                       | 100      | Not Hazardous              |

#### 4. FIRST AID MEASURES

**Inhalation:** No first aid needed.

**Skin contact:** No first aid needed. These products are intended to be used in contact with the skin.

**Eye contact:** No first aid needed.

**Ingestion:** Not a relevant route of exposure.

**Most Important symptoms and effects, both acute and delayed:** No adverse effects.

**Indication of any immediate medical attention and special treatment needed:** None required.



## SAFETY DATA SHEET

### HALYARD\* PUREZERO\* HG3 Nitrile Gloves

#### 5. FIRE-FIGHTING MEASURES

**Suitable (and unsuitable) Extinguishing Media:** Use media suitable for surrounding materials.

**Specific Hazards Arising from the Chemical:** These products can melt in a fire. Molten material may flow or drip and spread the fire.

**Hazardous Combustion Products:** Combustion may produce toxic and irritating gases and vapors.

**Special Protective Equipment and Precautions for Fire-fighters:** None required.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment, and Emergency Procedures:** None required.

**Environmental Precautions:** None required.

**Methods and Materials for Containment and Cleaning Up:** No special precautions required. Pick up and dispose of in an appropriate container.

#### 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** No special handling is required.

**Conditions for Safe Storage, including any Incompatibilities:** Store away from heat and flames.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

##### Exposure limit(s)

| Chemical Name             | Exposure limit(s) |
|---------------------------|-------------------|
| Non-Hazardous Ingredients | None established  |

**Appropriate Engineering Controls:** None required.

**Individual Protection Measures, such as Personal Protective Equipment:**

**Respiratory Protection:** None required.

**Protective Gloves:** None required.

**Eye Protection:** None required.



## SAFETY DATA SHEET

### HALYARD\* PUREZERO\* HG3 Nitrile Gloves

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                               |                                                            |
|-----------------------------------------------|------------------------------------------------------------|
| Appearance and Odor                           | Solid Gloves, blue or white                                |
| Odor Threshold:                               | Not applicable                                             |
| Boiling point/range                           | Not applicable                                             |
| Melting point/range                           | Not determined                                             |
| Relative Density (water=1)                    | Not determined                                             |
| Vapor pressure                                | Not applicable                                             |
| Vapor density (air=1)                         | Not applicable                                             |
| Solubility                                    | Insoluble                                                  |
| pH                                            | Not applicable                                             |
| Partition coefficient (n-octanol/water):      | Not applicable                                             |
| Evaporation Rate (Butyl acetate=1)            | Not applicable                                             |
| Viscosity:                                    | Not applicable                                             |
| Volatile Organic Carbon Compounds (VOC) (g/L) | Not applicable                                             |
| Flashpoint:                                   | None.                                                      |
| Flammable Limits in Air % by Volume:          | LEL (Lower): Not applicable<br>UEL (Upper): Not applicable |
| Autoignition temperature:                     | Not determined.                                            |
| Decomposition temperature:                    | Not determined                                             |
| Flammability (solid, gas):                    | Not a flammable solid                                      |

#### 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive.

**Chemical Stability:** Stable at ambient temperature and pressure.

**Possibility of Hazardous Reactions:** None known.

**Conditions to Avoid:** Avoid heat and flames.

**Incompatible Materials:** None known.

**Hazardous Decomposition Products:** Thermal decomposition may produce carbon and nitrogen oxides and unidentified hydrocarbon fragments.



## SAFETY DATA SHEET

### HALYARD\* PUREZERO\* HG3 Nitrile Gloves

#### 11. TOXICOLOGICAL INFORMATION

**Symptoms/Effects of Overexposure:** These gloves are manufactured articles. Their use will not result in exposure to any hazardous materials.

**Inhalation:** Not applicable.

**Skin contact:** None. Intended for skin contact. These products contain no natural latex.

**Eye contact:** None expected.

**Ingestion:** Not applicable.

**Chronic toxicity:** None expected.

**Carcinogenicity Data:** None of the components of this product is listed as a carcinogen by IARC, NTP, US OSHA or the EU CLP Annex VI.

**Reproductive Toxicity:** None known.

**Numerical Measures of Toxicity:**  
Not acutely toxic.

#### 12. ECOLOGICAL INFORMATION

**Ecotoxicity:** These gloves are manufactured articles. Their use will not result in adverse environmental effects.

**Persistence and Degradability:** Not degradable.

**Bioaccumulative Potential:** Not bioaccumulative.

**Mobility in Soil:** Not mobile.

**Other Adverse Effects:** None currently known.

#### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all state, local and federal regulations. If unused, the product may be disposed of as a non-hazardous material.

#### 14. TRANSPORT INFORMATION

**US DOT Shipping Description:** Not regulated

**IATA Shipping Description (Air):** Not regulated

**IMDG Shipping Description (Vessel):** Not regulated

#### 15. REGULATORY INFORMATION

**US Regulations**

**EPA Toxic Substances Control Act (TSCA):** These gloves are articles and exempt from the TSCA regulations.



## SAFETY DATA SHEET

**HALYARD\* PUREZERO\* HG3 Nitrile Gloves**

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**SARA 302 Listed Chemicals:** None.

