

HALYARD* **PUREZERO*** HG3 LIGHT BLUE STERILE CLEANROOM GLOVES

DATA PACK



For the Cleanroom Environment
For Industrial Use Only

HALYARD* **PUREZERO*** HG3 LIGHT BLUE STERILE CLEANROOM GLOVES DATA PACK

All documents depicted here are FOR EXAMPLE ONLY. For specific documents related to lot numbers, please visit www.halyardhealth.com/information, or ask your Distributor or HALYARD* Representative.

TABLE OF CONTENTS

| | |
|---|----|
| Technical Data Sheet | 3 |
| COA – Certificate of Analysis | 6 |
| COI – Certificate of Irradiation | 7 |
| Package Labels | |
| Case Label..... | 12 |
| Pouch Label..... | 13 |
| Sterilization/Irradiation Label | 14 |
| Packaging Certificates | |
| Pouch COA | 16 |
| Wallet COA | 19 |
| Dose Mapping Report | 24 |
| Safety Data Sheet | 35 |
| REACH Regulation Letter | 37 |
| Certificate of Registration 9001: 2015 | 38 |
| Certificate of Registration ISO 13485:2016 | 40 |

TECHNICAL DATA SHEET



TECHNICAL DATA SHEET

Description

HALYARD* **PUREZERO*** HG3 Light Blue 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/C/D cleanrooms. Because HALYARD* **PUREZERO*** HG3 Sterile Cleanroom Gloves are made with an **accelerator-free**¹ nitrile polymer, there is a reduced risk of allergies and skin irritation associated with accelerator chemicals in other nitrile gloves.



Cleanliness Properties

| | | |
|---|--------------------------------|---------------|
| Max Particle Count | >0.5µm / cm ² <1200 | IEST RP-CC005 |
| Max Endotoxin Level | <20 EU | |
| Ionic Content (Extractable ions) | Max Level (ug/g) | IEST RP-CC005 |
| Calcium | 50 | |
| Chloride | 35 | |
| Magnesium | 5 | |
| Nitrate | 20 | |
| Potassium | 5 | |
| Sodium | 10 | |
| Sulfate | 10 | |
| Zinc | 25 | |
| Ammonium | 5 | |

Physical Properties

| | |
|--|------------------|
| AQL | 1.0 |
| Sterile | ✓ |
| Hand Specific Pairs | ✓ |
| Smooth Grip | ✓ |
| Textured Fingertips and Palms | ✓ |
| Accelerator-Free ¹ | ✓ |
| Low Dermatitis Potential | ✓ |
| Latex-Free | ✓ |
| Powder-Free | ✓ |
| Silicone-Free | ✓ |
| Static Dissipative in Use ² | ✓ |
| Tensile Strength ³ | 20 MPa (Target) |
| Ultimate Elongation ³ | 600% |
| Sterility Assurance Level (SAL) | 10 ⁻⁶ |
| Shelf Life | 5 Years |

TECHNICAL DATA SHEET

Glove Dimensions

| | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 10.0 |
|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Glove Length (inch/cm) | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 |
| Width of Palm (mm) | 80 | 87 | 94 | 98 | 109 | 114 | 120 | 128 |
| Middle finger length (mm) | 73.2 | 76.9 | 81.2 | 85.3 | 87.3 | 91.7 | 93.7 | 97.8 |
| Finger Tip Thickness | 0.10 mm (4 mil) | 0.10 mm (4 mil) | 0.10 mm (4 mil) | 0.10 mm (4 mil) | 0.10 mm (4 mil) | 0.10 mm (4 mil) | 0.10 mm (4 mil) | 0.10 mm (4 mil) |
| Palm Thickness | 0.08 mm (3.1 mil) | 0.08 mm (3.1 mil) | 0.08 mm (3.1 mil) | 0.08 mm (3.1 mil) | 0.08 mm (3.1 mil) | 0.08 mm (3.1 mil) | 0.08 mm (3.1 mil) | 0.08 mm (3.1 mil) |
| Cuff Thickness | 0.07 mm (2.75 mil) | 0.07 mm (2.75 mil) | 0.07 mm (2.75 mil) | 0.07 mm (2.75 mil) | 0.07 mm (2.75 mil) | 0.07 mm (2.75 mil) | 0.07 mm (2.75 mil) | 0.07 mm (2.75 mil) |

Packaging Data

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

300 pairs per case: one glove pair/ poly wallet & pouch X 30 sealed pouches per PE bag x 10 PE bags per lined carton

Packaged in ISO Class 5 Cleanroom

Quality & Regulatory Standards

Compliant to these regulatory standards:

ISO 9001
ISO 13485

Compliant to these food handling regulatory standards:

FDA 21 CFR 177-2600
Commission Regulation (EU) No 10/2011
Japan Food Sanitation Act

FDA 21 CFR part 820 accreditation

CE 2797 PPE Category III according to Regulation (EU) 2016/425 EEC

EN ISO 374-5:2016 Virus Protection
EN ISO 374-1:2016/Type C K-Low Chemical Protection
EN 420:2003 +A1:2009

Compliant with the REACH regulation

Static Dissipative in Use

Tested per ANSI/ ESD SP 15.1

Tested against EN 1149: Protective Clothing - Electrostatic Properties

CE 2797
(PPE Cat. III)

ISO 374-5:2016

VIRUS

ISO 374-1:2016/Type C

K-Low Chemical



Additional Glove Information

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

Made in Thailand

Declaration of Conformity (DoC) and Certificates of Analysis (COA) and Certificates of Irradiation (COI) for every production lot available on-line at halyardhealth.com/information

Manufactured in our Safeskin Medical & Scientific (Thailand) Ltd. location

Ordering Information

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

| Size | Code | Size | Code |
|------|-----------|------|-----------|
| 6.0 | CLN923260 | 8.0 | CLN923280 |
| 6.5 | CLN923265 | 8.5 | CLN923285 |
| 7.0 | CLN923270 | 9.0 | CLN923290 |
| 7.5 | CLN923275 | 10.0 | CLN923210 |

For additional information or samples, contact your local distributor or visit www.purezerogloves.com

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

² Tested against ANSI SP 15.1 and EN 1149 (Protective Clothing - electrostatic properties)

³ Tested per ASTM D6519, EN 455-2

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.

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

CERTIFICATE OF ANALYSIS

Product Description : HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves - Pairs

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

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

Batches : SM209126X to SM212026X
SM209126V to SM212026V

Total Cases per Lot : 3,470
Date of Manufacture : Apr-22
Expiration Date : 2027-03-30

Physical Test Data

| | Watertight | Visual Defects | | Dimensions | Tensile (MPa) | Elongation (%) | Median Force at Break (N) |
|----------------------------|------------|----------------|------------|------------|---------------|----------------|---------------------------|
| | | Minor | Negligible | | Pre Aging | Pre Aging | Pre Aging |
| Sample Size : | 3055 | 2557 | 2434 | 519 | 272 | 272 | 272 |
| AQL Level : | 1.0 | 2.5 | 4.0 | 4.0 | 4.0 | 4.0 | 4.0 |
| Failures Allowed per AQL : | 40 | 88 | 130 | 33 | 14 | 14 | 14 |
| Failures : | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Inspection Results : | Accept | Accept | Accept | Accept | Accept | Accept | Accept |
| Averages: | | | | | 32.90 | 586 | 7.80 |

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 #/cm ² | Min | Max | Average Particles/cm ² | Inspection Result |
|----------------------------|-----|-----|-----------------------------------|-------------------|
| | 361 | 947 | 730 | Accept |

Particulate Level (≥0.5 microns) #/cm²

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data

| | Anions Results | | | | Cations Results | | | |
|---------------------|-----------------|------------------------------|-------------------------------|-----------------|------------------------------|----------------|------------------|------------------|
| | Chloride | Nitrate | Sulfate | Sodium | Ammonium | Potassium | Magnesium | Calcium |
| Units : | Cl ⁻ | NO ₃ ⁻ | SO ₄ ⁻² | Na ⁺ | NH ₄ ⁺ | K ⁺ | Mg ⁺² | Ca ⁺² |
| µg/g glove | 26.913 | 14.126 | 3.119 | 3.463 | 1.789 | 0.000 | 1.680 | 32.958 |
| Inspection Result : | Accept | Accept | Accept | Accept | Accept | Accept | Accept | Accept |

Trace Element Results

| | Zinc |
|---------------------|--------|
| Units : | Zn |
| µg/g glove | 2.78 |
| Inspection Result : | Accept |

Test Method : IEST-RP-CC005.4

Endotoxin Test Data

Test Result : BD Endotoxin Units/ device
Specification : ≤ 20 Endotoxin Units/ device

Detection Limit is ≤ 0.4 EU/device : BD = Below Detection Limit
Test Method : Limulus Amebocyte Lysate (LAL) Test : Kinetic Turbidimetric Technique

Sterility Data

This product conforms to standards for sterility ISO11737 with sterility assurance level (SAL) 10⁻⁶. A Certificate of Irradiation is also available to assure that the product has received the specified radiation dosage.

