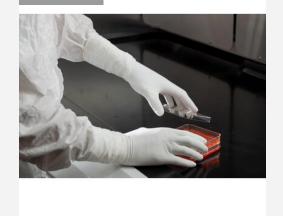
pure¹¹

Halyard



Empfohlene Reinraumklassen

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

GMP CD



Nitril-Handschuhe PUREZERO HG3 (white) #CLN3031XS

pure¹¹-Nr.: 1105011, Marke: Halyard

Eigenschaften

Marke: Halyard

Handschuhtyp: Dünnfilm

• Länge in cm: 30,5 cm

• Chemikalienbeständigkeit - Typ: Typ C

Puderfrei

Material: Nitril

Texturierte Fingerspitzen

Zytostatikageeignet

• Lebensmittelkonformität

Silikonfrei

Vulkanisationsbeschleunigerfrei

Verpackungsform: Beutel

• AQL (Acceptable Quality Level)-Wert: 0,65

• Chemikalienbeständig gegen Isopropanol (100%): Level 3 (60-120min)

• Chemikalienbeständig gegen Isopropanol (70%): Level 3 (60-120min)

• Länge in Inches: 12 In

Latexfrei

• Materialzusammensetzung: Reinmaterial

• Oberflächenbeschaffenheit: griffig

AG München HRB 171307

T +49 89 5589434 0

F +49 89 5589434 //

www.pure11.de

nfo@pure11.de

pure¹¹

- Reißfestigkeit EN 455-2 ASTM in MPa: 20-30
- Schutz vor Blut und K\u00f6rpersekreten ISO 16604:2004
- Passform Hand: beidhändig
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,16 mm

Material

Nitril

Verpackung

• 1000STK

Produktvarianten

pure11-Nr.: 1105011WHXS, Nitril-Handschuhe PUREZERO HG3 (white) #CLN3031XS

Farbe: Weiß; Größe: XS / VE: 1000STK

pure¹¹-Nr.: 1105011WHL, Nitril-Handschuhe PUREZERO HG3 (white) #CLN3031LG

Farbe: Weiß; Größe: L / VE: 1000STK

pure¹¹-Nr.: 1105011WHM, Nitril-Handschuhe PUREZERO HG3 (white) #CLN3031MD

Farbe: Weiß; Größe: M / VE: 1000STK

pure11-Nr.: 1105011WHS, Nitril-Handschuhe PUREZERO HG3 (white) #CLN3031SM

Farbe: Weiß; Größe: S / VE: 1000STK

pure¹¹ GmbH

Bavariafilmplatz / | D-82031 Grunwald

Geschäftsführung: Julian Kropp, Linda Vereycken, Lars Engelei

AG München HRB 171307

T +49 89 5589434 0

F +49 89 5589434 77

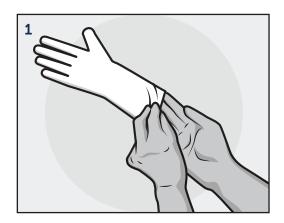
www.pure i i.de

nto@pure11.de

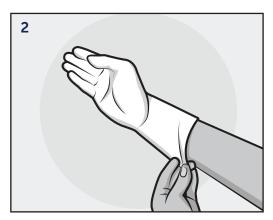


GUIDE TO DONNING AND DOFFING OF NON-STERILE CLEANROOM GLOVES

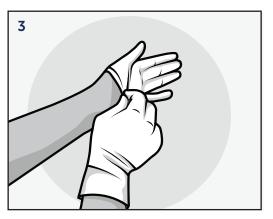
DONNING GLOVES



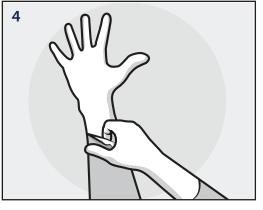
Grasp the beaded cuff of one glove and carefully pull over the opposite hand.



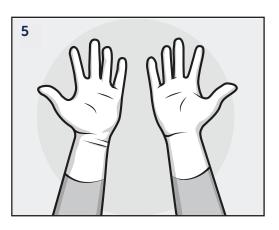
Gently ease the glove up over the hand and wrist.



Grasp the second glove at the edge of the beaded cuff.

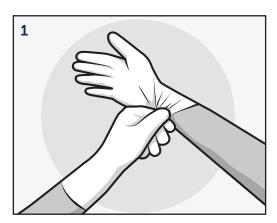


Gently ease the glove up over the hand and wrist.

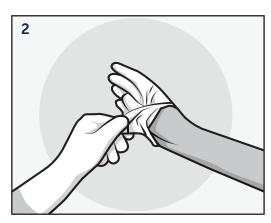


You are now ready to perform your task.