**SARA 311/312 Hazard Categories:** Not applicable to articles

**SARA 313 This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under the SARA Section 313 (40 CFR 372):** Not applicable to articles.

|                              |
|------------------------------|
| <b>16. OTHER INFORMATION</b> |
|------------------------------|

**Date Prepared:** 6/24/2021

**HMIS Rating:** Health 0 Fire 1 Physical Hazard 0

The information contained herein is true and correct to the best of O&M Halyard, Inc's knowledge. However, no warranty, expressed or implied, is made. Nothing herein should be interpreted as a recommendation to infringe existing patents or violate any laws or regulations. Final determination of the suitability of the material is the sole responsibility of the user.



July 11, 2023

**RE: HALYARD\* PUREZERO\* HG3 and HG5 Cleanroom Nitrile Gloves**

O&M Halyard, Inc. confirms that our Halyard **PUREZERO\*** HG3 and Halyard **PUREZERO** HG5 Nitrile Cleanroom Glove families are fully compliant with the related requirements of the European Union Regulation (EC) 1907/2006 concerning Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH).

O&M Halyard, Inc. hereby confirms that our Halyard **PUREZERO\*** HG3 and Halyard **PUREZERO** HG5 Nitrile Cleanroom Gloves either do not contain the presence of greater than 0.1% of substances identified on the SVHC Candidate list according to Article 33 of the REACH Regulation and/or do not contain any of the listed substances.

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at [PIQ@hyh.com](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

Sincerely,

A handwritten signature in black ink, appearing to read 'Caitlin Senter', with a stylized flourish at the end.

**Caitlin Senter**  
Director  
Global Regulatory Affairs  
O&M Halyard, Inc.



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

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

Holds Certificate Number:

**FM 697757**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design and Development, Production and Distribution of Industrial Gloves-Sterile and Non-Sterile Examination Gloves.

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2018-08-12

Latest Revision Date: 2022-09-01

Effective Date: 2022-09-01

Expiry Date: 2025-08-31

Page: 1 of 2



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

# ISO 9001:2015 (continued)

Certificate No: **FM 697757**

Location

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

Registered Activities

Design and Development, Production and Distribution of  
Industrial Gloves-Sterile and Non-Sterile Examination Gloves.

Including the following support function:  
Owens & Minor Halyard Incorporation. 5405 Windward  
Parkway, Alpharetta, GA, USA : Design and Development of  
Industrial Gloves-Sterile and Non-Sterile Examination Gloves.



Original Registration Date: 2018-08-12

Latest Revision Date: 2022-09-01

Effective Date: 2022-09-01

Expiry Date: 2025-08-31

Page: 2 of 2

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Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.



By Royal Charter

## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.  
9120 Lockwood Blvd  
Mechanicsville  
Virginia  
23116  
USA

Holds Certificate Number:

**MD 735497**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of sterile and non-sterile medical examination gloves.

For and on behalf of BSI:

  
Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-11-25

Latest Revision Date: 2023-01-05

Effective Date: 2023-01-09

Expiry Date: 2026-01-08

Page: 1 of 2



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# ISO 13485:2016 (continued)

Certificate No: **MD 735497**

| Location                                                                                                                                           | Registered Activities                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| O & M Halyard, Inc.<br>9120 Lockwood Blvd<br>Mechanicsville<br>Virginia<br>23116<br>USA                                                            | Headquarter management activities.                                                                       |
| O & M Halyard, Inc.<br>1 Edison Drive<br>Alpharetta<br>Georgia<br>30005<br>USA                                                                     | The design and development of sterile and non-sterile medical examination gloves.                        |
| Safeskin Medical & Scientific<br>(Thailand) Ltd.<br>200 Moo 8, Kanchanavanich Road,<br>Tambol Prik, Amphur Sadao,<br>Songkhla<br>90120<br>Thailand | Design, development, manufacture and distribution of sterile and non-sterile medical examination gloves. |

Original Registration Date: 2020-11-25  
Latest Revision Date: 2023-01-05

Effective Date: 2023-01-09  
Expiry Date: 2026-01-08

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).



## Certificate of Registration

### ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

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

Holds Certificate Number:

**EMS 772160**

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

The Manufacturing of Medical and Scientific Gloves.

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2022-10-27

Latest Revision Date: 2022-10-27

Effective Date: 2022-10-27

Expiry Date: 2025-10-26

Page: 1 of 1



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Further clarifications regarding the scope of this certificate and the applicability of ISO 14001:2015 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.



May 4, 2023

RE: **HALYARD\* PUREZERO\* HG3 and HG5 Nitrile Gloves**

Dear Valued Customer,

This letter is in response to your recent accelerator-free inquiry for the **HALYARD\* PUREZERO\* HG3 and HG5 Nitrile Gloves**.

The following gloves are accelerator-free and are not formulated with the following vulcanizing chemicals and accelerators: Sulfur, Thiurams, Thioxoles, Guanidines, Carbamates.†

**HALYARD\* PUREZERO\* HG3 White Nitrile Gloves**  
**HALYARD\* PUREZERO\* HG3 Light Blue Nitrile Gloves**  
**HALYARD\* PUREZERO\* HG3 White SGX\* Nitrile Gloves**  
**HALYARD\* PUREZERO\* HG3 White Sterile Nitrile Gloves**  
**HALYARD\* PUREZERO\* HG3 Light Blue Sterile Nitrile Gloves**

**HALYARD\* PUREZERO\* HG5 White Nitrile Gloves**  
**HALYARD\* PUREZERO\* HG5 Blue SGX\* Nitrile Gloves**

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at [PIQ@hyh.com](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

Sincerely,

*Shannon Smith*

**Shannon Smith**  
Associate Product Manager  
O&M Halyard, Inc.

† The chemicals and accelerators shown is not a comprehensive list.