Review By :

[Signature]
09 May 2022
(QA Sr. Manager)



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 02-Nov-2020

MY03S12498738-1-1

This is to certify that Synergy Sterilisation (M) Sdn. Bhd., a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
 EN ISO 9001 Quality Management System
 EN ISO 13485 Quality System - Medical Devices

Safeskin Medical & Scientific (Thailand) Ltd
 200 MOO 8 KANCHANAVANICH ROAD
 PRIK SADAO
 Amphur Sadad
 SONGKHLA 90120
 THAILAND

Order Information

| | |
|--------------------------------------|---|
| Account Number: | 101195 |
| Synergy Health Sales Part Reference: | 1132653 |
| Customer Reference Number: | 4027016730 |
| Product Description: | HALYARD* PUREZERO* HG3 STERILE LIGHT BLUE NITRILE GLOVES - PAIRS |
| Validation Reference: | 0.0697 Rev01 |
| Quantity Received: | 120 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 50.0 |
| Customer Unit Lot/Batch Number: | SEE BELOW |

Processing Site: Plot 203, Kuala Ketil Industrial Park, Kuala Ketil, 09300 Phone No: +60(0)44152111

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA

VAT Number: 000859889664

Page 1 of 3

NOR AZWIN BT. YUSUF
 QA Executive
 Synergy Sterilisation (M) Sdn. Bhd.
 +60(0)44152111



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 02-Nov-2020

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Safeskin Medical & Scientific (Thailand) Ltd
 200 MOO 8 KANCHANAVANICH ROAD
 PRIK SADAO
 Amphur Sadad
 SONGKHLA 90120
 THAILAND

Other Process Details:

HALYARD* PUREZERO* HG3 Sterile Light Blue
 Nitrile Gloves - Pairs
 'Catalog Numbers : CLN923260, CLN923265,
 CLN923270, CLN923275, CLN923280,
 CLN923285, CLN923290, CLN923210.

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

| Catalog Number(s) | Lot No./Batch No. | Quantity |
|--------------------|-------------------|----------|
| CLN923270 48174-00 | NIL/SM02972XX | 15 |
| CLN923270 48174-00 | NIL/SM02922XX | 25 |
| CLN923275 48175-00 | NIL/SM02972XX | 4 |
| CLN923275 48175-00 | NIL/SM02922XX | 23 |
| CLN923275 48175-00 | NIL/SM02782XX | 13 |
| CLN923280 48176-00 | NIL/SM02972XX | 27 |
| CLN923280 48176-00 | NIL/SM02922XX | 13 |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 02-Nov-2020 01:25 |
| Reference Dose Range kGy: | 31.3 - 31.5 |
| Calculated Minimum Dose kGy: | 25.6 |
| Calculated Maximum Dose kGy: | 34.8 |

Processing Site: Plot 203, Kuala Ketil Industrial Park, Kuala Ketil, 09300 Phone No: +60(0)44152111

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA

VAT Number: 000859889664

Page 2 of 3

02/11/2020
 NOR AZWIN BT. YUSUF
 QA Executive
 Synergy Sterilisation (M) Sdn. Bhd.
 +60(0)44152111



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 02-Nov-2020

MY03S12498738-1-1

This is to certify that Synergy Sterilisation (M) Sdn. Bhd., a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
 EN ISO 9001 Quality Management System
 EN ISO 13485 Quality System - Medical Devices

Safeskin Medical & Scientific (Thailand) Ltd
 200 MOO 8 KANCHANAVANICH ROAD
 PRIK SADAO
 Amphur Sadad
 SONGKHLA 90120
 THAILAND

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

Processing Site: Plot 203, Kuala Ketil Industrial Park, Kuala Ketil, 09300 Phone No: +60(0)44152111

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA

VAT Number: 000859889664

Page 3 of 3

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 QA Executive
 Synergy Sterilisation (M) Sdn. Bhd.
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http://www.steris-ast.com

Certificate of Irradiation

Date Issued : 24-Jun-2022

STT20221382

This is to certify the STERIS TOMOE (THAILAND) LTD. has where appropriate delivered an irradiation process in accordance with:

| | |
|----------------|---------------------------------------|
| EN ISO 11137-1 | Sterilisation of Health Care Products |
| EN ISO 13485 | Quality System – Medical Devices |

SAFESKIN MEDICAL & SCIENTIFIC (THAILAND) LTD.

200 MOO 8, KANJANAVANICH ROAD
TAMBOL PRIK, AMPHUR SADAO
SONGKHLA
90120
THAILAND

Order Information

| Account Number : | 327776 | | | | | | |
|--------------------------------------|---|-------------------|-------------------|----------|--------------------|---------------|----|
| STERIS TOMOE Sales Part Reference : | Process Specification no. STT-SP-SPG-112 | | | | | | |
| Customer Reference Number : | 4027020047 | | | | | | |
| Product Description : | HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves - Pairs | | | | | | |
| Validation Reference : | PQ Report no. CHONII-PQ0017 | | | | | | |
| Quantity Received : | 30 | | | | | | |
| Customer Minimum Specification kGy : | 25.0 | | | | | | |
| Customer Maximum Specification kGy : | 50.0 | | | | | | |
| Customer Unit Lot/Batch Number : | SEE BELOW | | | | | | |
| Other Process Details : | HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves - Pairs Catalog Numbers : CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210 OMH Code : 48172-80, 48173-80, 48174-80, 48175-80, 48176-80, 48177-80, 48178-80, 48179-80 | | | | | | |
| | <table border="1"> <thead> <tr> <th>Catalog Number(s)</th> <th>Lot No./Batch No.</th> <th>Quantity</th> </tr> </thead> <tbody> <tr> <td>CLN923210 48179-80</td> <td>NIL/SM217126X</td> <td>30</td> </tr> </tbody> </table> | Catalog Number(s) | Lot No./Batch No. | Quantity | CLN923210 48179-80 | NIL/SM217126X | 30 |
| Catalog Number(s) | Lot No./Batch No. | Quantity | | | | | |
| CLN923210 48179-80 | NIL/SM217126X | 30 | | | | | |

Irradiation Data

| | |
|--------------------------------|-------------|
| Date and Time of Irradiation : | 23-Jun-2022 |
| Reference Dose Range kGy : | 30.9 - 31.0 |
| Calculated Minimum Dose kGy : | 27.0 |
| Calculated Maximum Dose kGy : | 39.8 |