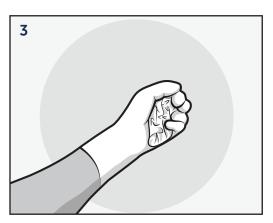
DOFFING GLOVES



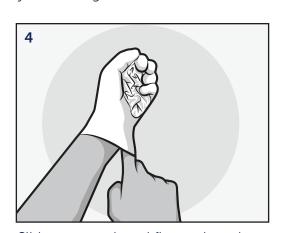
Grasp the exterior of one glove with your other gloved hand.



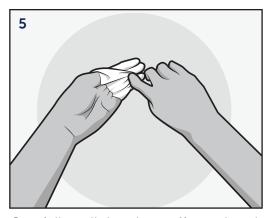
Carefully pull the glove off your hand, turning it inside-out.



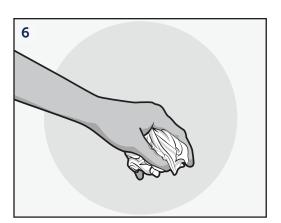
Ball the glove up and hold in your other gloved hand.



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



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



Discard appropriately.

For more information, contact your HALYARD* representative or distributor, or visit www.purezerogloves.com





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



HALYARD* **PURE**ZERO* HG3 WHITE NON-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* PUREZERO* HG3 White Nitrile Gloves

For the Cleanroom Environment For Industrial Use Only

TECHNICAL DATA SHEET

Description

HALYARD* **PURE**ZERO* HG3 White Nitrile Cleanroom Gloves are designed for semiconductor, pharmaceutical and medical device manufacturing applications. These gloves are clean processed (washed repeatedly in deionized water) to ensure consistent control of low particles and extractables and are recommended for use in ISO Class 3 or higher and Grade B/C/D cleanrooms. Because HALYARD* **PURE**ZERO* White Nitrile Gloves have an **accelerator-free**¹ formulation, there is a reduced risk of allergies and skin irritation associated with accelerator chemicals in other nitrile gloves.



Manufactured at OUR OWN Safeskin Facility in Thailand.

Cleanliness Properties

<950 Particles/cm ²	IEST RP-CC005
Max Level (ug/g)	IEST RP-CC005
50	
35	
5	
20	
5	
10	
10	
7	
5	
	50 35 5 20 5 10 10

Physical Properties

AQL	1.0
Non-Sterile	✓
Ambidextrous	✓
Tacky Grip	✓
Textured Fingertips	✓
Accelerator-Free ¹	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Static Dissipative in Use	✓
Tensile Strength ²	35 MPa (Target)
Ultimate Elongation ²	600%
Shelf Life	3 Years

Glove Dimensions

	X-SMALL	SMALL	MEDIUM	LARGE	X-LARGE
Glove Length (inch/cm)	12"/30.5	12"/30.5	12"/30.5	12"/30.5	12"/30.5
Middle Finger Length (mm)	71	78.5	80.5	88.1	91.6
Width of Palm (mm)	70	80	95	110	120
Finger Tip Thickness	0.16 mm (6.2 mil)				
Palm Thickness	0.13 mm (5.1 mil)				
Cuff Thickness	0.10 mm (3.9 mil)				



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

For the Cleanroom Environment For Industrial Use Only

TECHNICAL DATA SHEET

Packaging Data

Double bag, plus case liner

1000 gloves per case: 100 gloves 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

ISO 14001

Compliant to these food handling regulatory standards:

FDA 21 CFR 177-2600

FDA 21 CFR 180.22

Commission Regulation (EU) No 10/2011

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

EN 16523-1:2015+A1:2018

EN ISO 374-2:2019

EN ISO 374-4:2019

EN ISO 374-5:2016 Bacteria, Fungi, and Virus Protection

EN ISO 374-1:2016+A1:2018/ Type B

EN ISO 21420:2020 Dexterity Classification: Level 5

Compliant with the REACH regulation

RoHS 2011/65/EU Annex II

Static Dissipative in Use

Tested per ANSI/ ESD SP 15.1

Meets USP <800> Guidelines

C € 2797







Additional Glove Information

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

Tested against 29 chemicals, 14 chemotherapy drugs and Fentanyl.

Made in Thailand

Declaration of Conformity (DoC) and Certificates of Analysis (COA) for every production lot available online at halyardhealth.com/information

Storage Instructions

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

Ordering Information

HALYARD* PUREZERO* HG3 WHITE NITRILE GLOVES, NON-STERILE, AMBIDEXTROUS, TACKY

Size	Code
XS	CLN3031XS
SM	CLN3031SM
MD	CLN3031MD
LG	CLN3031LG
XL	CLN3031XL

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

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.



