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HALYARD*

HALYARD* **PURE**ZERO* HG3 WHITE STERILE CLEANROOM GLOVES

DATA PACK

For the Cleanroom Environment
For Industrial Use Only

HALYARD* **PURE**ZERO* HG3 WHITE 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.

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TECHNICAL DATA SHEET

HALYARD

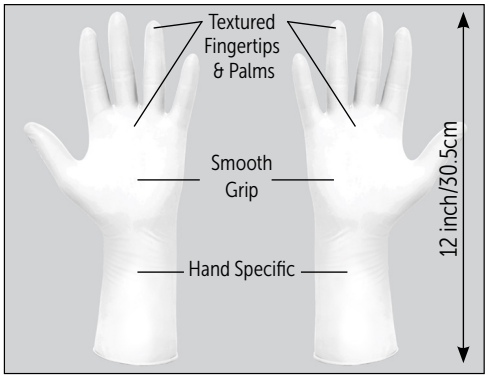
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves

For the Critical Cleanroom Environment
For Industrial Use Only

TECHNICAL DATA SHEET

Description

HALYARD* **PURE**ZERO* 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/C/D cleanrooms. Because HALYARD* **PURE**ZERO* 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 <950	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

HALYARD

HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves

For the Critical Cleanroom Environment
For Industrial Use Only

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)	70.8	72.4	80.6	83.9	86.0	90.1	92.7	96.2
Finger Tip Thickness	0.16 mm (6 mil)	0.16 mm (6 mil)	0.16 mm (6 mil)	0.16 mm (6 mil)	0.16 mm (6 mil)	0.16 mm (6 mil)	0.16 mm (6 mil)	0.16 mm (6 mil)
Palm Thickness	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)
Cuff 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)

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

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	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**

1 Not formulated with these commonly used vulcanizing chemicals: Sulfur, Thiurams, Thiaxoles, Guanidines and Carbamates.
2 Tested against ANSI SP 15.1 and EN 1149 (Protective Clothing - electrostatic properties)
3 Tested per ASTM D6319, 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.

Owens & Minor

HALYARD* is an Owens & Minor brand

Owens & Minor HALYARD

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

CERTIFICATE OF ANALYSIS

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

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

OMH Code : 48192-00, 48193-00, 48194-00, 48195-00, 48196-00, 48197-00, 48198-00, 48199-00

Batches : SM209125X to SM212025X
SM209125V to SM212025V

Total Cases per Lot : 1,481
Date of Manufacture : Apr-22
Expiration Date : 2027-03-30

Physical Test Data

		Visual Defects			Tensile (MPa)	Elongation (%)	Median Force at Break (N)
	Watertight	Minor	Negligible	Dimensions	Pre Aging	Pre Aging	Pre Aging
Sample Size :	2021	1271	1086	358	228	228	228
AQL Level :	1.0	2.5	4.0	4.0	4.0	4.0	4.0
Failures Allowed per AQL :	22	40	54	20	11	11	11
Failures :	0	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
				Averages:	37.11	600	13.06

Test Methods : Water tight test ASTM D 5151, EN 455-1, Elongation and Tensile ASTM D 412, ASTM D 6319, Median Force at Break EN 455-2, Dimension ASTM D 6319, EN 455-2

Particle Test Data

Particle	Min	Max	Average Particles/cm³	Inspection Result
#/cm2:	545	944	844	Accept

Particulate Level (≥0.5 microns) #/cm²

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data

	Anions Results			Cations Results				
	Chloride	Nitrate	Sulfate	Sodium	Ammonium	Potassium	Magnesium	Calcium
Units :	Cl^-	NO_3^-	SO_4^{-2}	Na^+	NH_4^+	K^+	Mg^{+2}	Ca^{+2}
µg/g glove	25.687	9.381	4.384	3.506	1.535	1.870	1.168	26.804
Inspection Result :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

Trace Element Results

	Zinc
Units :	Zn
µg/g glove	2.53
Inspection Result :	Accept

Test Method : IEST-RP-CC005.4

Endotoxin Test Data

Test Result :	FALSE	**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 : 09 May 2022

(QA Sr. Manager)

FORM-28014/6

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 09-Nov-2020 MY03S12502016-1-1

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:	1132652
Customer Reference Number:	4027016775
Product Description:	HALYARD* PUREZERO* HG3 STERILE WHITE NITRILE GLOVES - PAIRS
Validation Reference:	0.0767 Rev01
Quantity Received:	278
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	50.0
Customer Unit Lot/Batch Number:	SEE BELOW

09/11/2020
NORAZWIN BT. YUSUF
QA Executive
Synergy Sterilisation (M) Sdn. Bhd.
+60(0)44152111

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 09-Nov-2020 MY03S12502016-1-1

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

Other Process Details:

HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves - Pairs
'Catalog Numbers : CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323285, CLN323290,CLN323210.