\*Registered Trademark or Trademark of O&M Halyard or its affiliates.

COPY-04632

## HG3 Nitrile Cleanroom Gloves

### ADDED PROTECTION FROM THE RISK OF CHEMICAL EXPOSURE

It's critical to protect staff from exposure to potentially hazardous chemicals and chemotherapy drugs. In addition to providing a barrier to chemical splash, microorganisms and viruses, **PUREZERO\* HG3 Cleanroom Gloves are now tested against 29 chemicals, 14 chemotherapy drugs and Fentanyl.**

### CHEMOTHERAPY DRUG RESISTANCE GUIDE<sup>4</sup>

| Chemotherapy Agent (Concentration in mg/ml) | HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves |                                                                          |
|---------------------------------------------|------------------------------------------------------------|--------------------------------------------------------------------------|
|                                             | Minimum Breakthrough Detection Time (minutes)              | Average Steady State Perm. Rate ( $\mu\text{g}/\text{cm}^2/\text{min}$ ) |
| Carmustine (BCNU) (3.3)                     | 158.5                                                      | 0.06                                                                     |
| Cisplatin (1.0)                             | >240                                                       | N/A                                                                      |
| Cyclophosphamide (20.0)                     | >240                                                       | N/A                                                                      |
| Dacarbazine (10.0)                          | >240                                                       | N/A                                                                      |
| Doxorubicin HCL (2.0)                       | >240                                                       | N/A                                                                      |
| Etoposide (20.0)                            | >240                                                       | N/A                                                                      |
| Fluorouracil (50.0)                         | >240                                                       | N/A                                                                      |
| Ifosfamide (50.0)                           | >240                                                       | N/A                                                                      |
| Methotrexate (25.0)                         | >240                                                       | N/A                                                                      |
| Mitomycin C (0.5)                           | >240                                                       | N/A                                                                      |
| Mitoxantrone (2.0)                          | >240                                                       | N/A                                                                      |
| Paclitaxel (6.0)                            | >240                                                       | N/A                                                                      |
| Thiotepa (10.0)                             | >240                                                       | N/A                                                                      |
| Vincristine (1.0)                           | >240                                                       | N/A                                                                      |
| <b>Additional Tests</b>                     |                                                            |                                                                          |
| Fentanyl Citrate Injection, 100 mcg/2mL     | >240                                                       | N/A                                                                      |

Use the rating system below to determine the chemotherapy compatibility for exposure:

|          |                                                                                                                                             |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------|
| <10      | Not recommended for use - breakthrough can occur in less than 10 minutes.                                                                   |
| 11 - 239 | Use with caution - breakthrough can occur between 11 and 239 minutes.                                                                       |
| >240     | Recommended for protection - no breakthrough up to 240 minutes.                                                                             |
| N/A      | The chemotherapy drug did not reach the minimum permeation rate ( $0.01 \mu\text{g}/\text{cm}^2/\text{min}$ ) as defined within ASTM D6978. |

**CAUTION:** It's the user's responsibility to determine the applicability of these gloves for their intended use with chemotherapy drugs.

### DEFINITION OF TERMS

**Breakthrough time:** The time required for the test chemical to be detected on the inside of the glove. Essentially, this is the amount of time that the glove can resist a chemical when the glove is fully immersed in the chemical.

**Permeation:** The process where chemicals, such as liquids, gases and vapors can pass through a glove film (or other PPE interfaces) without penetrating directly through a pinhole, tear or other visible opening.

**Permeation rate:** The flowrate of the chemical after the chemical breaks through the inside of the glove. It is measured in amount per surface area of the glove per time ( $\mu\text{g}/\text{cm}^2/\text{min}$ ).