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

² Tested per ASTM D412

CERTIFICATE OF ANALYSIS





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 White Nitrile Gloves

Catalog Numbers: CLN3031XS, CLN3031SM, CLN3031MD, CLN3031LG, CLN3031XL

OMH Code: 48167-81, 48168-81, 48169-81, 48170-81, 48171-81

Batches: SM318223X to SM321223X

SM318223V to SM321223V

Total Cases per Lot: 4,511

Date of Manufacture: Jul-23

Expiration Date: 2026-06-30

	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 :	3555	3555	3440	403	286	286	286				
AQL Level :	1.0	2.5	4.0	4.0	4.0	4.0	4.0				
Failures Allowed per AQL :	54	130	192	31	22	22	22				
Failures :	1	0	0	0	0	0	0				
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept				
				Averages:	43.12	620	15.09				

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

Particle Test Data

Particle

Total Particles/cm² Inspection Result

#/cm2: 830

Accept

Particulate Level (≥0.5 microns) #/cm²

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data

•		Anions Results	3		9	Cations Result	<u>s</u>	
- Units :	Chloride Cl	Nitrate N0 ₃	Sulfate S0 ₄ -2	Sodium Na ⁺	Ammonium NH₄⁺	Potassium K ⁺	Magnesium Mg ⁺²	Calcium Ca ⁺²
µg/g glove	25,912	4.810	1.325	1.754	1.286	1.749	1.274	42.222
Inspection Result:	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

Trace Element Results

Zinc Units : Zn

μg/g glove

Zn 3.48

Inspection Result :

Accept

Test Method: IEST-RP-CC005.4

Review By :

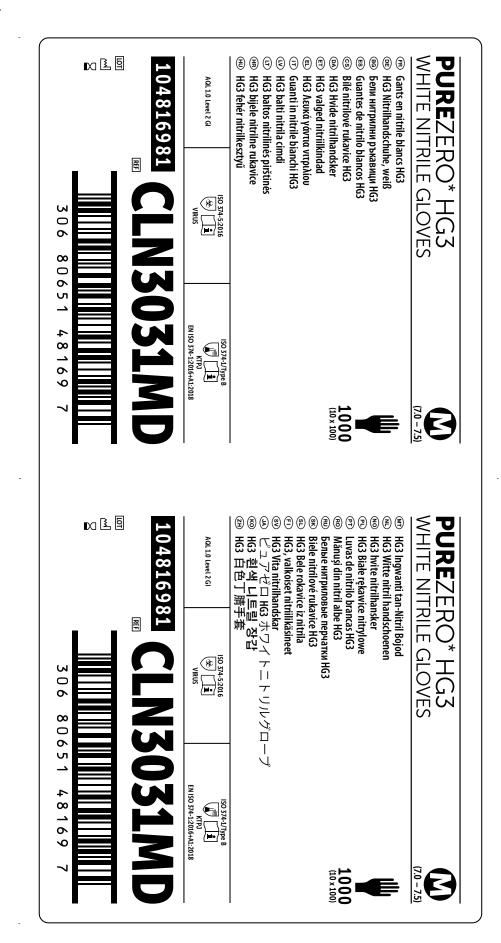
(QA Sr. Manager)

FORM-28013/7

PACKAGE LABELS



CASE LABEL





PUREZERO* HG3 WHITE NITRILE GLOVES

For the Cleanroom Environment

For Industrial Use Only 12 in. / 30.5 cm

- ® Gants en nitrile blancs HG3 Pour l'environnement des salles blanches Pour usage industriel uniquement Sans accélérateur • Ambidextres
- 🐵 HG3 Nitrilhandschuhe, weiß Für Reinraumumgebungen Nur für den industriellen Gebrauch Beschleunigerfrei • Beidhändig
- Guantes de nitrilo blancos HG3 Para entornos de sala blanca Solo para uso industrial Sin aceleradores • Ambidiestro
- Guanti in nitrile bianchi HG3 Per camera bianca Solo per uso industriale Privi di acceleranti • Basso potenziale di dermatite Ambidestri
- ## HG3 Witte nitril handschoenen Voor gebruik in kritieke schone ruimtes/deanrooms Alleen voor industrieel gebruik Versnellervrij* Symmetrisch
- 🐵 Luvas de nitrilo brancas HG3 Para ambiente de sala limpa Exclusivamente para utilização industrial Sem aceleradores • Baixo potencial de dermatite Ambidestras
- ® Белые нитриловые перчатки HG3 Для стерильных условий Только для промышленного использования Без химических присадок • Амбидекстральные
- ⑩ ピュアゼロ HG3ホワイトニトリルグローブ・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⁴ •左右兼用
- ⑩ HG3 흰색 니트릴 장갑·클린룸 환경용·산업용으로만 사용·촉진제 없음◆·양손형
- ② HG3 白色丁腈手套·适用于洁净室环境·仅限工业使用·无催化剂◆·左右手通用

Manufactured at our SAFESKIN* Facility

ACCELERATOR FREE' XS (5.5) = CLN3031XS Ambidextrous S (6.0 - 6.5) = CLN3031SM M(7.0 - 7.5) = CLN3031MDL (8.0 - 8.5) = CLN3031LG **C**€ 2797 DOC halyardhealth.com/information 100 AQL 1.0 Level 2 GI XL(9.0 - 10.0) = CLN3031XL