'OMH Code : 48192-00, 48193-00, 48194-00, 48195-00, 48196-00, 48197-00, 48198-00, 48199-00

Catalog Number(s)		Lot No./Batch No.	Quantity
CLN323260	48192-00	NIL/SM03022XX	24
CLN323260	48192-00	NIL/SM02982XX	3
CLN323265	48193-00	NIL/SM02992XX	5
CLN323270	48194-00	NIL/SM02992XX	74
CLN323270	48194-00	NIL/SM02982XX	26
CLN323270	48194-00	NIL/SM02732XX	10
CLN323275	48195-00	NIL/SM03022XX	8
CLN323275	48195-00	NIL/SM02992XX	70
CLN323275	48195-00	NIL/SM02972XX	24
CLN323285	48197-00	NIL/SM02992XX	4
CLN323290	48198-00	NIL/SM03022XX	15
CLN323210	48199-00	NIL/SM03022XX	15

Irradiation Data

09/11/2020
NOR AZWIN BT. YUSUF
QA Executive
Synergy Sterilisation (M) Sdn. Bhd.
+60(0)44152111

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 09-Nov-2020 MY03S12502016-1-1

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

Date and Time of Irradiation:	07-Nov-2020 07:48
Reference Dose Range kGy:	30.8 - 31.7
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	35.6

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

09/11/2020
NOR AZWIN BT. YUSUF
QA Executive
Synergy Sterilisation (M) Sdn. Bhd.
+60(0)44152111

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued : **29-Apr-2022** **STT20220960**

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 :	4027019723
Product Description :	HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves - Pairs
Validation Reference :	PQ Report no. CHONII-PQ0017
Quantity Received :	103
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 White Nitrile Gloves - Pairs Catalog Numbers : CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323285, CLN323290,CLN323210. OMH Code : 48192-00, 48193-00, 48194-00, 48195-00, 48196-00, 48197-00, 48198-00, 48199-00

Catalog Number(s)	Lot No./Batch No.	Quantity
CLN323260 48192-00	NIL/SM210625X	17
CLN323265 48193-00	NIL/SM211525X	26
CLN323270 48194-00	NIL/SM211525X	25
CLN323275 48195-00	NIL/SM210025X	15
CLN323275 48195-00	NIL/SM209525X	7
CLN323280 48196-00	NIL/SM210025X	13

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued : **29-Apr-2022** **STT20220960**

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

Irradiation Data

Date and Time of Irradiation :	29-Apr-2022
Reference Dose Range kGy :	32.1 - 33.5
Calculated Minimum Dose kGy :	28.0
Calculated Maximum Dose kGy :	43.0

Irradiation Release Authorised By STERIS TOMOE (THAILAND) LTD., a STERIS Company Rungliwa S. 29 Apr. 2022

Paradee Thammajanya
QA Manager

PACKAGE LABELS

CASE LABEL

PUREZERO* HG3
STERILE WHITE NITRILE GLOVES

8

(FR) Gants stériles en nitrile blancs HG3
(DE) HG3 Sterile Nitrilhandschuhe, weiß
(BG) Стерилни бели нитрилни ръкавици HG3
(ES) Guantes de nitrilo estériles blancos HG3
(CS) Sterilní bílé nitrilové rukavice HG3
(DA) HG3 Sterile hvide nitrilhandsker
(ET) HG3 steriilsed valged nitriilkindad
(EL) HG3 Λευκά αποστειρωμένα γάντια νιτριλίου
(IT) Guanti in nitrile sterili bianchi HG3
(LV) HG3 sterili, balti nitrila cimdi
(LT) HG3 sterilios baltos nitrilinės pirštinės
(HR) HG3 sterilne bijele nitrilne rukavice
(HU) HG3 steril fehér nitrilkesztyű

200

AQL 1.0 Level 2 GI	ISO 374-5:2016 VIRUS	ISO 374-1/Type C K-Low Chemical EN ISO 374-1:2016+A1:2018

104819680 REF **CLN323280**

LOT

306 80651 48196 3

PUREZERO* HG3
STERILE WHITE NITRILE GLOVES

8

(MT) HG3 Ingwanti tan-Nitril Bojod Sterili
(NL) HG3 Witte steriele nitril handschoenen
(NO) HG3 sterile hvite nitrilhansker
(PL) HG3 Sterylne białe rękawice nitrylowe
(PT) Luvas de nitrilo brancas HG3 esterilizadas
(RO) Mănuși din nitril albe sterile HG3
(RU) Стерильные белые нитриловые перчатки HG3
(SK) Sterilné biele nitrilové rukavice HG3
(SL) HG3 Sterilne bele rokavice iz nitrila
(FI) HG3, steriilit valkoiset nitriilikäsineet
(SV) HG3 Sterila vita nitrilhandskar
(JA) HG3ホワイト滅菌ニトリルグローブ
(KO) HG3 흰색 니트릴 장갑
(ZH) HG3 无菌白色丁腈手套