Irradiation Release Authorised By STERIS TOMOE (THAILAND) LTD., a STERIS Company

Paradee 7. 27 Jun. 2022

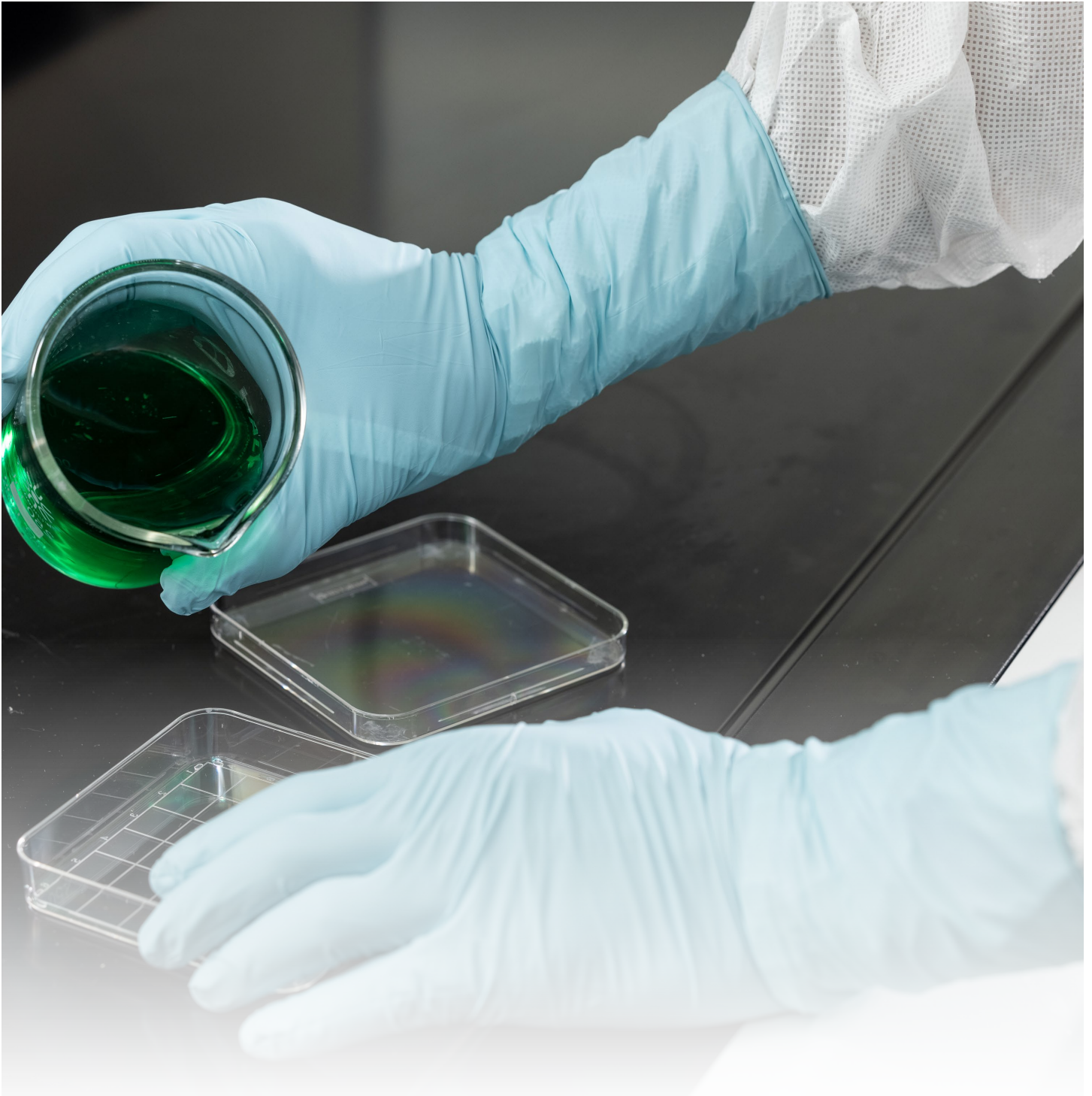
Paradee Thammajanya
QA Manager

Processing Site: STERIS TOMOE (Thailand) Ltd.

Registered Office: 700/644 Moo 3, Tambon Bankao, Amphur Panthong, CHONBURI 20160 THAILAND. VAT Number: 0205562031751

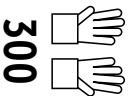
Page 1 of 1

PACKAGE LABELS



PUREZERO* HG3
STERILE LIGHT BLUE NITRILE GLOVES **8**

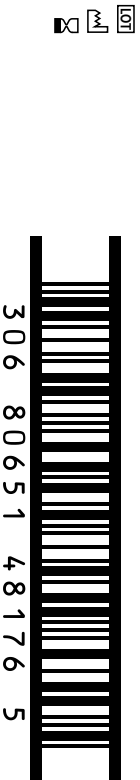
- ⓇⓇ Gants stériles en nitrile bleu clair HG3
- ⓇⓈ HG3 Sterile Nitrilhandschuhe, hellblau
- ⓇⓉ Стерилни светлосини нитрилни ръкавици HG3
- ⓇⓋ Gantes de nitrilo estériles celestes HG3
- ⓇⓌ Sterilni svjetle modré nitrilové rukavice HG3
- ⓇⓎ HG3 Sterile lyseblå nitrilhandsker
- ⓇⓏ HG3 sterilised helesinised nitrilkindad
- ⓇⓁ HG3 Γαλάζια αποστειρωμένα γάντια νιτριλίου
- ⓇⓂ Ganti in nitrile sterili azzurri HG3
- ⓇⓃ HG3 sterili, gaísi zili nitrila cimdi
- ⓇⓅ HG3 sterillos šviesiai mėlynos nitrilinės pirštinės
- ⓇⓆ HG3 sterine svjetlo plave nitrilne rukavice
- ⓇⓇ HG3 sterili világoskék nitrilkesztyű



300

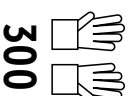
| | |
|---|---|
| <p>AOL 1.0 Level 2 GI</p> <p>ISO 374-5:2016 VIRUS</p> | <p>ISO 374-JType C K-Low Chemical EN ISO 374-1:2015+A1:2018</p> |
|---|---|

104817680 **CLN923280**



PUREZERO* HG3
STERILE LIGHT BLUE NITRILE GLOVES **8**

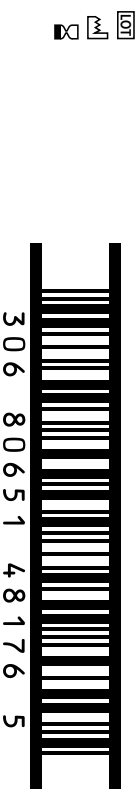
- ⓇⓇ HG3 Ingwanti tan-Nitril Blu Cari Sterili
- ⓇⓈ HG3 Lichtblauwe steriele nitril handschoenen
- ⓇⓉ HG3 sterile lyseblå nitrilhansker
- ⓇⓋ HG3 Sterylne jasnoblábeskie rukavice nitrilowe
- ⓇⓌ Luvas de nitrilo azuis-claras HG3 esterilizadas
- ⓇⓎ Mānuši din nitril albastru deschis sterile HG3
- ⓇⓏ Sterilné bledomodré nitrilové rukavice HG3
- ⓇⓁ Sterilne sveto modre rokavice iz nitrila
- ⓇⓂ HG3, sterilitt vaaleansiniset nitrilikkäsineet
- ⓇⓃ HG3 Sterilia ljusbå nitrilhandskar
- ⓇⓅ HG3 ライトブルー滅菌ニトリルグローブ
- ⓇⓆ HG3 하얗색 니트릴 장갑
- ⓇⓇ HG3 无菌浅蓝色丁腈手套



300

| | |
|---|---|
| <p>AOL 1.0 Level 2 GI</p> <p>ISO 374-5:2016 VIRUS</p> | <p>ISO 374-JType C K-Low Chemical EN ISO 374-1:2015+A1:2018</p> |
|---|---|

104817680 **CLN923280**



POUCH LABEL



REF **CLN923280**
8

LOT




FPO
 6 80651 48176 4


HALYARD*

PUREZERO* HG3

STERILE LIGHT BLUE NITRILE GLOVES

For the Critical Environment

12 in. / 30.5 cm

Hand Specific

Ⓜ Gants stériles en nitrile bleu clair HG3 • Pour les environnements critiques • Pour usage industriel uniquement
 • Sans accélérateur* • Faible potentiel de dermatite • S'adaptent à la main

Ⓞ HG3 Sterile Nitrilhandschuhe, hellblau • Für kritische Umgebungen • Nur für den industriellen Gebrauch • Beschleunigerfrei*
 Faible potentiel de dermatite • Handspezifisch

Ⓢ Guantes de nitrilo estériles celestes HG3 • Para entornos críticos • Solo para uso industrial • Sin aceleradores*
 Potential de provocar dermatitis bajo • Especifico para cada mano

Ⓜ Guanti in nitrile sterili azzurri HG3 • Per ambiente critico • Solo per uso industriale • Privi di acceleranti* • Basso potenziale di
 dermatite • Destri e sinistri

Ⓜ HG3 Lichtblauwe steriele nitril handschoenen • Voor gebruik in kritieke schone ruimtes/cleanrooms • Alleen voor industrieel
 gebruik • Versnellervrij* • Laag dermatitispotentieel • Handspecifiek

Ⓜ Luvas de nitrilo azuis-claras HG3 esterilizadas • Para ambientes de salas limpas críticos • Exclusivamente para utilização
 industrial • Sem aceleradores* • Baixo potencial de dermatite • Especificas para mãos

Ⓜ Стерильные голубые нитриловые перчатки HG3 • Для критических условий • Только для промышленного
 использования • Без химических присадок* • Низкий потенциал дерматита • На правую и левую руки