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

Product of Thailand

■ O&M Halyard, Inc., 9120 Lockwood Blvd., Mechanicsville, VA 23116 • In USA, please call 1-844-425-9273 • halyardhealth.com [CIREP] ArcRoyal Unlimited Company, Virginia Road, Kells, Co Meath, Ireland 動のM Halyard Belgium BV, Berkenlandan BB, 1831 Machelen (Brab.), Belgium Forduct certified to the Regulation (EU) 2016/425 by Notified Body 2797 BSI Group The Netherlands B.V., Say Building, John M, Keynesplein 9, 1066 EP Amsterdam, and to the Regulation (EU) 2016/425 on personal protective equipment, as amended to apply in Great Britain by Approved Body BSI Assarace UK Ltd (Doß6 (Kitemark Court, Davy Avenue, Mitton Keynes, MKS 8PP. UK RP *RLD Quality Limited Centenary House, Peninsula Park, Rydon Lane, Exeter, EXZ 7XE, United Kingdom Sponsored in Australia by O&M Halyard Australia Py Ltd., Tenandy, 1, Level 1, Trinti 3, 39 belin Road, North Ryde NSW 2113 販売売ご O&M Halyard Japan合同会社 東京都港区支公園でもう支公園フロントタワー12階

*Registered Trademark or Trademark of O&M Halyard, Inc., or its affiliates. © 2018. All rights reserved.

06-HM-089-0-02

Place Label Here

PACKAGING CERTIFICATES



BAG COC



Date Reviewed: 30.11.2017 CORPORATION SDN BHD (18759-A)

Lot 608, Jalan Sungai Sop, Batu 14, 43100 Hulu Langat, Selangor, Malaysia. Tel: +603-9021 3985 E-mail: sales@tipcorp.com Website: www.tipcorp.com



FORM: QC-07 REV 10

CERTIFICATE OF CONFORMANCE

THIS IS TO CERTIFY THAT THE FOLLOWING PRODUCT CONFORM/PASS THE SPECIFICATION LISTED BELOW:-

CUSTOMER

: SAFESKIN

DESCRIPTION

: C/R EASY TEAR LDPE -PRT -355X405X0.05MM

QUANTITY

: 20,000 PCS

LOT NO

: 61200

PART NO

: 06-HM-039-0-00

P.O NO. & DATE : 4561162599

TEST DATE

: 12.07.2021

OUR INVOICE NO: TPL 16374

PALLET REFERENCE

NUMBER (IF ANY):

PACKING LIST NUMBER: TPL16374

DATE OF MANUFACTURING:

DATE OF EXPIRED:

C'afall-in	Thailand
	B RESERVE

D/O No.

TPL16374

IQA Batch

12107139

Date

16-202,2021

Signature Dy:

Ohals

SURFACE RESISTIVITY TEST - (Reference ASTM D257, ANSI / ESD S541 & ANSI / ESD STM 11.11)

		DISSIPATIVE $: \ge 1 \times 10^5 \text{ AND} \le 1 \times 10^{12} \text{ OHMS/SQ}$
		CONDUCTIVE : < 1 X 10 ⁵ OHMS/SQ
		VISUAL TEST
		DIMENSION CHECK (WIDTH, LENGTH & THICKNESS)
		WATER LEAK TEST
		LPC TEST
		SEAL/PEEL STRENGTH TEST
	1	PRINTING
		AMIDE & SILICON FREE
		CENTRE SEAL / WITH PERFORATION LINE
		NO CENTRE SEAL / WITHOUT PERFORATION
Clau		July-
TESTED BY: R	ubaiyat DEPAR	FMENT VERIFIED BY : VA EXECUTIVE