200

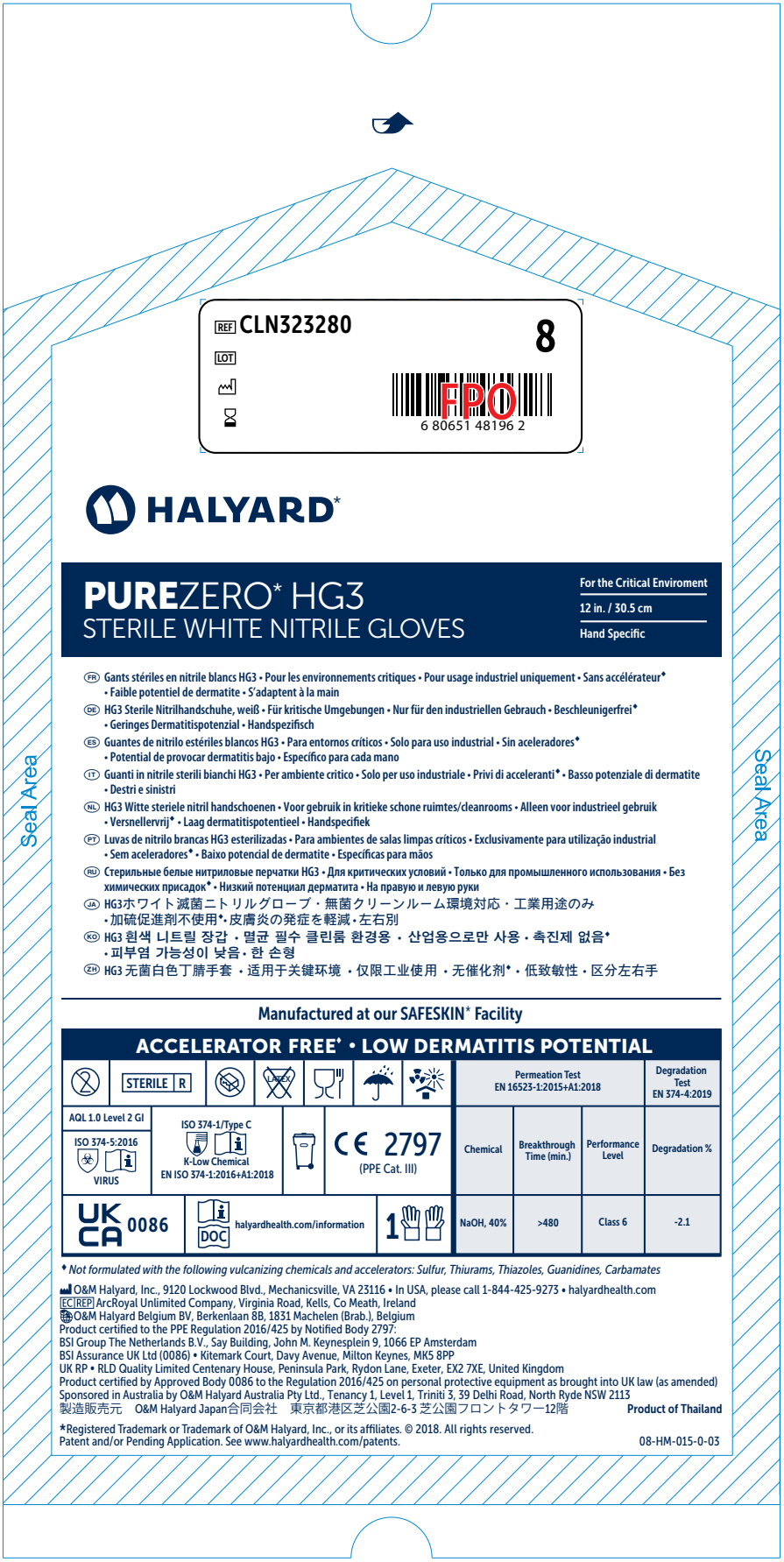
AQL 1.0 Level 2 GI	ISO 374-5:2016 VIRUS	ISO 374-1/Type C K-Low Chemical EN ISO 374-1:2016+A1:2018