# HG3 Nitrile Cleanroom Gloves

## CHEMICAL RESISTANCE GUIDE<sup>5</sup>

| Chemical (Concentration %)               | HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves |                                           |
|------------------------------------------|-----------------------------------------------------|-------------------------------------------|
|                                          | Minimum Breakthrough Time (minutes)                 | Permeation Rate (µg/cm <sup>2</sup> /min) |
| 1-Butanol (99)                           | 85.6                                                | 4.0                                       |
| Acetic Acid (30)                         | >480                                                | <1.0                                      |
| Acrylamide (40)                          | >480                                                | <1.0                                      |
| Benzalkonium Chloride (1)                | >480                                                | <1.0                                      |
| Chloroform (70)                          | 0                                                   | N/A                                       |
| Citric Acid (30)                         | >480                                                | <1.0                                      |
| Citric Acid (70)                         | >480                                                | <1.0                                      |
| Cyclohexane (99)                         | 147.8                                               | 2.7                                       |
| Didecyltrimethylammonium Chloride (0.04) | >480                                                | <1.0                                      |
| Dimethylformamide (99)                   | 0                                                   | N/A                                       |
| Dimethyl Sulfoxide (99)                  | 10.7                                                | N/A                                       |
| Ethanol (70)                             | 19.1                                                | 1.2E+01                                   |
| Ethanol (99)                             | 16.3                                                | 2.5E+01                                   |
| Ethidium Bromide (1)                     | >480                                                | <1.0                                      |
| Formaldehyde (37)                        | >480                                                | <1.0                                      |
| Glycolic Acid (10)                       | >480                                                | <1.0                                      |
| Glutaraldehyde (50)                      | >480                                                | <1.0                                      |
| Heptane (99)                             | >480                                                | <1.0                                      |
| Hydrazine Monohydrate (55)               | >480                                                | <1.0                                      |
| Hydrochloric Acid (30)                   | >480                                                | <1.0                                      |
| Hydrogen Peroxide (30)                   | 310.0                                               | 1.0                                       |
| Isopropyl Alcohol (70)                   | 189.5                                               | 1.0                                       |
| Isopropyl Alcohol (99)                   | 105.3                                               | 3.5                                       |
| Methanol (99)                            | 7.7                                                 | 1.9E+01                                   |
| Nitric Acid (65)                         | 12.0                                                | 1.7E+02                                   |
| Peracetic Acid (5)                       | >480                                                | <1.0                                      |
| Phosphoric Acid (70)                     | >480                                                | <1.0                                      |
| Sodium Hydroxide (50)                    | >480                                                | <1.0                                      |
| Sodium Hypochlorite (10-13)              | >480                                                | <1.0                                      |
| Spor-Klenz (N/A)                         | >480                                                | <1.0                                      |
| Sulfuric Acid (50)                       | >480                                                | <1.0                                      |
| Sulfuric Acid (99)                       | 11.0                                                | N/A                                       |

Use the rating system below to determine the chemical compatibility for exposure:

|          |                                                                                                                                                                                                          |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <10      | Not recommended for use - breakthrough can occur in less than 10 minutes.                                                                                                                                |
| 11 - 479 | Use with caution - breakthrough can occur between 11 and 479 minutes.                                                                                                                                    |
| >480     | Permeation breakthrough is excellent. Permeation does not occur during the test (8 hours).                                                                                                               |
| N/A      | The chemical did not reach the minimum permeation rate (1 µg/cm <sup>2</sup> /min) as defined within EN 16523-1. There is a possibility for trace amounts of the chemical to permeate through the glove. |
| —        | The permeation rate was beyond the range of the detection instruments. The permeation of the chemical through the glove film may be too high for the detector to reach a steady-state reading.           |

CAUTION: It's the user's responsibility to determine the applicability of these gloves for their intended use.



November 13<sup>th</sup>, 2023

RE: **ESD Testing for HALYARD\* PUREZERO\* Nitrile Gloves**

Dear Valued Customer,

This letter is in response to your recent inquiry regarding ESD testing of **HALYARD\* PUREZERO\* Nitrile Gloves**.

The following **HALYARD\* PUREZERO\* Nitrile Glove** families have been tested against ANSI/ESD STM15.1:2019 "In-Use Resistance Testing of Gloves and Finger Cots":

**HALYARD\* PUREZERO\* HG3 Cleanroom Nitrile Gloves**

| <b><u>Glove Description</u></b>                            | <b><u>Code</u></b> |
|------------------------------------------------------------|--------------------|
| HALYARD* <b>PUREZERO*</b> HG3 White Nitrile Gloves         | CLN3031XS          |
| HALYARD* <b>PUREZERO*</b> HG3 White Nitrile Gloves         | CLN3031SM          |
| HALYARD* <b>PUREZERO*</b> HG3 White Nitrile Gloves         | CLN3031MD          |
| HALYARD* <b>PUREZERO*</b> HG3 White Nitrile Gloves         | CLN3031LG          |
| HALYARD* <b>PUREZERO*</b> HG3 White Nitrile Gloves         | CLN3031XL          |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Nitrile Gloves          | CLN9031XS          |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Nitrile Gloves          | CLN9031SM          |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Nitrile Gloves          | CLN9031MD          |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Nitrile Gloves          | CLN9031LG          |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Nitrile Gloves          | CLN9031XL          |
| HALYARD* <b>PUREZERO*</b> HG3 White SGX* Nitrile Gloves    | CLN3231XS          |
| HALYARD* <b>PUREZERO*</b> HG3 White SGX* Nitrile Gloves    | CLN3231SM          |
| HALYARD* <b>PUREZERO*</b> HG3 White SGX* Nitrile Gloves    | CLN3231MD          |
| HALYARD* <b>PUREZERO*</b> HG3 White SGX* Nitrile Gloves    | CLN3231LG          |
| HALYARD* <b>PUREZERO*</b> HG3 White SGX* Nitrile Gloves    | CLN3231XL          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323260          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323265          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323270          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323275          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323280          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323285          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323290          |
| HALYARD* <b>PUREZERO*</b> HG3 White Sterile Nitrile Gloves | CLN323210          |

|                                                           |           |
|-----------------------------------------------------------|-----------|
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923260 |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923265 |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923270 |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923275 |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923280 |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923285 |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923290 |
| HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves | CLN923210 |