TOP IN PERFORMANCE

BAG COC

	I N COI	MING QUALIT	Y INSPECTION	110	TIP CORE	PORATIO	N SDN BHD			√	OUT GOING	QUALITY INS	PECTION REF	PORT				Date Implement : 0 REF NO : DATE 1	05.04.2018 QC -01 2.07.2021
TOMER	SUPPLIER		SAFESKIN				L	OT NO	6120	00				SAMPLING P	LAN 0.65 single	Plan Normal I	spection SJ		
														Lot Qtty			SS	Accept / Reject	
A	C/R EASY TE	AR LDPE -PF	RT -355X4053	(0.05MM				MANTITY	20,000 pcs					501 to 3,2	00pcs		13	Acc / Rei: 0/1	
														3,201 to 3	5.000pcs		20	Acc / Re : D/1	
TNO	06-HM-039-0	00													500,000pcs		32	Acc / Re : 0/1	
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	WIDTH	MAX	MIN	LENGTH	MAX	MIN	THICKNESS	XAM	MIN	OK/NG		OPEN	STRENGTH	GUSSET	1	OHM/SQ	SEAL	DISSIPATIVE	
C	3554/-5	360	350	405+/-10	415	395	0.05+/-0.01	0.06	0.04	OK	OK	OK	OK	OK	NO	RIGHT	LEFT	INSULATOR	
1	353		1	410			0.05								1	10	11	TEST METHOD	
2	354			411			0.05								2	11	11	(ASTM D 257)	
3	353			410			0.05								3	11	10	OTHER	
4	354			410			0.05								4	10	11		
5	353			411			0.05								5	11	10	Remarks	
6	354			410			0.05								6	10	11	1	
7	353			411			0.05								7	11	10		
8	354			410			0.05								8	10	11		
9	353			411			0.05								9	11	10	For Incoming visua	al:
10	354	OK		411	OK		0.05	OK		OK	OK	OK	OK	OK	10	11	11	Bag no torn , dama	
11	353			410			0.05								11	10	10	Reject for the bag	is broken
12	354			410			0.05								12	11	11		
13	353			411			0.05								13	10	10	Equipment for Inst	
14	354			411			0.05								14	11	11	Dimension - Measur	
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16	354			411			0.05								16	11	11	Surface Resistivity -	SRM
17	353			410			0.05								17	10	11	SUMMARY OF OUT	
18	354			411			0.05								18	11	10	INSPECTION RE	
19	353			410			0.05								19	11	10		MVTR- N/A
20	354			411			0.05								20	10	11		Easy to open: OK
21															21				Mixed: NO
22											-				22			Seal Strength : OK	Water Leak Test Nr.
23	-									-	-	-			23	-	-	Printing per spec: OK	
24	1										-	-	-	-	24	-	1	Surface Resistivity: N/A	/A
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26	-					1				-	-	-	-	-	26	-	-		IDITION INSPECTION
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31	-	-		-			1		-		-				32	-		Label In vs Out	
32									1		1		1	Prepared		7.		Verified By :	No.
															-	Um			OV
		REMARKS:		ACCEPT			REJECT							Final disp	osition:	OK		Final Disposition	1 OK



FORM: QC-07 REV 10

Date Reviewed: 30.11.2017

TIP CORPORATION SDN BHD (1872)0-A)

Lot 608, Jalan Sungai Sop, Batu 14, 43100 Hulu Langat, Selangor, Malaysia. Tel: +603-9021 3985 E-mail: sales@tipcorp.com Website: www.tipcorp.com





CERTIFICATE OF CONFORMANCE

THIS IS TO CERTIFY THAT THE FOLLOWING PRODUCT CONFORM/PASS THE SPECIFICATION LISTED BELOW;-

CUSTOMER

: SAFESKIN

DESCRIPTION

: C/R EASY TEAR LDPE BAG -355X405X0.045MM

QUANTITY

: 48,000 PCS

LOT NO

: 61448

PART NO

: 06-HM-041-0-00

P.O NO. & DATE : 4561164448

TEST DATE

: 10.08.2021

OUR INVOICE NO: TPL16679

PALLET REFERENCE NUMBER (IF ANY):

PACKING LIST NUMBER :TPL16679

DATE OF MANUFACTURING:

DATE OF EXPIRED:

0 0		
Safeskin	18.8	67 7
DESTRIES	8 8 8 3	RESCOURT

D/O No.

TPL 16679

IQA Batch

P2108109

Date

Signature By :

14-AUG 2021

SURFACE RESISTIVITY TEST - (Reference ASTM D257, ANSI / ESD S541 & ANSI / ESD STM 11.11)

		DISSIPATIVE :≥1 x 10 ⁵ AND <1 x 10 ¹² OHMS/SQ
		CONDUCTIVE : < 1 X 10 ⁵ OHMS/SQ
	Z	VISUAL TEST
	Z	DIMENSION CHECK (WIDTH, LENGTH & THICKNESS)
		WATER LEAK TEST
	D	LPC TEST
	Z	SEAL/PEEL STRENGTH TEST
		PRINTING
	D	AMIDE & SILICON FREE
		CENTRE SEAL / WITH PERFORATION LINE
		NO CENTRE SEAL / WITHOUT PERFORATION
- Opn		
TESTED BY: Rul	Balyat	VERIFIED BY : QA EXECUTIVE