104819680 REF **CLN323280**

LOT

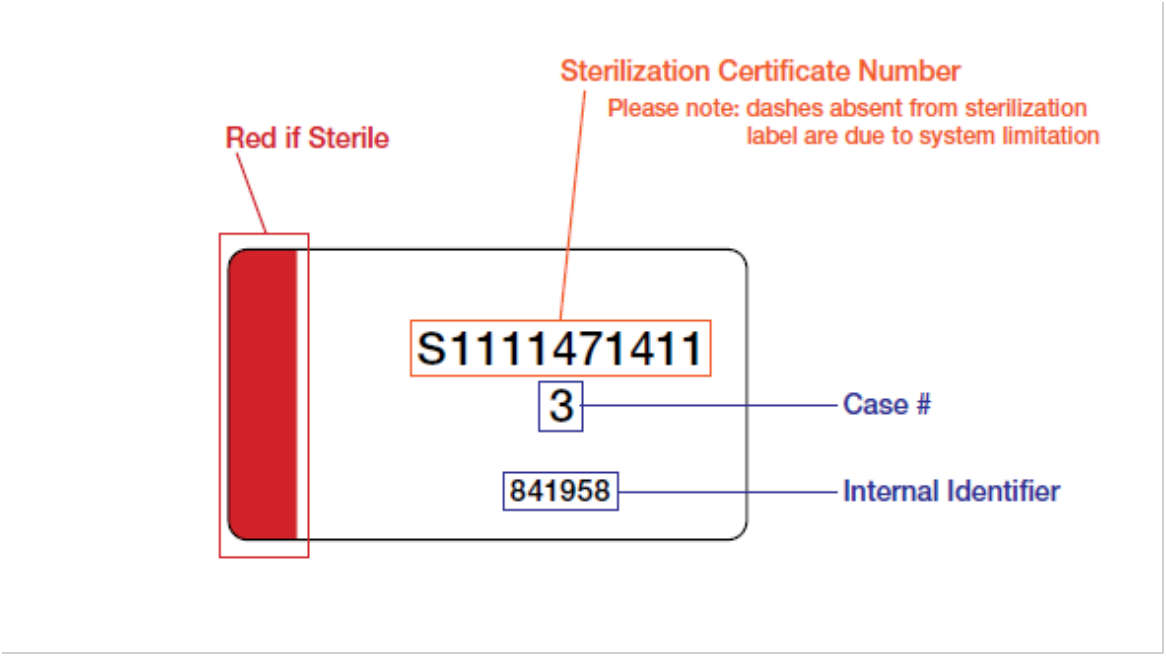
306 80651 48196 3

POUCH LABEL


REF CLN323280
8
LOT
FPO
6 80651 48196 2
HALYARD*
PUREZERO* HG3
STERILE WHITE NITRILE GLOVES
For the Critical Enviroment
12 in. / 30.5 cm
Hand Specific
Seal Area
Seal Area
(FR) Gants stériles en nitrile blancs HG3 • Pour les environnements critiques • Pour usage industriel uniquement • Sans accélérateur♦ • Faible potentiel de dermatite • S'adaptent à la main
(DE) HG3 Sterile Nitrilhandschuhe, weiß • Für kritische Umgebungen • Nur für den industriellen Gebrauch • Beschleunigerfrei♦ • Geringes Dermatitispotenzial • Handspezifisch
(ES) Guantes de nitrilo estériles blancos HG3 • Para entornos críticos • Solo para uso industrial • Sin aceleradores♦ • Potencial de provocar dermatitis bajo • Específico para cada mano
(IT) Guanti in nitrile sterili bianchi HG3 • Per ambiente critico • Solo per uso industriale • Privi di acceleranti♦ • Basso potenziale di dermatite • Destri e sinistri
(NL) HG3 Witte steriele nitril handschoenen • Voor gebruik in kritieke schone ruimtes/cleanrooms • Alleen voor industrieel gebruik • Versnellervrij♦ • Laag dermatitispotentieel • Handspecifiek
(PT) Luvas de nitrilo brancas HG3 esterilizadas • Para ambientes de salas limpas críticos • Exclusivamente para utilização industrial • Sem aceleradores♦ • Baixo potencial de dermatite • Específicas para mãos
(RU) Стерильные белые нитриловые перчатки HG3 • Для критических условий • Только для промышленного использования • Без химических присадок♦ • Низкий потенциал дерматита • На правую и левую руки
(JA) HG3ホワイト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
(KO) HG3 흰색 니트릴 장갑 • 멸균 필수 클린룸 환경용 • 산업용으로만 사용 • 촉진제 없음♦ • 피부염 가능성이 낮음 • 한 손형
(ZH) HG3 无菌白色丁腈手套 • 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
LATEX
AQL 1.0 Level 2 GI
ISO 374-5:2016
VIRUS
ISO 374-1/Type C
K-Low Chemical
EN ISO 374-1:2016+A1:2018
CE 2797
(PPE Cat. III)
UK CA 0086
DOC
halyardhealth.com/information
1
Permeation Test EN 16523-1:2015+A1:2018
Degradation Test EN 374-4:2019
Chemical
Breakthrough Time (min.)
Performance Level
Degradation %
NaOH, 40%
>480
Class 6
-2.1
♦ 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 • halyardhealth.com
EC REP ArcRoyal Unlimited Company, Virginia Road, Kells, Co Meath, Ireland
O&M Halyard Belgium BV, Berkenlaan 8B, 1831 Machelen (Brab.), Belgium
Product certified to the PPE Regulation 2016/425 by Notified Body 2797:
BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam
BSI Assurance UK Ltd (0086) • Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP
UK RP • RLD Quality Limited Centenary House, Peninsula Park, Rydon Lane, Exeter, EX2 7XE, United Kingdom
Product certified by Approved Body 0086 to the Regulation 2016/425 on personal protective equipment as brought into UK law (as amended)
Sponsored in Australia by O&M Halyard Australia Pty Ltd., Tenancy 1, Level 1, Triniti 3, 39 Delhi Road, North Ryde NSW 2113
製造販売元 O&M Halyard Japan合同会社 東京都港区芝公園2-6-3 芝公園フロントタワー12階
Product of Thailand
*Registered Trademark or Trademark of O&M Halyard, Inc., or its affiliates. © 2018. All rights reserved.
Patent and/or Pending Application. See www.halyardhealth.com/patents.
08-HM-015-0-03