#### **HALYARD\* **PUREZERO\*** HG5 Cleanroom Nitrile Gloves**

| <b><u>Glove Description</u></b>                        | <b><u>Code</u></b> |
|--------------------------------------------------------|--------------------|
| HALYARD* <b>PUREZERO*</b> HG5 White Nitrile Gloves     | CLN30512XS         |
| HALYARD* <b>PUREZERO*</b> HG5 White Nitrile Gloves     | CLN30512SM         |
| HALYARD* <b>PUREZERO*</b> HG5 White Nitrile Gloves     | CLN30512MD         |
| HALYARD* <b>PUREZERO*</b> HG5 White Nitrile Gloves     | CLN30512LG         |
| HALYARD* <b>PUREZERO*</b> HG5 White Nitrile Gloves     | CLN30512XL         |
| HALYARD* <b>PUREZERO*</b> HG5 Blue SGX* Nitrile Gloves | CLN92512XS         |
| HALYARD* <b>PUREZERO*</b> HG5 Blue SGX* Nitrile Gloves | CLN92512SM         |
| HALYARD* <b>PUREZERO*</b> HG5 Blue SGX* Nitrile Gloves | CLN92512MD         |
| HALYARD* <b>PUREZERO*</b> HG5 Blue SGX* Nitrile Gloves | CLN92512LG         |
| HALYARD* <b>PUREZERO*</b> HG5 Blue SGX* Nitrile Gloves | CLN92512XL         |

#### **HALYARD\* **PUREZERO\*** Nitrile Exam Gloves**

| <b><u>Glove Description</u></b>                           | <b><u>Code</u></b> |
|-----------------------------------------------------------|--------------------|
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Exam Gloves      | LFS111XS           |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Exam Gloves      | LFS111SM           |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Exam Gloves      | LFS111MD           |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Exam Gloves      | LFS111LG           |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Exam Gloves      | LFS111XL           |
| HALYARD* <b>PUREZERO*</b> MARIN-XTRA* Nitrile Exam Gloves | LFS121XS           |
| HALYARD* <b>PUREZERO*</b> MARIN-XTRA* Nitrile Exam Gloves | LFS121SM           |
| HALYARD* <b>PUREZERO*</b> MARIN-XTRA* Nitrile Exam Gloves | LFS121MD           |
| HALYARD* <b>PUREZERO*</b> MARIN-XTRA* Nitrile Exam Gloves | LFS121LG           |
| HALYARD* <b>PUREZERO*</b> MARIN-XTRA* Nitrile Exam Gloves | LFS121XL           |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Exam Gloves      | LFS311XS           |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Exam Gloves      | LFS311SM           |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Exam Gloves      | LFS311MD           |

|                                                             |          |
|-------------------------------------------------------------|----------|
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Exam Gloves        | LFS311LG |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Exam Gloves        | LFS311XL |
| HALYARD* <b>PUREZERO*</b> LIMON-XTRA* Nitrile Exam Gloves   | LFS321XS |
| HALYARD* <b>PUREZERO*</b> LIMON-XTRA* Nitrile Exam Gloves   | LFS321SM |
| HALYARD* <b>PUREZERO*</b> LIMON-XTRA* Nitrile Exam Gloves   | LFS321MD |
| HALYARD* <b>PUREZERO*</b> LIMON-XTRA* Nitrile Exam Gloves   | LFS321LG |
| HALYARD* <b>PUREZERO*</b> LIMON-XTRA* Nitrile Exam Gloves   | LFS321XL |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Exam Gloves | LFS511XS |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Exam Gloves | LFS511SM |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Exam Gloves | LFS511MD |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Exam Gloves | LFS511LG |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Exam Gloves | LFS511XL |

#### **HALYARD\* **PUREZERO\*** Nitrile Gloves**

| <b><u>Glove Description</u></b>                        | <b><u>Code</u></b> |
|--------------------------------------------------------|--------------------|
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves        | LFS1117XS          |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves        | LFS1117SM          |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves        | LFS1117MD          |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves        | LFS1117LG          |
| HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves        | LFS1117XL          |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves        | LFS3117XS          |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves        | LFS3117SM          |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves        | LFS3117MD          |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves        | LFS3117LG          |
| HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves        | LFS3117XL          |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves | LFS5117XS          |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves | LFS5117SM          |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves | LFS5117MD          |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves | LFS5117LG          |
| HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves | LFS5117XL          |

Based on the ANSI/ESD STM15.1:2019 test results from an external laboratory at conditions of 12% RH and 23°C, all **HALYARD\* **PUREZERO\*** Nitrile Glove** product families listed above are within the dissipative classification range (Resistance =  $10^4$  to  $10^{11}$  ohms) as defined by ANSI/ESD standards.

Therefore, **HALYARD\* **PUREZERO\*** Nitrile Gloves** are considered to be static dissipative in-use. Please note that this is based on a standardized test method in a laboratory environment, and the resistance test results and classification do not fully characterize the glove for all electrostatic properties. Other electrostatic properties, such as charge accumulation, and specific process conditions may need to be assessed based on your particular application prior to use.



Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at [PIQ@hyh.com](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

Sincerely,

**Caitlin Senter**  
Director  
Global Regulatory Affairs  
O&M Halyard, Inc.

**Ryan Solan**  
Manager  
Global Research and Development  
O&M Halyard, Inc.

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COPY-04825



RE: Compliance statement – HALYARD\* **PUREZERO\*** Nitrile Gloves

Please be advised that to the best of O&M Halyard knowledge, the **PUREZERO\*** HG3 Nitrile Gloves and HALYARD\* **PUREZERO\*** HG5 Nitrile Gloves are produced entirely from materials of synthetic origin and therefore are free from human or any other animal derived materials including bovine products (Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE)).