QC DEPARTMENT

TOP IN PERFORMANCE

BAG 2 COC

USTOMER	IN CON	IING QUALITY	INSPECTION	TIP N REPORT	TIP COR	PORATIO	ON SON BHE	LOT NO	61448		OUT GOING	QUALITY INS	SPECTION RE	SAMPLING P	LAN 0.65 sing	gle Plan Normal	Inspection \$3	FORM : QC-01 REV 9 Date Implement : 05.04.2018 REF NO : QC -01 DATE : 10.08.2021
EM:	C/R EASY TEA	DI DDE DAG	arev tarve											Lot Qtty			SS	Accept / Reject
EM:	C/R EASY TEA	IR LDPE BAG	-355X405X0	0.045MM		-		QUANTITY	48,000 pcs	_				501 to 3,2	00pcs		13	Acc / Rej : 0/1
														3,201 to 3	5,000pcs		20	Acc / Rej : 0/1
ART NO:	06-HM-041-0-0	00												35,001 to	500,000pc	s	32	Acc / Rej : 0/1
						-								500,001 p			50	Acc / Rej : 0/1
					D	IMENSION	/ PHYSICAL II	NSPECTIO	N						SUKPACE N	SRM110)	A (EQUIPMENT	PROPERTIES OF MATERIAL
NO				DIME	ENSION CHE	CK	573	A. 110	West of the	VISUAL		EASY TO	SEAL	PRT/		SAMPLE N	0	CONDUCTIVE
	WIDTH	MAX	MIN	LENGTH	MAX	MIN	THICKNESS	MAX	MIN	OK/NG	REMARKS	OPEN	STRENGTH	GUSSET			SEAL	
PEC	355+/-5	360	350	405+/-10	415	395	0.045+/-0.01	0.055	0.035	OK	OK	OK	OK	G033E1	NO			
1	355	1		410	1		0.047			1	1	- OK	II.		NO 1	RIGHT	LEFT	INSULATOR
2	354			409			0.047		-				-		2	11	10	TEST METHOD
3	355			410			0.048	1		1			1	-	3	10		(ASTM D 257)
4	354			410			0.047								4	11	11	OTHÈR
5	355			409			0.048								5	10	10	Ddu
6	354			410			0.047						1		6	11	11	Remarks :
7	355			409			0.048		1				1		7	11	10	2 side seal-seal width 10mm min
8	354			410			0.047								8	10	11	
9	355			409			0.048								9	11	10	For Incoming visual :
10	354			410	1		0.047						11		10	11	11	
11	355			409			0.048								11	10	10	Bag no torn , damaged - Accept Reject for the bag is broken
12	354			410			0.047							- 1	12	11	11	Reject for the bag is broken
13	355			409			0.048								13	10	10	Equipment for large 4
14	354			410			0.047								14	11	11	Equipment for Inspection : - Dimension - Measuring Tape
15	355			409			0.048	-						1	15	10	11	Thickness - Thickness Checker
16	355	OK		410	ОК		0.047	OK		OK	OK	ОК	ОК		16	11	10	Surface Resistivity - SRM
17	354			409			0.048					1			17	11	11	SUMMARY OF OUTGOING OC
18	355			410			0.047								18	10	10	INSPECTION RESULT:
19	354			409			0.048								19	11	11	Visual : OK MVTR- N/A
20	354	-		410			0.047								20	11	10	Sticky : NO Easy to open: OK
21	355			409			0.047								21	10	11	LPC : OK Mixed: NO
22	354	-		410			0.048								22	11	10	Seal Strength : OK Water Leak Test N/A
	355	-		409			0.047								23	10	11	Printing per spec: N/A
24	354	-		409			0.048								24	11	10	Surface Resistivity: N/A
26	354 355			410			0.047								25	10	11	
27	355			410		-	0.048								26	11	10	PACKING CONDITION INSPECTION
28	354	1		409			0.048								27	10	11	SPEC ACTU
29	355 354	+		410			0.047								28	10	10	Qtty per bag
30	354 355			409			0.048								29	11	11	Otty per carton
31	355			410			0.047								30	10	10	Carton size
32	354			410			0.048								31	10	11	PN vs Actual
U.E.	334			410			0.048				1		1		32	11	11	Label In vs Out N
								_						Prepared B	y:	CIA		Verified By :
		REMARKS:		ACCEPT			REJECT							Final dispo		OK		Final Disposition OK
														Accept / Re		ACCEPT		Accept / Reject: ACCEPT

BAG 2 COC



TIP Corporation Sdn. Bhd.

Lot 608, Jalan Sg Sop, Off Jalan Sg Tekali, Batu 14 Hulu Langat, 43100 Selangor, MY.