STERILIZATION/IRRADIATION LABEL

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



PACKAGING CERTIFICATES

POUCH

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)
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 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 Counts	Blank Cts 2 Counts	Blank Ct 3 Counts	Average Blank (A) 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 Total counts	3.0
5.0 micron	0.0	0.0	0.0	0.0	

W Sample Particle Counts (Cumulative)

	Washed Cts 1 Counts	Washed Cts 2 Counts	Washed Cts 3 Counts	Average Washed (B) 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 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	10.0
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

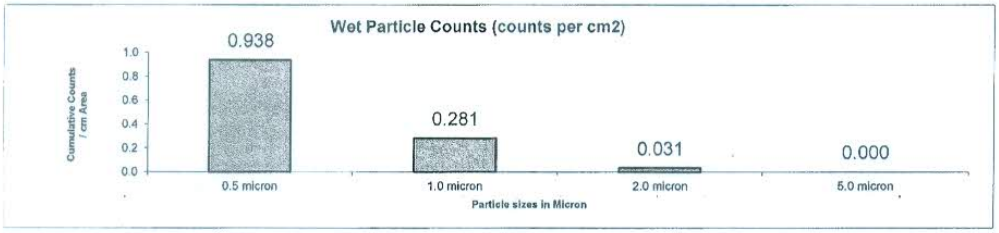
Total Washed Area	853 cm^2

(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^2 (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^2

Tested By : SUHAIDA
Date : 26.10.2020

Verified By : RUDY
Date : 26.10.2020

TIP CORPORATION SDN BHD QA RUDY

POUCH

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)

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 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
		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	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	Total counts	3.7
5.0 micron	0.0	0.0	0.0	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	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	Total counts	21.7
5.0 micron	1.0	1.0	0.0	0.7		

(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

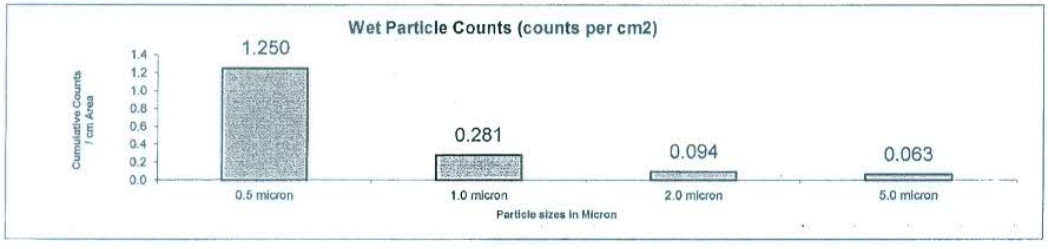
Total Washed Area 853 cm^2

(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^2 (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^2

Tested By : SUHAIDA
Date : 26.10.2020

Verified By : RUDY
Date : 26.10.2020

TIP CORPORATION SDN. BHD. QA RUDY

POUCH

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)

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 EASY PEEL-PRT
Testing Date: 26.10.2020
Customer : SAFESKIN

Lot No: K34514(Outgoing C)
Size: 152.4 X 304.8 X 0.07MM
Method: BY HAND
Machine: BS-5

Blank Particle Counts (Cumulative)

	Blank Cts 1 Counts	Blank Cts 2 Counts	Blank Ct 3 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 Counts	Washed Cts 2 Counts	Washed Cts 3 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

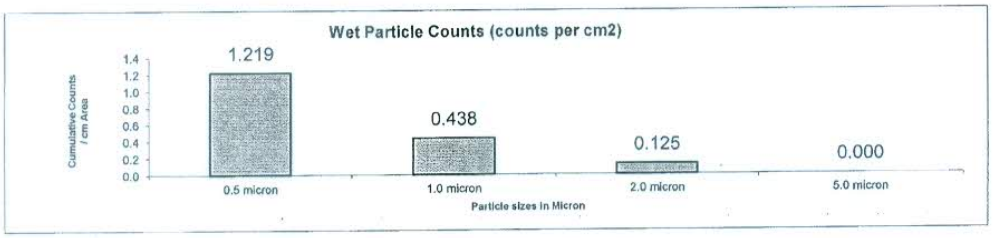
Total Washed Area 853 cm^2

(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^2 (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^2

Tested By : SUHAIDA
Date : 26.10.2020

Verified By : RUDY
Date : 26.10.2020

TIP CORPORATION SDN BHD QA RUDY

WALLET

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)