- *Under various environmental protection and product safety regulations, directives, standards, and initiatives “intentionally introduced” means “deliberately utilized during the manufacture of the components and/or for the formulation of a material or component where its continued presence is desired in the final product to provide a specific property, appearance or quality.”*

This information is based on O&M Halyard, Inc.'s knowledge of these products at the time of publication.

If you have any questions or need additional information, please do not hesitate to contact us at [PIQ@hyh.com](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

*–This statement is valid unsigned –*

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March 14<sup>th</sup>, 2023

RE: **HALYARD\* PUREZERO\* Nitrile Gloves**

Dear Valued Customer,

This letter is in response to your recent inquiry regarding storage conditions of **HALYARD\* PUREZERO\* Nitrile Gloves**.

As displayed by the indications on the packaging labeling, **HALYARD\* PUREZERO\* Nitrile Gloves** shall be stored in conditions where the product is kept dry (away from moisture), away from direct sunlight, away from sources of heat, and away from radioactive sources. To reduce the potential of accelerated aging, it is recommended to store the product at standard room temperature conditions, when possible.

Thank you for your interest in HALYARD\* products. If you have any questions or need additional information, please do not hesitate to contact us at [PIQ@hyh.com](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

Sincerely,

**Ryan Solan**  
R&D Senior Engineer  
Global Research and Development  
O&M Halyard, Inc.

**Theresa McCoy**  
Global Product Manager  
Global Strategic Marketing  
O&M Halyard, Inc.

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COPY-04606



September 24, 2023

**RE: HALYARD\* PUREZERO\* HG3 and HG5 Nitrile Gloves**

Dear Valued Customer,

This letter is in response to your recent inquiry regarding the presence of silicone for the **PUREZERO\*** HG3 White Nitrile Gloves, **PUREZERO\*** HG3 White SGX\* Nitrile Gloves, **PUREZERO\*** HG3 Light Blue Nitrile Gloves, **PUREZERO\*** HG3 Sterile Light Blue Nitrile Gloves, **PUREZERO\*** HG3 Sterile White Nitrile Gloves, **HALYARD\*** **PUREZERO\*** HG5 White Nitrile Gloves, and **HALYARD\*** **PUREZERO\*** HG5 Blue SGX\* Nitrile Gloves.

According to ASTM E1252 Standard Practice for General Techniques for Obtaining Spectra for Qualitative Analysis, the results below reflect the detectable limits of silicone covering the spectral range from 4000cm<sup>-1</sup> to 50cm<sup>-1</sup> via FT-IR (Fourier Transform Infrared Analysis). The results below indicate that the **HALYARD\*** **PUREZERO\*** HG3 NITRILE GLOVES and **HALYARD\*** **PUREZERO\*** HG5 NITRILE GLOVES have no silicone detectable on the outside surface and inside surface of either gloves sampled per 3<sup>rd</sup> party testing.

The following product codes are applicable: **PUREZERO\*** HG3 White Nitrile Gloves: CLN92512XS, CLN92512SM, CLN92512MD, CLN92512LG, CLN92512XL; **PUREZERO\*** HG3 Light Blue Nitrile Gloves: CLN90511XS, CLN90511SM, CLN90511MD, CLN90511LG, CLN90511XL; **PUREZERO\*** HG3 White SGX\* Nitrile Gloves: CLN3031XS, CLN3031SM, CLN3031MD, CLN3031LG, CLN3031XL; **PUREZERO\*** HG3 Sterile White Nitrile Gloves: CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323290, CLN323210; **PUREZERO\*** HG3 Sterile Light Blue Nitrile Gloves: CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210; **HALYARD\*** **PUREZERO\*** HG5 White Nitrile Gloves: CLN30512XS, CLN30512SM, CLN30512MD, CLN30512LG, and CLN30512XL; **HALYARD\*** **PUREZERO\*** HG5 Blue SGX\* Nitrile Gloves: CLN92512XS, CLN92512SM, CLN92512MD, CLN92512LG, and CLN92512XL.

| Fourier Transform Infrared Analysis (FT-IR)<br>Per ASTM E1252-98(21) |                     |
|----------------------------------------------------------------------|---------------------|
| Gloves                                                               | Results             |
| <b>PUREZERO*</b> HG3 and HG5<br>Nitrile Gloves                       | No silicon detected |

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at [PIQ@hyh.com](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

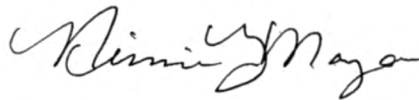
Sincerely

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COPY-04662



**Caitlin Senter**  
Director  
Global Regulatory Affairs  
O&M Halyard, Inc.



**Nimia Maya**  
R&D Engineer II  
Global Research and Development  
O&M Halyard, Inc.

**TITLE:** HALYARD\* PUREZERO\* HG3 & HG5 Nitrile Gloves Packaging

**UPDATE:** Alternate packaging supplier for HALYARD\* PUREZERO\* HG3 and HG5 Nitrile Gloves

**WHAT YOU NEED TO KNOW:**

There will be an alternate supplier for the packaging (poly bag, poly pouch and poly wallet) used for **HALYARD\* PUREZERO\* HG3 and HG5 Nitrile Gloves**

**WHAT YOU CAN EXPECT:**

There is an alternate supplier being qualified to supply the poly bag, poly pouch and poly wallet used to package **HALYARD\* PUREZERO\* HG3 and HG5 Nitrile Gloves**. The alternate supplier, TAKO Astatic Technology SDN BHD, will supply the same packaging as our current supplier, Tip Corporation SDN BHD. All specifications for the packaging, including the material, composition, dimensions, thickness, and ink, will be identical to the current packaging. There will be no change to the appearance of the packaging or printing. There will be no change to the sterilization process or the sterility assurance level of the products. Additionally, there will be no changes to the product codes or product labeling.