Ⓜ HG3 ライトブルー滅菌ニトリルグローブ • 無菌クリーンルーム環境対応 • 工業用途のみ
 • 加硫促進剤不使用* • 皮膚炎の発症を軽減 • 左右別

Ⓜ HG3 하늘색 니트릴 장갑 • 클린룸 환경용 • 산업용으로만 사용 • 촉진제 없음*
 • 피부염 가능성이 낮음 • 양손형

Ⓜ HG3 无菌浅蓝色丁腈手套 • 适用于关键环境 • 仅限工业使用 • 无催化剂* • 低致敏性 • 区分左右手

Manufactured at our SAFESKIN* Facility

ACCELERATOR FREE* • LOW DERMATITIS POTENTIAL

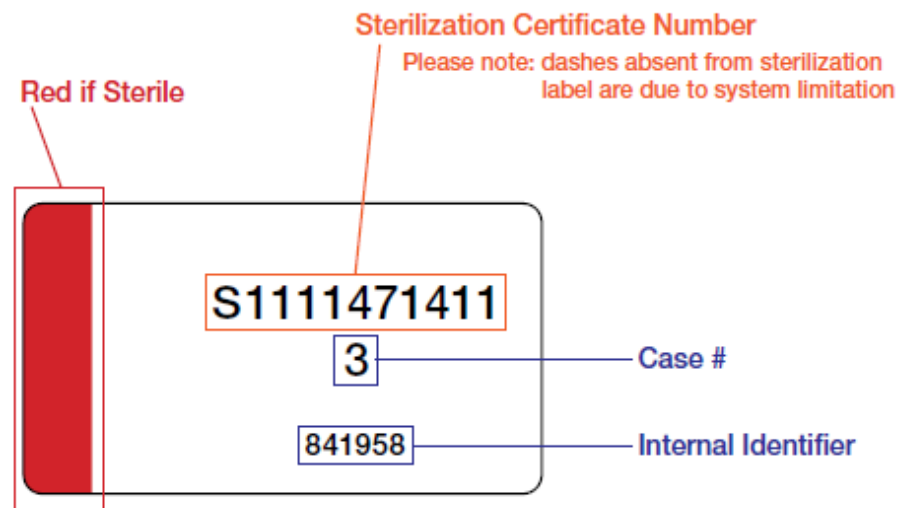
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|---|---|---|---|---|---|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  | STERILE R |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| AQL 1.0 Level 2 GI | ISO 374-1/Type C K-Low Chemical EN ISO 374-1:2016+A1:2018 | VIRUS |  |  2797 (PPE Cat. III) | Chemical | Breakthrough Time (min.) | Performance Level | Degradation % | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  0086 |  halyardhealth.com/information |  | NaOH, 40% | >480 | Class 6 | -69.1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

* Not formulated with the following vulcanizing chemicals and accelerators: Sulfur, Thiurams, Thiazoles, Guanidines, Carbamates

Ⓜ O&M Halyard, Inc., 9120 Lockwood Blvd., Mechanicsville, VA 23116 • In USA, please call 1-844-425-9273 • <

STERILIZATION/IRRADIATION LABEL

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



PACKAGING CERTIFICATES



POUCH



TIP CORPORATION SDN BHD

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E-mail: sales@tipcorp.com Website: www.tipcorp.com
SST No: W24-1808-21017734



FORM QC-21

LPC Test Report

Item: C/R EASY PEEL-PRT Lot No: K34521(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 Counts | Blank Cts 2 Counts | Blank Ct 3 Counts | Average Blank (A) Counts | |
|------------|-----------------------|-----------------------|----------------------|-----------------------------|-----|
| 0.5 micron | 1.0 | 2.0 | 5.0 | 2.7 | |
| 1.0 micron | 0.0 | 0.0 | 1.0 | 0.3 | |
| 2.0 micron | 0.0 | 0.0 | 0.0 | 0.0 Total counts | 3.0 |
| 5.0 micron | 0.0 | 0.0 | 0.0 | 0.0 | |

Wash Sample Particle Counts (Cumulative)

| | Washed Cts 1 Counts | Washed Cts 2 Counts | Washed Cts 3 Counts | Average Washed (B) Counts | |
|------------|------------------------|------------------------|------------------------|------------------------------|------|
| 0.5 micron | 13.0 | 16.0 | 11.0 | 13.3 | |
| 1.0 micron | 1.0 | 3.0 | 2.0 | 2.0 | |
| 2.0 micron | 1.0 | 2.0 | 0.0 | 1.0 Total counts | 16.3 |
| 5.0 micron | 0.0 | 0.0 | 0.0 | 0.0 | |

(C) Wet Particle Counts

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

| | |
|------------|------|
| 0.5 micron | 10.7 |
| 1.0 micron | 1.7 |
| 2.0 micron | 1.0 |
| 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

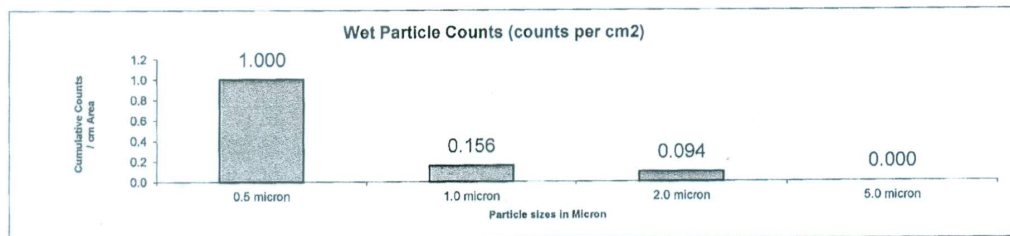
Total Washed Area 853 cm²

Particle counts per ml (G = C / E)

| | |
|------------|-------|
| 0.5 micron | 2.133 |
| 1.0 micron | 0.333 |
| 2.0 micron | 0.200 |
| 5.0 micron | 0.000 |

(H) Total Wet Part Cts / cm² (H = G X D / F)

| | |
|------------|-------|
| 0.5 micron | 1.000 |
| 1.0 micron | 0.156 |
| 2.0 micron | 0.094 |
| 5.0 micron | 0.000 |



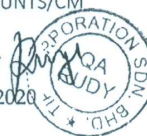
Cts/cm²

Total Particle (≥0.5) : 1.250

SPEC: ≥ 0.5u < 100 COUNTS/CM²

Tested By: SUHAIDA
Date: 26.10.2020

Verified By: RUDY
Date: 26.10.2020



POUCH



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 E-mail: sales@tipcorp.com Website: www.tipcorp.com
 SST No: W24-1808-21017734



FORM QC-21

LPC Test Report

Item: C/R EASY PEEL-PRT Lot No: K34521(Outgoing B)
 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 Counts | Blank Cts 2 Counts | Blank Ct 3 Counts | Average Blank (A) Counts | |
|------------|-----------------------|-----------------------|----------------------|-----------------------------|-----|
| 0.5 micron | 5.0 | 6.0 | 5.0 | | |
| 1.0 micron | 0.0 | 0.0 | 1.0 | 5.3 | |
| 2.0 micron | 0.0 | 0.0 | 0.0 | 0.3 | |
| 5.0 micron | 0.0 | 0.0 | 0.0 | 0.0 | 5.7 |
| | | | | 0.0 | 0.0 |

Wash Sample Particle Counts (Cumulative)

| | Washed Cts 1 Counts | Washed Cts 2 Counts | Washed Cts 3 Counts | Average Washed (B) Counts | |
|------------|------------------------|------------------------|------------------------|------------------------------|------|
| 0.5 micron | 12.0 | 14.0 | 16.0 | | |
| 1.0 micron | 2.0 | 2.0 | 4.0 | 14.0 | |
| 2.0 micron | 1.0 | 0.0 | 1.0 | 2.7 | |
| 5.0 micron | 0.0 | 0.0 | 0.0 | 0.7 | 17.3 |
| | | | | 0.0 | |

(C) Wet Particle Counts

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

| | |
|------------|-----|
| 0.5 micron | 8.7 |
| 1.0 micron | 2.3 |
| 2.0 micron | 0.7 |
| 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

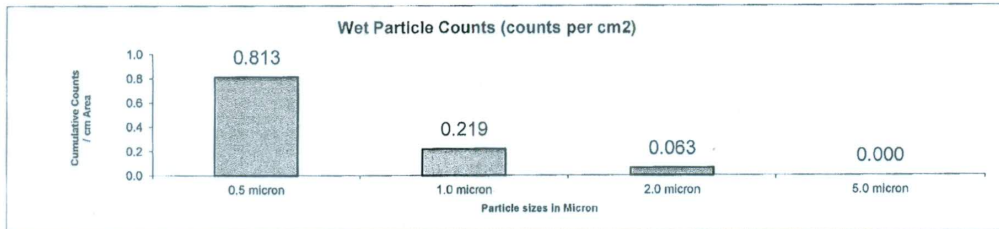
Total Washed Area 853 cm²

Particle counts per ml (G = C / E)

| | |
|------------|-------|
| 0.5 micron | 1.733 |
| 1.0 micron | 0.467 |
| 2.0 micron | 0.133 |
| 5.0 micron | 0.000 |