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:	K55532
Testing Date:	09.11.2020	Size:	220X340X0.06MM
Customer :	SAFESKIN	Method:	BY HAND
			KCCS-17

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	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

ash Sample Particle Counts (Cumulative)

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

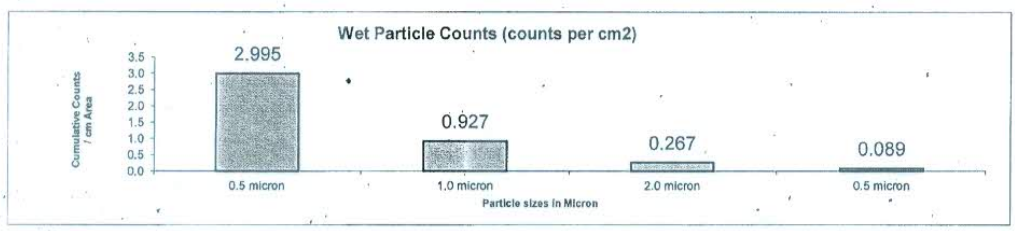
Total Washed Area 1496 cm^2

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

.nicron	11.200
1.0 micron	3.467
2.0 micron	1.000
0.5 micron	0.333

(H) Total Wet Part Cts / cm^2 (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^2

Tested By : SUHAIDA
Date : 09.11.2020

Verified By : RUDY
Date : **09.11.2020**

WALLET

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)

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:	K55753
Testing Date:	09.11.2020	Size:	220X340X0.06MM
Customer :	SAFESKIN	Method:	BY HAND
			KCCS-17

Blank Particle Counts (Cumulative)

	Blank Cts 1 Counts	Blank Cts 2 Counts	Blank Ct 3 Counts	Average Blank (A) 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 Total counts	3.0

ash Sample Particle Counts (Cumulative)

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

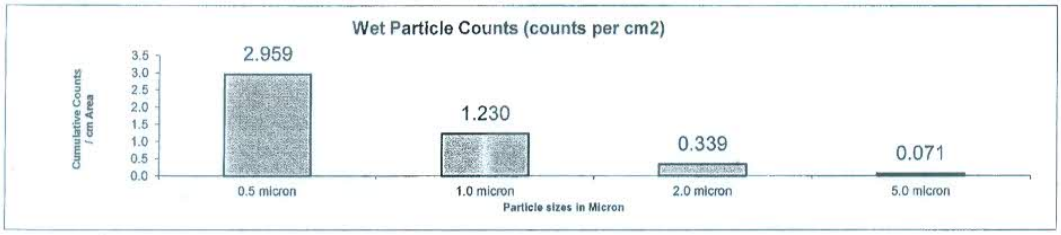
Total Washed Area 1496 cm^2

(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^2 (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^2

Tested By : SUHAIDA
Date : 09.11.2020

Verified By : RUDY
Date : 09.11.2020

TIP CORPORATION SDN BHD QA RUDY

WALLET

TIP CORPORATION SDN BHD Reg. No. 198901010228 (187530-A)

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:	K55752
Testing Date:	09.11.2020	Size:	220X340X0.06MM
Customer :	SAFESKIN	Method:	BY HAND
			KCCS-17

Blank Particle Counts (Cumulative)

	Blank Cts 1 Counts	Blank Cts 2 Counts	Blank Ct 3 Counts	Average Blank (A) 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 Total counts	7.0

Wash Sample Particle Counts (Cumulative)

	Washed Cts 1 Counts	Washed Cts 2 Counts	Washed Cts 3 Counts	Average Washed (B) Counts	
0.5 micron	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 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

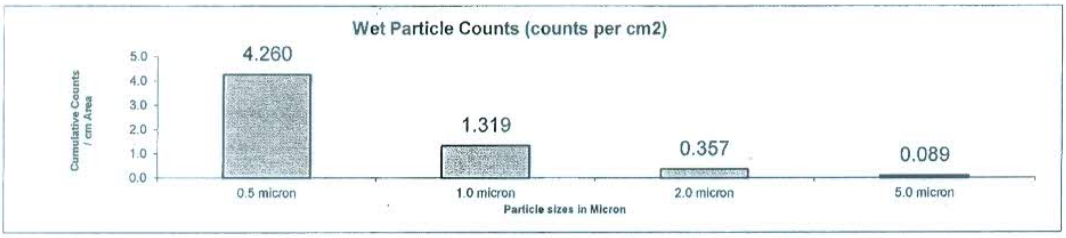
Total Washed Area 1496 cm^2

(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^2 (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/CM^2

Tested By : SUHAIDA
Date : 09.11.2020

Verified By : RUDY
Date : 09.11.2020

WALLET

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)
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:	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 Counts	Blank Cts 2 Counts	Blank Ct 3 Counts	Average Blank (A) 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	Total counts	1.3

Wash Sample Particle Counts (Cumulative)