**TIMING OF CHANGE:** There will be a rolling change for the alternate supplier's packaging that will enter our inventory as early as December 2023. Both packaging vendors could be used based on supply chain availability.



**PRODUCTS IMPACTED BY THIS CHANGE:**

|                                                        |
|--------------------------------------------------------|
| <b>PUREZERO* HG3 White Nitrile Gloves</b>              |
| <b>CODE</b>                                            |
| CLN3031XS                                              |
| CLN3031SM                                              |
| CLN3031MD                                              |
| CLN3031LG                                              |
| CLN3031XL                                              |
| <b>PUREZERO* HG3 Light Blue Nitrile Gloves</b>         |
| <b>CODE</b>                                            |
| CLN9031XS                                              |
| CLN9031SM                                              |
| CLN9031MD                                              |
| CLN9031LG                                              |
| CLN9031MD                                              |
| <b>PUREZERO* HG3 White SGX* Nitrile Gloves</b>         |
| <b>CODE</b>                                            |
| CLN3231XS                                              |
| CLN3231SM                                              |
| CLN3231MD                                              |
| CLN3231LG                                              |
| CLN3231XL                                              |
| <b>PUREZERO* HG3 White Sterile Nitrile Gloves</b>      |
| <b>CODE</b>                                            |
| CLN323260                                              |
| CLN323265                                              |
| CLN323270                                              |
| CLN323275                                              |
| CLN323280                                              |
| CLN323285                                              |
| CLN323290                                              |
| CLN323210                                              |
| <b>PUREZERO* HG3 Light Blue Sterile Nitrile Gloves</b> |
| <b>CODE</b>                                            |
| CLN923260                                              |
| CLN923265                                              |
| CLN923270                                              |
| CLN923275                                              |
| CLN923280                                              |
| CLN923285                                              |
| CLN923290                                              |
| CLN923210                                              |



|                                               |
|-----------------------------------------------|
| <b>PUREZERO* HG5 White Nitrile Gloves</b>     |
| <b>CODE</b>                                   |
| CLN30512XS                                    |
| CLN30512SM                                    |
| CLN30512MD                                    |
| CLN30512LG                                    |
| CLN30512XL                                    |
| <b>PUREZERO* HG5 Blue SGX* Nitrile Gloves</b> |
| <b>CODE</b>                                   |
| CLN92512XS                                    |
| CLN92512SM                                    |
| CLN92512MD                                    |
| CLN92512LG                                    |
| CLN92512XL                                    |

Thank you for your interest in HALYARD\* products. If you have any questions or need additional information including example certifications, please do not hesitate to contact us at [PIQ@hyh.com](mailto:PIQ@hyh.com), call us directly at 1-844-425-9273 or reach out to your O&M Halyard commercial representative or distributor.

Sincerely,

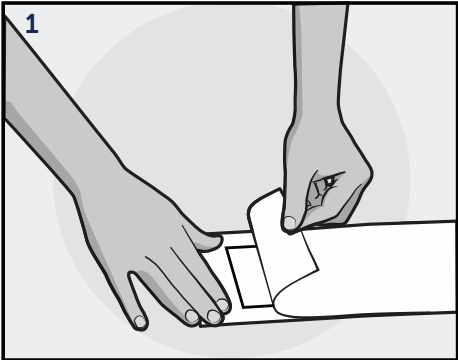
Gustavo Fiallos  
Director Global Quality Operations, Owens & Minor

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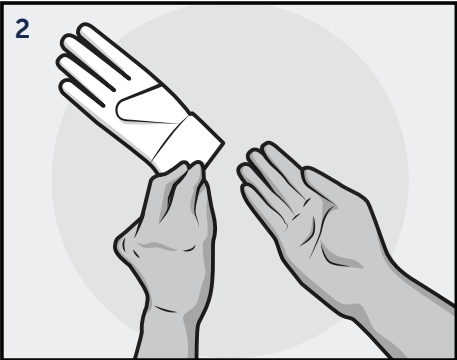
1 Edison Drive, Alpharetta, GA 30005 | 844.425.9273  
[owens-minor.com](http://owens-minor.com) | [halyardhealth.com](http://halyardhealth.com) | [byramhealthcare.com](http://byramhealthcare.com)

# GUIDE TO DONNING AND DOFFING OF STERILE CLEANROOM GLOVES

## DONNING GLOVES



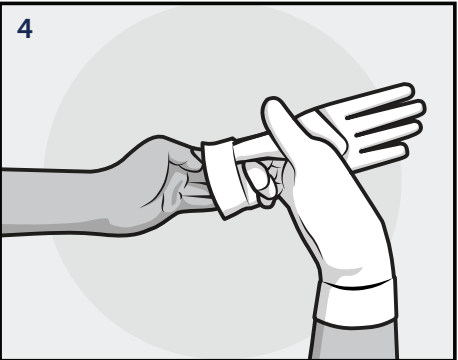
Peel open the pouch which keeps the product sterile. Open clear wallet.