(H) Total Wet Part Cts / cm² (H = G X D / F)

| | |
|------------|-------|
| 0.5 micron | 0.813 |
| 1.0 micron | 0.219 |
| 2.0 micron | 0.063 |
| 5.0 micron | 0.000 |



Cts/cm²

Total Particle (≥0.5) : 1.094

SPEC: ≥ 0.5u ≤ 100 COUNTS/CM²

Tested By : SUHAIDA
 Date : 26.10.2020

Verified By : RUDY
 Date : 26.10.2020



POUCH



TIP CORPORATION SDN BHD

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SST No: W24-1808-21017734



FORM QC-21

LPC Test Report

Item: C/R EASY PEEL-PRT Lot No: K34521(Outgoing C)
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 Counts | Blank Cts 2 Counts | Blank Ct 3 Counts | Average Blank (A) Counts | |
|------------|-----------------------|-----------------------|----------------------|-----------------------------|-----|
| 0.5 micron | 8.0 | 4.0 | 4.0 | | |
| 1.0 micron | 1.0 | 0.0 | 0.0 | 5.3 | |
| 2.0 micron | 0.0 | 0.0 | 0.0 | 0.3 | |
| 5.0 micron | 0.0 | 0.0 | 0.0 | 0.0 Total counts | 5.7 |
| | | | | 0.0 | |

Washed Sample Particle Counts (Cumulative)

| | Washed Cts 1 Counts | Washed Cts 2 Counts | Washed Cts 3 Counts | Average Washed (B) Counts | |
|------------|------------------------|------------------------|------------------------|------------------------------|------|
| 0.5 micron | 12.0 | 14.0 | 16.0 | | |
| 1.0 micron | 3.0 | 3.0 | 4.0 | 14.0 | |
| 2.0 micron | 1.0 | 1.0 | 2.0 | 3.3 | |
| 5.0 micron | 0.0 | 0.0 | 2.0 | 1.3 Total counts | 19.3 |
| | | | | 0.7 | |

(C) Wet Particle Counts

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

| | |
|------------|-----|
| 0.5 micron | 8.7 |
| 1.0 micron | 3.0 |
| 2.0 micron | 1.3 |
| 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

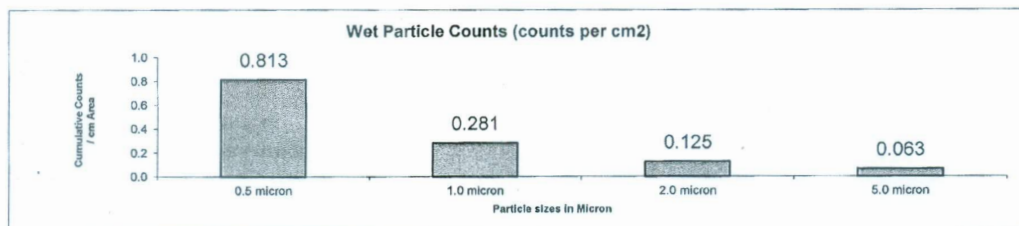
Total Washed Area 853 cm²

Particle counts per ml (G = C / E)

| | |
|------------|-------|
| 0.5 micron | 1.733 |
| 1.0 micron | 0.600 |
| 2.0 micron | 0.267 |
| 5.0 micron | 0.133 |

(H) Total Wet Part Cts / cm² (H = G X D / F)

| | |
|------------|-------|
| 0.5 micron | 0.813 |
| 1.0 micron | 0.281 |
| 2.0 micron | 0.125 |
| 5.0 micron | 0.063 |



Total Particle (≥0.5) : 1.282 Cts/cm²

SPEC: ≥ 0.5u <100 COUNTS/CM²

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



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 Ct 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 Total counts |
| | | | | 0.7 |

Wash 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 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

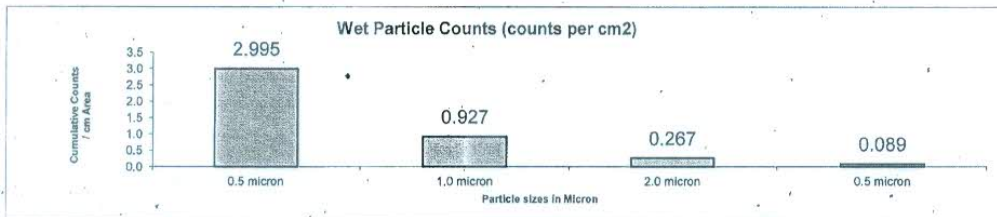
Total Washed Area 1496 cm²

(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 / cm² (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/CM²

Tested By: SUHAIDA

Verified By: RUDY

Date: 09.11.2020

Date: 09.11.2020





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SST No: W24-1808-21017734



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) KCCS-17

| | Blank Cts 1 | Blank Cts 2 | Blank Ct 3 | Average Blank (A) |
|------------|-------------|-------------|------------|---------------------|
| | Counts | Counts | Counts | 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 |

Washed Sample Particle Counts (Cumulative)

| | Washed Cts 1 | Washed Cts 2 | Washed Cts 3 | Average Washed (B) |
|------------|--------------|--------------|--------------|----------------------|
| | Counts | Counts | Counts | 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 |

(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

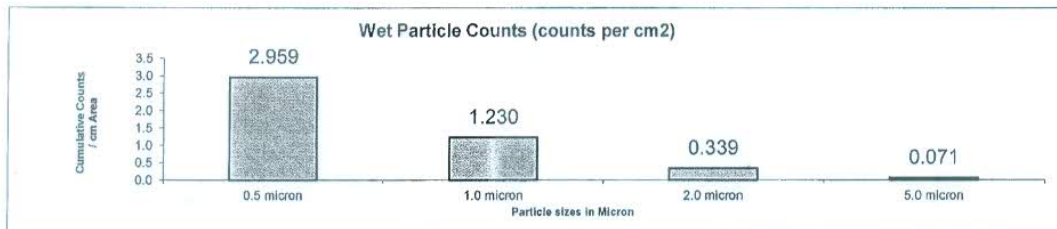
Total Washed Area 1496 cm²

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

| | |
|------------|--------|
| 0.5 micron | 11.067 |
| 1.0 micron | 4.600 |
| 2.0 micron | 1.267 |
| 5.0 micron | 0.267 |

(H) Total Wet Part Cts / cm² (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 |



Total Particle (≥0.5): 4.599 Cts/cm²

SPEC: ≥ 0.5u ≤100 COUNTS/CM²

Tested By: SUHAIDA
Date: 09.11.2020

Verified By: RUDY
Date: 09.11.2020



WALLET



TIP CORPORATION SDN BHD

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SST No: W24-1808-21017734



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 | Blank Cts 2 | Blank Ct 3 | Average Blank (A) |
|------------|-------------|-------------|------------|-------------------|
| | Counts | Counts | Counts | 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 | Washed Cts 2 | Washed Cts 3 | Average Washed (B) |
|------------|--------------|--------------|--------------|--------------------|
| | Counts | Counts | Counts | 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

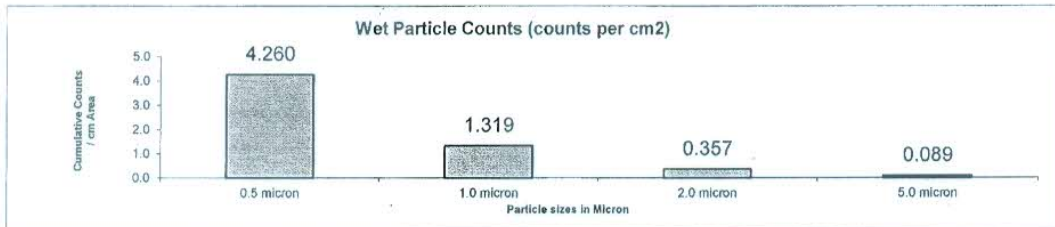
Total Washed Area 1496 cm²

(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 / cm² (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/cm²

Total Particle (≥0.5): 6.025

SPEC: ≥ 0.5u <100 COUNTS/CM²

Tested By: SUHAIDA

Date: 09.11.2020

Verified By: RUDY

Date: 09.11.2020



WALLET



TIP CORPORATION SDN BHD

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SST No: W24-1808-21017734



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
Blank Particle Counts (Cumulative) Machine: KL-2

| | Blank Cts 1 | Blank Cts 2 | Blank Ct 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