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

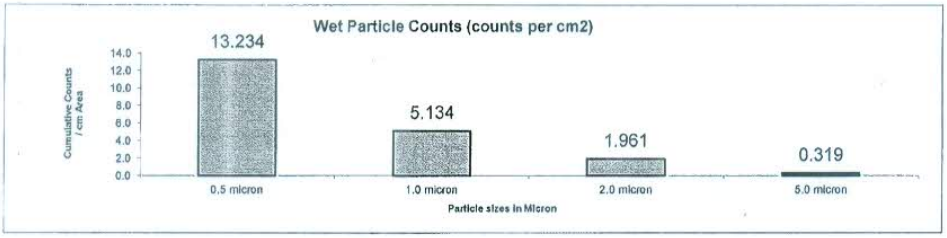
Total Washed Area 4181 cm^2

(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^2 (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^2

SPEC: ≥ 0.5u ≤10 COUNTS/CM^2

Tested By : SUHAIDA
Date : 09.11.2020

Verified By : RUDY
Date : 09.11.2020

TIP CORPORATION SDN BHD QA RUDY

WALLET

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)
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
			KCCS-17

Blank Particle Counts (Cumulative)

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

ash Sample Particle Counts (Cumulative)

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

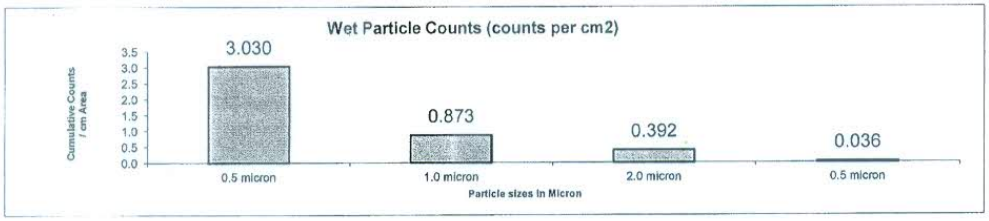
Total Washed Area 1496 cm^2

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

micron	11.333
1.0 micron	3.267
2.0 micron	1.467
0.5 micron	0.133

(H) Total Wet Part Cts / cm^2 (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^2

Tested By : SUHAIDA
Date : 09.11.2020

Verified By : RUDY
Date : 09.11.2020

TIP CORPORATION SDN BHD QA RUDY

DOSE MAPPING REPORT

STERIS
Applied Sterilization Technologies

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 White Nitrile Gloves - Pairs**
The validation ref no:	**0.0969 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)

STERIS
Applied Sterilization Technologies

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 if the Customer to routinely provide product in the presentation and orienation 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 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

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^2overall) **0.28**
Minimum detectable difference (б) **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	**0.876**
1/Rmax	**1.096**

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

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	**35.2**	√-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		**35.4**	√-MAX	**35.1**	√-MAX	**35.1**	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	**26.8**	√-MIN	**26.7**	√-MIN	**26.8**	√-MIN	**26.8**	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^2overall) **0.53**

Minimum detectable difference (б) **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	**0.832**
1/Rmax	**1.091**

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

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)

				Weight (LD)	:	**6.45** kg
Current Cobalt Loading	:	**4,591,067**	Curries	Weight (HD)	:	**8.20** 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)	:	**0.168** g/cm^3
Type of package	:	**Corrugated carton**		Density (HD)	:	**0.214** g/cm^3
Dose Range Specification (kGy)	:	**25**	Min	Tote Fit	:	**15** ctn/tote
		50	Max			