Grasp the interior of one glove and carefully pull over the opposite hand.



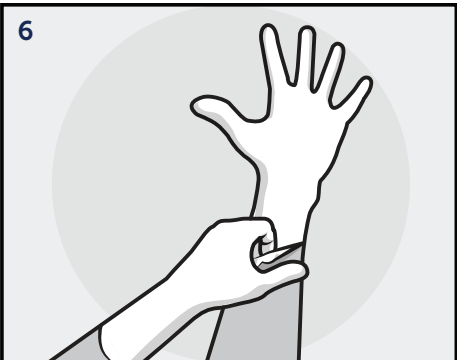
Gently ease the glove up over the hand and wrist, leaving the cuff folded.



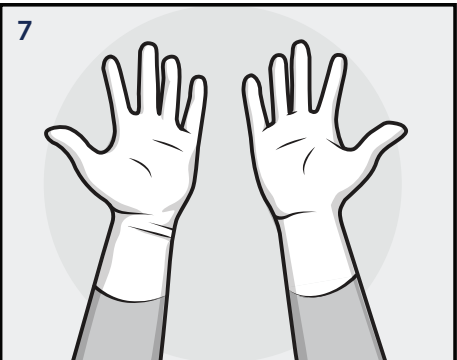
Lift the second glove under the folded cuff using gloved fingers.



Slide your second hand into the glove by holding it under the folded cuff, then unfold the cuff over the wrist and arm.

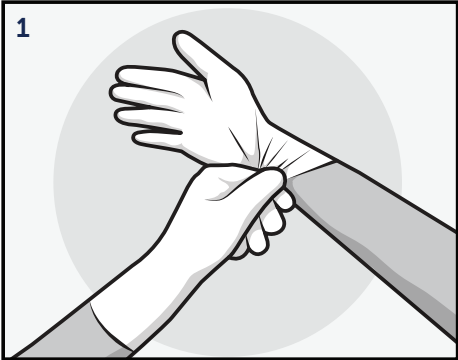


Using gloved fingers, unfold the second cuff over your wrist and arm.

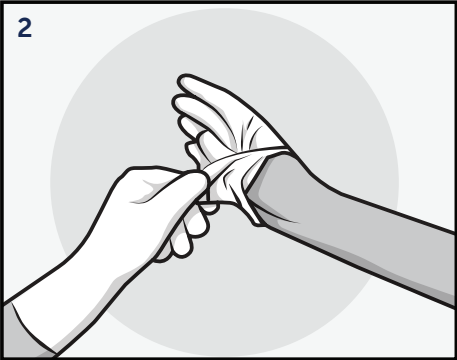


To remain sterile, do not touch anything with your gloved hands.

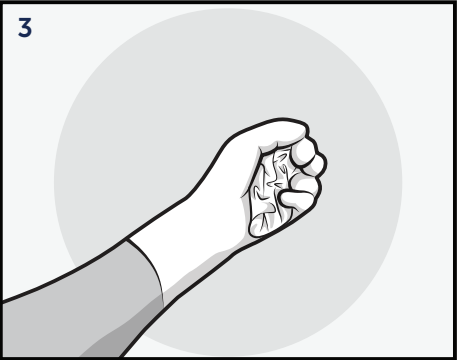
## DOFFING GLOVES



Grasp the exterior of one glove with your other gloved hand.



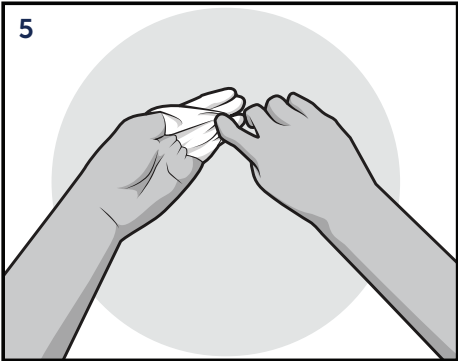
Carefully pull the glove off your hand, turning it inside-out.



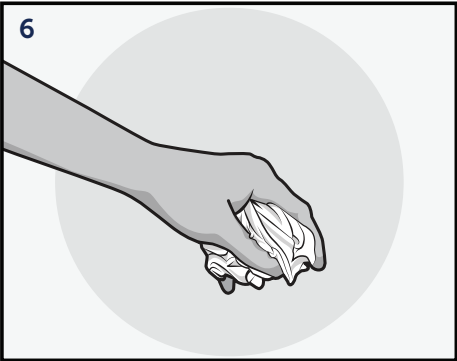
Ball the glove up and hold in your other gloved hand.



Slide your ungloved fingers into the opening of the other glove.



Carefully pull the glove off your hand, turning it inside-out and wrapping it around the doffed glove in your palm.



Discard appropriately.

HALYARD\* recommends double donning/gloving. Don the gloves so that the sleeve cuffs are between the two pairs of gloves.

For more information, contact your HALYARD\* representative or distributor, or visit [www.purezerogloves.com](http://www.purezerogloves.com)