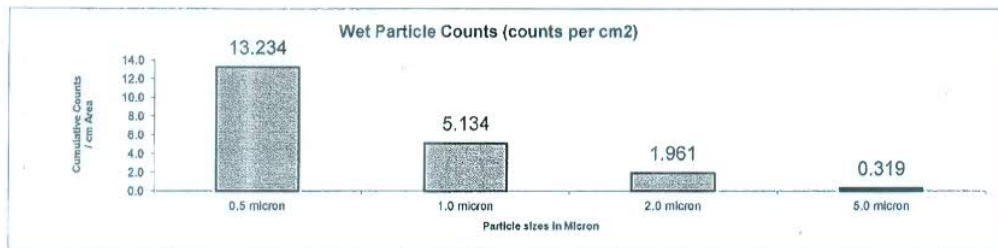
Total Washed Area 4181 cm²

(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 / cm² (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 |



Total Particle (≥0.5): 20.649

SPEC: ≥ 0.5u ≤ 30 COUNTS/CM²
SPEC: ≥ 0.5u ≤ 10 COUNTS/CM²

Tested By: SUHAIDA
Date: 09.11.2020

Verified By: RUDY
Date: 09.11.2020





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



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 | Blank Cts 2 | Blank Ct 3 | Average Blank (A) | |
|------------|-------------|-------------|------------|-------------------|-----|
| | Counts | Counts | Counts | 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 |

Washed Sample Particle Counts (Cumulative)

| | Washed Cts 1 | Washed Cts 2 | Washed Cts 3 | Average Washed (B) | |
|------------|--------------|--------------|--------------|--------------------|------|
| | Counts | Counts | Counts | 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

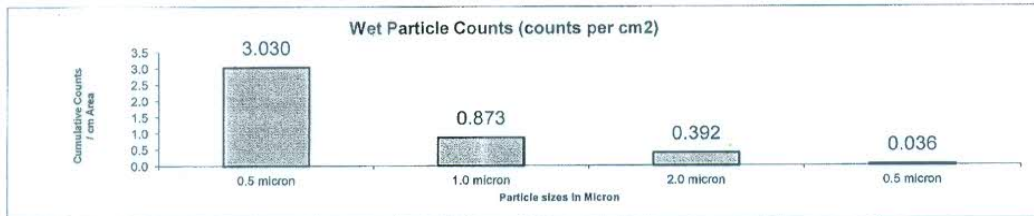
Total Washed Area 1496 cm²

(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 / cm² (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 |



Total Particle (≥0.5): 4.332 Cts/cm²

SPEC: ≥ 0.5u <100 COUNTS/CM²

Tested By: SUHAIDA
Date: 09.11.2020

Verified By: RUDY
Date: 09.11.2020



DOSE MAPPING REPORT



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: **HALYARD*PUREZERO* HG3 Sterile Light Blue Nitrile Gloves - Pairs**
The validation ref no: **0.0968 Rev 01**

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

Customer Acknowledge,

Name :
Designation :
(Please sign this section and scan a copy to huehkoon_yow@steris.com)

DOSE MAPPING REPORT
Safeskin Medical & Scientific (Thailand) Ltd
For

HALYARD*PUREZERO* HG3
Sterile Light Blue Nitrile Gloves - Pairs

Validation Report Number : 0.0968 Rev 01

Performance Qualification STERIS Kuala Ketil
Summary of Performance Qualification:

Customer Name : **Safeskin Medical & Scientific (Thailand) Ltd**
 Report Ref. : **0.0968 Rev 01**
 Issue Date : **29.04.2021**

Product Description: : **HALYARD*PUREZERO* HG3 Sterile Light Blue Nitrile
Gloves - Pairs**
 Type of package: : **Corrugated carton**
 Carton dimension : : **345 mm (L) x 285 mm (W) x 390 mm (H) (12 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 | 27.0 | 45.9 |
| Dwell time(s) | 123 | 205 |
| Number of Xs | 32 | 54 |
| Correction Factor (Rmin/Rmax) | 0.927 | 1.089 |

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 if 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.

Product description: **HALYARD*PUREZERO* HG3 Sterile Light Blue 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 : 0.0968 Rev 01

Product: HALYARD*PUREZERO* HG3 Sterile Light Blue 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 | 32.2 | | 32.7 | | 32.4 | | 32.4 | 0.25 | 0.77 | 0.13 |
| A21 | 32.1 | | 32.2 | | 32.3 | | 32.2 | 0.10 | 0.31 | 0.02 |
| A31 | 30.7 | | 31.7 | | 33.0 | | 31.8 | 1.15 | 3.62 | 2.66 |
| A41 | 31.9 | | 32.2 | | 32.0 | | 32.0 | 0.15 | 0.47 | 0.05 |
| A51 | 33.5 | | 33.7 | | 33.2 | | 33.5 | 0.25 | 0.75 | 0.13 |
| A15 | 33.7 | | 33.9 | | 33.3 | | 33.6 | 0.31 | 0.92 | 0.19 |
| A25 | 32.5 | | 33.0 | | 32.7 | | 32.7 | 0.25 | 0.76 | 0.13 |
| A35 | 33.5 | | 33.8 | | 33.4 | | 33.6 | 0.21 | 0.63 | 0.09 |
| A45 | 34.0 | | 34.1 | | 34.3 | | 34.1 | 0.15 | 0.44 | 0.05 |
| A55 | 33.0 | | 33.1 | | 33.2 | | 33.1 | 0.10 | 0.30 | 0.02 |
| A19 | 33.3 | | 34.2 | | 33.5 | | 33.7 | 0.47 | 1.39 | 0.45 |
| A29 | 35.4 | √-MAX | 34.8 | | 34.1 | | 34.8 | 0.65 | 1.87 | 0.85 |
| A39 | 34.1 | | 34.4 | | 34.9 | | 34.5 | 0.40 | 1.16 | 0.33 |
| A49 | 34.3 | | 35.2 | | 35.0 | | 34.8 | 0.47 | 1.35 | 0.45 |
| A59 | 35.3 | | 35.6 | √-MAX | 35.1 | √-MAX | 35.3 | 0.25 | 0.71 | 0.13 |
| B11 | 30.7 | | 31.2 | | 31.2 | | 31.0 | 0.29 | 0.94 | 0.17 |
| B21 | 31.2 | | 31.1 | √-MIN | 31.1 | | 31.1 | 0.06 | 0.19 | 0.01 |
| B31 | 30.4 | √-MIN | 31.4 | | 31.1 | | 31.0 | 0.51 | 1.65 | 0.53 |
| B41 | 31.0 | | 31.1 | √-MIN | 31.4 | | 31.2 | 0.21 | 0.67 | 0.09 |
| B51 | 30.8 | | 32.0 | | 30.4 | √-MIN | 31.1 | 0.83 | 2.67 | 1.39 |
| B15 | 32.7 | | 31.8 | | 31.5 | | 32.0 | 0.62 | 1.94 | 0.78 |
| B25 | 32.0 | | 31.8 | | 32.5 | | 32.1 | 0.36 | 1.12 | 0.26 |
| B35 | 31.8 | | 31.7 | | 31.0 | | 31.5 | 0.44 | 1.40 | 0.38 |
| B45 | 31.7 | | 31.3 | | 32.0 | | 31.7 | 0.35 | 1.10 | 0.25 |
| B55 | 31.2 | | 33.0 | | 32.5 | | 32.2 | 0.93 | 2.89 | 1.73 |
| B19 | 31.7 | | 31.7 | | 31.1 | | 31.5 | 0.35 | 1.11 | 0.24 |
| B29 | 31.6 | | 32.0 | | 31.9 | | 31.8 | 0.21 | 0.66 | 0.09 |
| B39 | 32.3 | | 32.1 | | 31.3 | | 31.9 | 0.53 | 1.66 | 0.56 |
| B49 | 31.1 | | 31.6 | | 31.3 | | 31.3 | 0.25 | 0.80 | 0.13 |
| B59 | 31.2 | | 31.9 | | 32.4 | | 31.8 | 0.60 | 1.89 | 0.73 |

Pooled variance (s²overall) **0.22**
 Minimum detectable difference (δ) **0.64**
 Mean Minimum dose (DMin) **31.0 B11, B31**
 Mean Maximum dose (DMax) **35.3 A59**

Expected value of Rmin (Dref/Dmin) **1.045 ***
 Expected value of Rmax (Dref/Dmax) **0.918 ***

| DRef Ratio : | |
|--------------|--------------|
| 1/Rmin | 0.957 |
| 1/Rmax | 1.089 |

Remarks: * incorporates an estimation of the uncertainty
 Customer Spec Min: **25.0** Max: **50.0**
 D reference Min: **26.1** Max: **45.9**
 Dose Uniformity Ratio (DUR): **1.14**