Tel: +603-90213985 / 6 / 7 Fax: +603-90213982/4 Email: sales@tipcorp.com

FORM QC-21

	**	LPC Test	Dar	nort	
:	Name of the latest the		VE	JOIL	
	C/R EASY TEAR LD	PE I Lot No	:	61448	
	10.8.2021 SAFESKIN	size	:	355 X 405 X 0.05MM OUTGOING	
	The state of the s	District 2			
Counts/ml	Counts/ml	Counts/ml		Counts/ml	
20.0	19.0	17.0		18.7	
3.0	4.0	2.0		3.0	
2.0	4.0	2.0		2.7	
1.0	2.0	4.0		2.3 Total counts	26.666667
	(Cumulative)				
Vashed Cts 1 Counts/ml	Washed Cts 2 Counts/ml	Washed Cts 3 Counts/ml		Average Washed (B) Counts/ml	
80.0	95.0	100.0		91.7	
13.0	14.0	17.0		14.7	
9.0	8.0	7.0		8.0	
5.0	7.0	9.0		7.0 Total counts	121.33333
Counts		(C)		Total Vol. for Washed Sam	ple (D
Ave.Blank (C =	B-A)			Washed Volume (ml)	400 ml
	73.0				
	11.7				
	5.3				(E
	4.7	-		Total Area for wash	2947 cm
Counts in Wash	ned Volume	(F)		Total Wet Part Cts / cm ²	(G
$(F = C \times D)$					(G=F/E)
				0.5 micron	9.9083814
					1.5835313
2133.3333 1866.6667				1.5 micron 2.0 micron	0.7239 0.6334125
	Blank Cts 1 Counts/ml 20.0 3.0 2.0 1.0 Particle Counts/ Vashed Cts 1 Counts/ml 80.0 13.0 9.0 5.0 Counts Ave.Blank (C =	Counts (Cumulative) Blank Cts 1 Blank Cts 2 Counts/ml Counts/ml 20.0 19.0 3.0 4.0 2.0 4.0 1.0 2.0 Particle Counts (Cumulative) Vashed Cts 1 Washed Cts 2 Counts/ml Counts/ml 80.0 95.0 13.0 14.0 9.0 8.0 5.0 7.0 Counts Ave.Blank (C = B - A) Counts in Washed Volume (F = C x D) 29200 4666.6667 2133.33333	Counts Cumulative	Counts (Cumulative) Blank Cts 1	Counts (Cumulative) 06-HM-041-0-00 Blank Cts 1 Blank Cts 2 Blank Ct 3 Average Blank (A) Counts/ml Counts/ml Counts/ml Counts/ml 20.0 19.0 17.0 18.7 3.0 4.0 2.0 3.0 2.0 4.0 2.0 2.7 1.0 2.0 4.0 2.3 Total counts Particle Counts (Cumulative) Vashed Cts 1 Washed Cts 2 Washed Cts 3 Average Washed (B) Counts/ml Counts/ml Counts/ml Counts/ml Counts/ml 80.0 95.0 100.0 91.7 14.7 9.0 8.0 7.0 8.0 7.0 Total counts Counts (C) Total Vol. for Washed Sam Washed Volume (ml) Total Area of Plastic Total Area for wash Counts in Washed Volume (F) Total Wet Part Cts / cm² (F) Cx D) 0.5 micron 1.0 micron 2133.3333 1.5 micron

1.0 micron

Total Particle: 12.8492252

0.5 micron

SPEC: $\geq 0.5u \leq 100 \text{ COUNTS/CM}^2$

0.7

1.5 micron

Tested By:

MARIAM

6.0 4.0 2.0

0.0

Date:

10.8.2021

Verified By: Date:

0.6

2.0 micron

CASE LINER COC

FORM: QC-07 REV 10

Date Reviewed: 30.11.2017



CORPORATION SDN BHD Reg NO 108991010225

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





CERTIFICATE OF CONFORMANCE

THIS IS TO CERTIFY THAT THE	FOLLOWING PRODUC	T CONFORM/PASS THE	SPECIFICATION LISTED BELOW:-

CUSTOMER

: SAFESKIN

DESCRIPTION

: CLEANROOM LDPE BAG WITH GUSSET 350 X 700 X 0.04mm + G150mm

QUANTITY

: 20,000 PCS

LOT NO

: K61449

PARTNO

: 06-HM-042-0-00

P.O NO. & DATE : 4561163570

TEST DATE

: 06.08.2021

OUR INVOICE NO: TPL16653

PALLET REFERENCE

NUMBER (IF ANY): -

PACKING LIST NUMBER: TPL16653

DATE OF MANUFACTURING: N/A

DATE OF EXPIRED: N/A

64	60	W 0	POTT OF	fland
Shi C	800	日アをなち	表 かた C.	100000000000000000000000000000000000000
1 300	8 8	27 1 4 5	25 4 8 8 7 7	1 0 0 0 1 3 C C C C

D/O No.

TPL 166 53

IQA Batch

£8080/69

11- AUB-2021

Signature By : _

SURFACE RESISTIVITY TEST - (Reference ASTM D257, ANSI / ESD S541 & ANSI / ESD STM 11.11)