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

Validation Ref : 0.0969 Rev 01

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

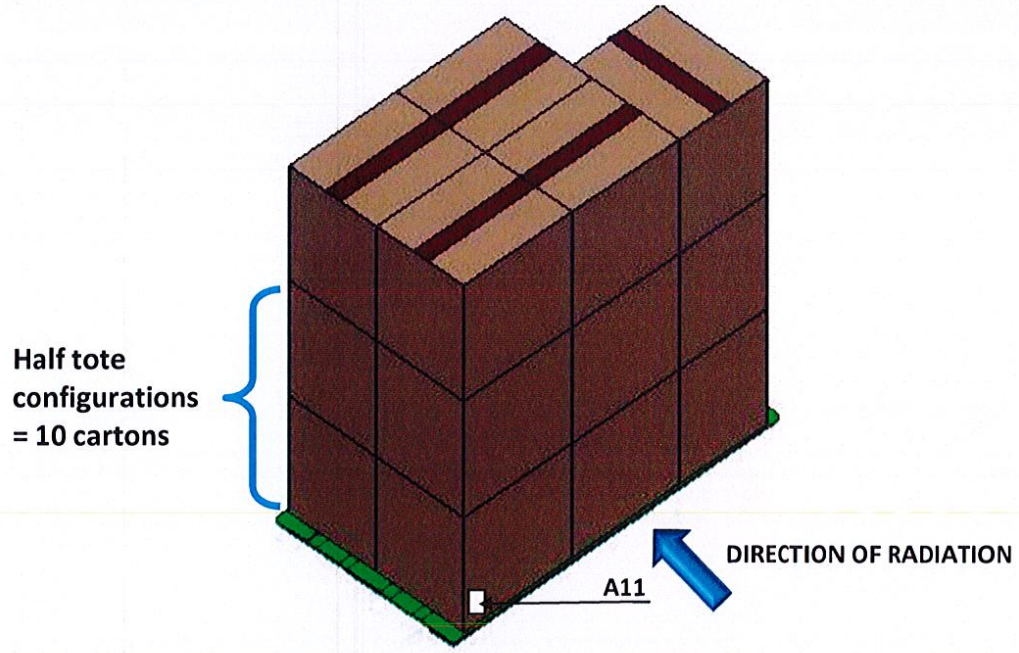
Type of Package : **Corrugated carton**

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

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

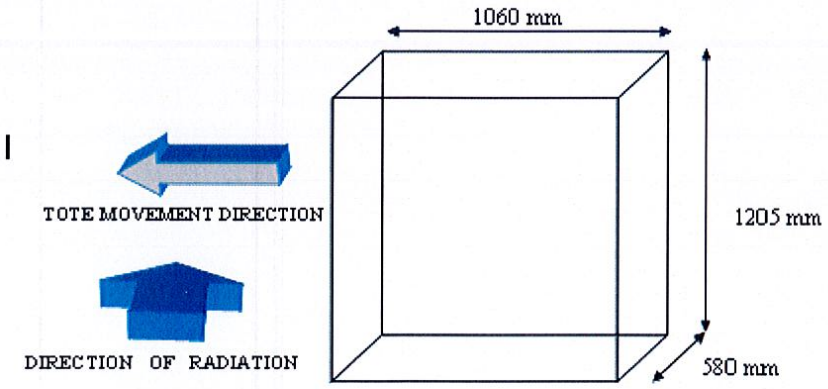
Type of Package : **Corrugated carton**

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

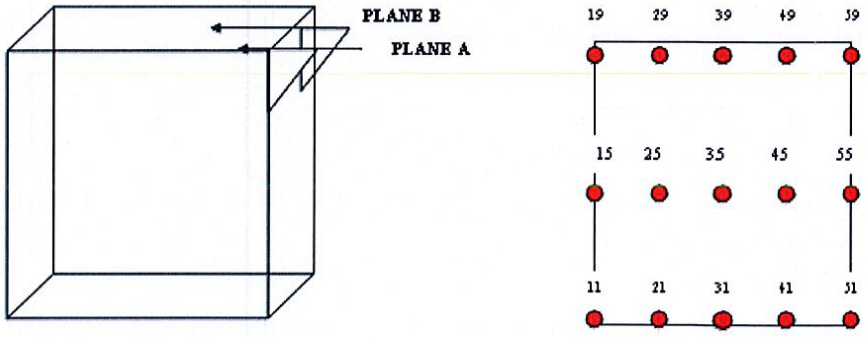
Issue Date : **29.04.2021**

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

TOTE CHARACTERISTICS AND ORIENTATION



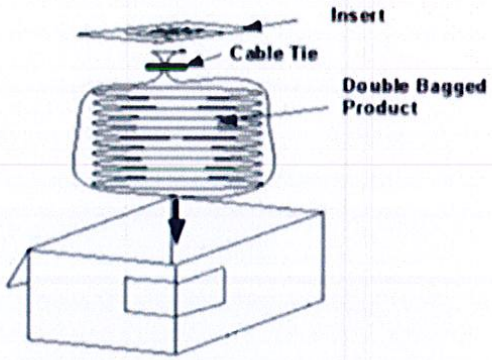
LOCATION OF DOSIMETERS



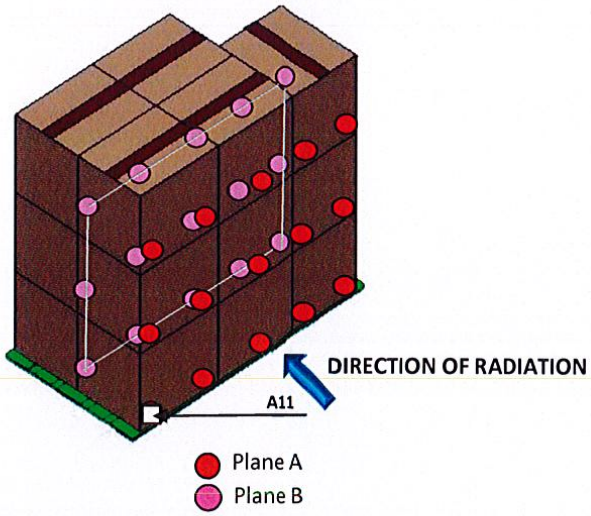
As per our Operational Qualification Report, from latest source loading replenishment, the dose distribution in the front plane (plane A) is the same as in the back plane (plane C).

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

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

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,

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

ISO 9001:2015

bsi.

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

ISO 13485:2016

bsi.

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

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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

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
Latest Revision Date: 2021-01-15

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

Page: 3 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
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
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