Performance Qualification STERIS Kuala Ketil

Applied Sterilization Technologies

Validation Ref : 0.0968 Rev 01

Product: HALYARD*PUREZERO* HG3 Sterile Light Blue 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 | 32.2 | | 32.7 | | 34.0 | | 33.0 | 0.93 | 2.82 | 1.73 |
| A21 | 32.0 | | 31.9 | | 32.5 | | 32.1 | 0.32 | 1.00 | 0.21 |
| A31 | 30.6 | | 31.5 | | 33.2 | | 31.8 | 1.32 | 4.15 | 3.49 |
| A41 | 32.4 | | 32.1 | | 32.4 | | 32.3 | 0.17 | 0.53 | 0.06 |
| A51 | 33.3 | | 32.8 | | 33.3 | | 33.1 | 0.29 | 0.88 | 0.17 |
| A15 | 33.1 | | 33.9 | | 34.3 | | 33.8 | 0.61 | 1.80 | 0.75 |
| A25 | 31.9 | | 32.4 | | 32.5 | | 32.3 | 0.32 | 0.99 | 0.21 |
| A35 | 33.3 | | 33.7 | | 34.2 | | 33.7 | 0.45 | 1.34 | 0.41 |
| A45 | 33.3 | | 34.2 | | 34.7 | | 34.1 | 0.71 | 2.08 | 1.01 |
| A55 | 32.2 | | 32.8 | | 34.5 | | 33.2 | 1.19 | 3.58 | 2.85 |
| A19 | 33.1 | | 33.9 | | 33.5 | | 33.5 | 0.40 | 1.19 | 0.32 |
| A29 | 33.6 | | 34.3 | | 35.1 | √-MAX | 34.3 | 0.75 | 2.19 | 1.13 |
| A39 | 34.7 | √-MAX | 34.6 | | 35.0 | | 34.8 | 0.21 | 0.60 | 0.09 |
| A49 | 34.4 | | 35.1 | √-MAX | 35.0 | | 34.8 | 0.38 | 1.09 | 0.29 |
| A59 | 34.1 | | 35.1 | √-MAX | 35.0 | | 34.7 | 0.55 | 1.59 | 0.61 |
| B11 | 29.9 | | 31.1 | | 30.7 | | 30.6 | 0.61 | 1.99 | 0.75 |
| B21 | 30.2 | | 31.7 | | 31.8 | | 31.2 | 0.90 | 2.88 | 1.61 |
| B31 | 30.1 | | 30.6 | √-MIN | 31.2 | | 30.6 | 0.55 | 1.80 | 0.61 |
| B41 | 31.5 | | 31.8 | | 29.8 | √-MIN | 31.0 | 1.08 | 3.48 | 2.33 |
| B51 | 29.6 | √-MIN | 30.8 | | 31.7 | | 30.7 | 1.05 | 3.42 | 2.22 |
| B15 | 31.3 | | 32.4 | | 32.1 | | 31.9 | 0.57 | 1.79 | 0.65 |
| B25 | 31.3 | | 31.8 | | 32.1 | | 31.7 | 0.40 | 1.26 | 0.33 |
| B35 | 31.1 | | 31.7 | | 31.5 | | 31.4 | 0.31 | 0.99 | 0.19 |
| B45 | 31.3 | | 31.7 | | 31.9 | | 31.6 | 0.31 | 0.98 | 0.19 |
| B55 | 31.1 | | 32.1 | | 33.7 | | 32.3 | 1.31 | 4.06 | 3.44 |
| B19 | 30.6 | | 32.1 | | 32.0 | | 31.6 | 0.84 | 2.66 | 1.41 |
| B29 | 30.7 | | 31.9 | | 31.2 | | 31.3 | 0.60 | 1.92 | 0.73 |
| B39 | 30.5 | | 31.6 | | 31.5 | | 31.2 | 0.61 | 1.96 | 0.74 |
| B49 | 30.7 | | 31.4 | | 31.8 | | 31.3 | 0.56 | 1.79 | 0.62 |
| B59 | 31.2 | | 31.2 | | 32.0 | | 31.5 | 0.46 | 1.46 | 0.43 |

Pooled variance (s²overall) **0.49**
 Minimum detectable difference (δ) **0.95**
 Mean Minimum dose (DMin) **30.6 B11, B31**
 Mean Maximum dose (DMax) **34.8 A39, A49**

Expected value of Rmin (Dref/Dmin) **1.079 ***
 Expected value of Rmax (Dref/Dmax) **0.948 ***

| Dref Ratio : | |
|--------------|--------------|
| 1/Rmin | 0.927 |
| 1/Rmax | 1.055 |

Remarks: * incorporates an estimation of the uncertainty
 Customer Spec Min: **25.0** Max: **50.0**
 D reference Min: **27.0** Max: **47.4**
 Dose Uniformity Ratio (DUR): **1.14**

Performance Qualification STERIS Kuala Ketil

Applied Sterilization Technologies

Product Detail Validation Ref : 0.0968 Rev 01

Customer Name : Safeskin Medical & Scientific (Thailand) Ltd

Issue Date : 29.04.2021

Product Description : HALYARD*PUREZERO* HG3 Sterile Light Blue Nitrile Gloves - Pairs

Plant Batch No : S12562825-1-1 (LD - low density, size 6.0)
S12562825-1-2 (HD - high density, size 10.0)

| | | | |
|--------------------------------|---------------------|--------------|---------------------------|
| Current Cobalt Loading | : 4,591,067 Curries | Weight (LD) | : 8.00 kg |
| | | Weight (HD) | : 9.90 kg |
| Standard Plant Dwell Time | : 146 Sec | Length | : 345 mm |
| Actual Dwell Time | : 146 Sec | Width | : 285 mm |
| Number of Xs | : 38.0 | Height | : 390 mm |
| Value of X | : 3.83 | Density (LD) | : 0.209 g/cm ³ |
| Type of package | : Corrugated carton | Density (HD) | : 0.258 g/cm ³ |
| Dose Range Specification (kGy) | : 25 Min | Tote Fit | : 12 ctn/tote |
| | : 50 Max | | |

Low Density Dwell Time Control

| Minimum dwell time to achieve | Minimum dose | Maximum dose |
|-------------------------------|--------------|--------------|
| First tote | 120 ✓ | 206 |
| Second tote | 117 | 205 ✓ |
| Third tote | 120 ✓ | 208 |

High Density Dwell Time Control

| Minimum dwell time to achieve | Minimum dose | Maximum dose |
|-------------------------------|--------------|--------------|
| First tote | 123 ✓ | 210 |
| Second tote | 119 | 208 ✓ |
| Third tote | 122 | 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 : 0.0968 Rev 01

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

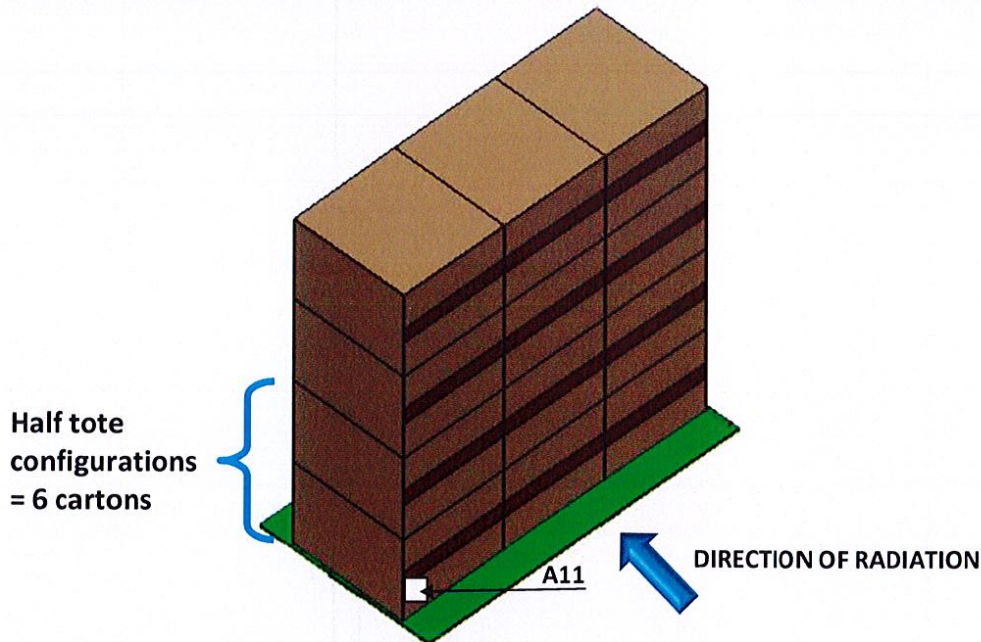
Type of Package : **Corrugated carton**

Product Description : **HALYARD*PUREZERO* HG3 Sterile Light Blue 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) (12 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 : 0.0968 Rev 01

Customer Name : Safeskin Medical & Scientific (Thailand) Ltd

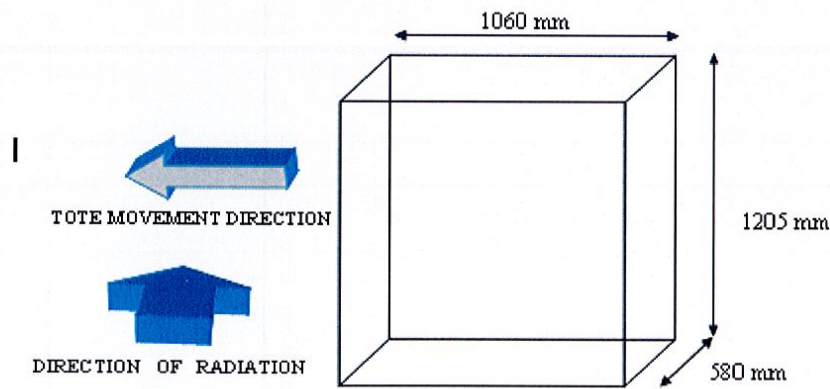
Type of Package : Corrugated carton

Product Description : HALYARD*PUREZERO* HG3 Sterile Light Blue Nitrile Gloves - Pairs

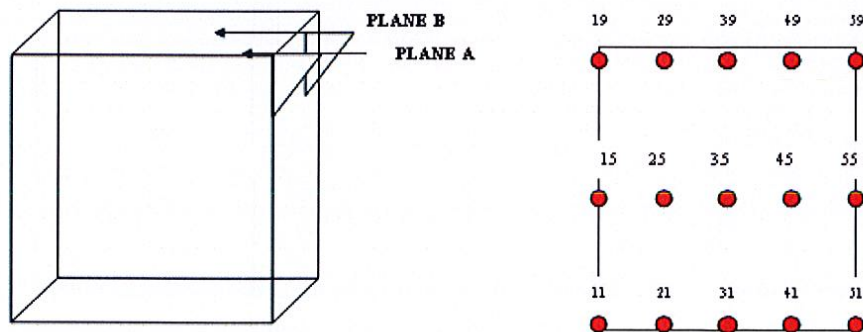
Issue Date : 29.04.2021

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

TOTE CHARACTERISTICS AND ORIENTATION



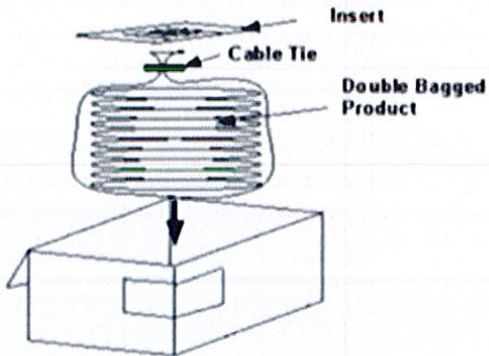
LOCATION OF DOSIMETERS



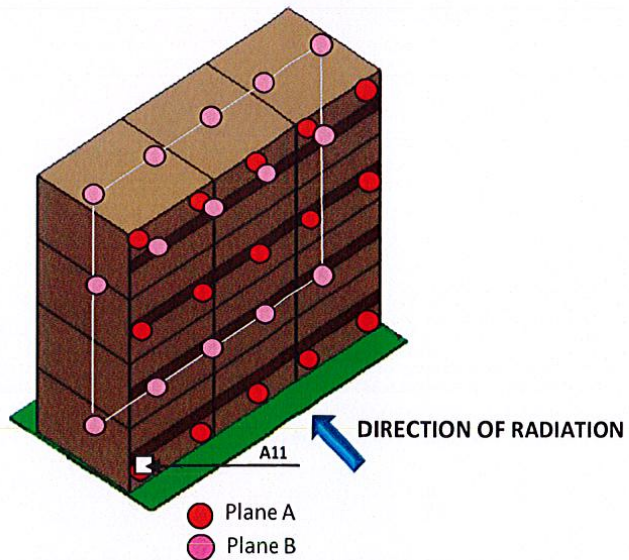
As per our Operational Qualification Report, from latest source loading replenishment, the dose distribution in the front plane (plane A) is the same as in the back plane (plane C).

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





June 24, 2021

Dear Customer,

O&M Halyard supplies the following items that meet the definition of an *article* under both OSHA and WHMIS. A Safety Data Sheet (SDS), therefore, is not required for them.

HALYARD* PUREZERO* SMOOTH HG3 WHITE NITRILE GLOVES
HALYARD* PUREZERO* HG3 WHITE NITRILE GLOVES
HALYARD* PUREZERO* HG3 LIGHT BLUE NITRILE GLOVES
HALYARD* PUREZERO* HG3 LIGHT BLUE STERILE NITRILE GLOVES
HALYARD* PUREZERO* HG3 WHITE STERILE NITRILE GLOVES

Under the Occupational Safety and Health Administration (OSHA) 1910.1200, the Hazard Communication Standard Safety Data Sheets (SDS) are required for all hazardous chemicals with certain exceptions. One exception is for manufactured articles. An *article*, as defined in section (c), is “a manufactured item: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which, under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical or health risk to employees.”

The Canadian WHMIS Regulation contains a similar exclusion for manufactured articles. While the EU Regulations do not specifically contain an exemption for manufactured articles, it is our opinion that those products sold by O&M Halyard that are considered articles in the U.S. and Canada would not be considered dangerous substances or preparations in the EU and would not require a Safety Data Sheet.

Since certain O&M Halyard products may be used to absorb bodily fluids or other potentially hazardous materials that may require special disposal, the user must determine the local, state, and federal regulations that apply to the disposal of the used products and ensure proper disposal.

Please feel free to contact us if you require any further information

William Swanger
Global Leader, Environment, Health, & Safety
William.swanger@hyh.com

*Registered Trademark or Trademark of O&M Halyard or its affiliates. ©2021. All rights reserved.



May 11, 2021

Dear HALYARD* Customers,

O&M Halyard confirms that all of our cleanroom gloves conform to Regulation (EU) 2011/65 as well as Regulation (EU) 2015/863.

O&M Halyard hereby confirms that all of our cleanroom gloves and packaging conform to the amendments of Annex XVII of Regulation 1907/2006, REACH. We confirm that our gloves do not exceed the maximum permitted presence of all listed substances and/or do not contain any of the listed substances.

O&M Halyard hereby confirms that our cleanroom gloves 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. This includes the presence of phthalates, which upon confirmatory laboratory testing, O&M Halyard cleanroom gloves does not contain phthalates.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stephanie', with a long horizontal flourish extending to the right.

Stephanie Christianson Hatcher, PhD
Regulatory Technical and Data Specialist
O&M Halyard, Inc. – Global Products



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:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2018-08-12

Latest Revision Date: 2021-07-16

Effective Date: 2021-08-12

Expiry Date: 2024-08-11

Page: 1 of 2



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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.

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: 2021-07-16

Effective Date: 2021-08-12

Expiry Date: 2024-08-11

Page: 2 of 2

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No:

FM 697013

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

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09

Effective Date: 2020-01-09

Latest Revision Date: 2021-01-15

Expiry Date: 2023-01-08



Page: 1 of 3

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

ISO 13485:2016 (continued)

Certificate No: **FM 697013**

| Location | Registered Activities |
|--|---|
| O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA | Headquarter management activities. |
| O & M Halyard, Inc. 1 Edison Drive Alpharetta Georgia 30005 USA | The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices. |
| Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA | The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens. |
| La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA | Receiving and Incoming Inspection, Warehouse and Distribution. The manufacture of non-sterile face masks and respirators. |
| O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras | The manufacture and distribution of disposable sterile and non-sterile surgical gowns. |
| La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico | Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials. |

Original Registration Date: 2014-12-09

Latest Revision Date: 2021-01-15

Effective Date: 2020-01-09

Expiry Date: 2023-01-08

Page: 2 of 3

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A Member of the BSI Group of Companies.

ISO 13485:2016 (continued)

Certificate No: **FM 697013**

| Location | Registered Activities |
|--|--|
| La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico | The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap. |
| La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico | The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery. |
| Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand | The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves. |

Original Registration Date: 2014-12-09

Effective Date: 2020-01-09


Latest Revision Date: 2021-01-15

Expiry Date: 2023-01-08

Page: 3 of 3

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