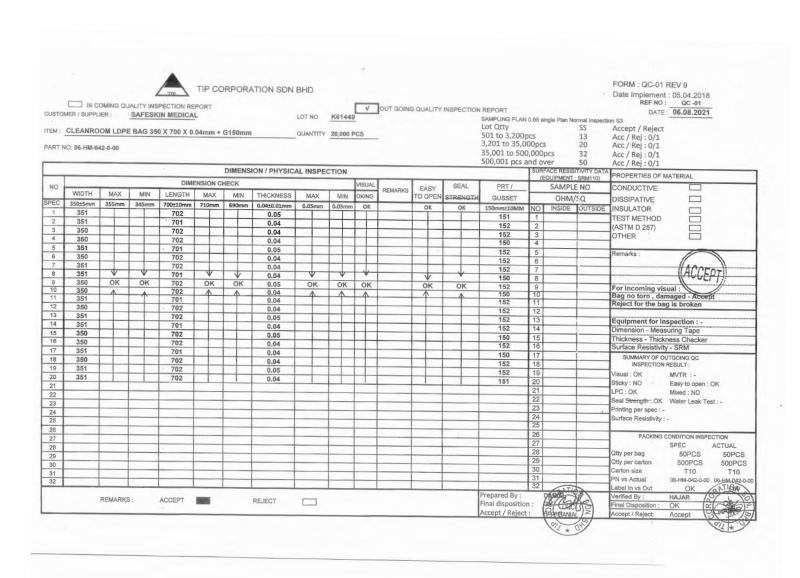
	DISSIPATIVE $:\ge 1 \times 10^5 \text{ AND} \le 1 \times 10^{12} \text{ OHMS/SQ}$
	CONDUCTIVE : < 1 X 10 ⁵ OHMS/SQ
Ø,	VISUAL TEST
Ø	DIMENSION CHECK (WIDTH, LENGTH & THICKNESS)
	WATER LEAK TEST
Z,	LPC TEST
	SEAL/PEEL STRENGTH TEST
	PRINTING
Z	AMIDE & SILICON FREE
	CENTRE SEAL / WITH PERFORATION LINE
	NO CENTRE SEAL / WITHOUT PERFORATION
DANT	TO JOR STANKER
Y: OFF	ONGOC VERIFIED BY CONTROL



TESTED BY: CEPCOING OC

TOP IN PERFORMANCE

CASE LINER COC



CASE LINER COC



P CORPORATION SDN BHD (195701010228

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

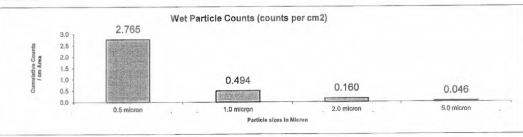
			LPC Test Report		
Item:	C/R LDPE BAG		Lot No:	K61449	
Testing Date:	06.08.2021		Size:	650X700X0.04MM	
Customer:	SAFESKIN		Method:	BY SHAKER	
Blank Particle	Counts (Cumula	tive)	Machine:	KCCS-6	
	Blank Cts 1	Blank Cts 2	Blank Ct 3	Average Blank (A)	
	Counts	Counts	Counts	Counts	
0.5 micron	4.0	. 2.0	0.0	2.0	
1.0 micron	1.0	0.0	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	2.3

Wash Sample Particle Counts (Cumulative)

	Washed Cts 1	Washed Cts 2	Washed Cts 3	Average Washed (B)	
	Counts	Counts	Counts	Counts	
0.5 micron	124.0	134.0	112.0	123.3	
1.0 micron	21.0	26.0	19.0	22.0	
2.0 micron	8.0	5,0	8.0	7.0	
5.0 micron	2.0	2.0	2.0	2.0 Total counts	154.3

(C) Wet Particle Counts		(D) Total Vol. for Washed S	ample
Ave.Washed - Ave.Blank	(C = B - A)	Washed Volume (ml)	1000 ml
0.5 micron	121.3		
1.0 micron	21.7	(E) Sampling size	5 ml
2.0 micron	7.0		
5.0 micron	2.0	(F) Total Area of Plastic	
		Total Washed Area	8775 cm ²

(G) Particle counts per m	1(G = C/E)	(H) Total Wet Part C	$ts/cm^2(H = GXD/F)$
0.5 micron	24.267	0.5 micron	2.765
1.0 micron	4.333	1.0 micron	0.494
2.0 micron	1.400	2.0 micron	0.160
5.0 micron	0,400	5.0 micron	0.046



Cts/cm2

Total Particle (≥0.5):

3.464 (PASSED)

SPEC: ≥ 0.5u ≤

Tested By: SUHAIDA 06.08.2021 Date:

Verified By

Date:

SAFETY DATA SHEET





HALYARD* PUREZERO* HG3 Nitrile Gloves

1. IDENTIFICATION

Product Name: HALYARD* PUREZERO* HG3 Nitrile Gloves

Product Number: Various

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

Product Use: Protective gloves.

2. HAZARDS IDENTIFICATION

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

GHS Labeling: No GHS labeling required.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No./ EINECS-No	%	GHS Classification:
Non-Hazardous Ingredients	Mixture	100	Not Hazardous

4. FIRST AID MEASURES

Inhalation: No first aid needed.

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

the skin.

Eye contact: No first aid needed.

Ingestion: Not a relevant route of exposure.

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

effects.

Indication of any immediate medical attention and special treatment

needed: None required.

SAFETY DATA SHEET



HALYARD* PUREZERO* HG3 Nitrile Gloves

5. FIRE-FIGHTING MEASURES

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

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

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

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

6. ACCIDENTAL RELEASE MEASURES

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

Environmental Precautions: None required.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling: No special handling is required.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)

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

Appropriate Engineering Controls: None required.

Individual Protection Measures, such as Personal Protective Equipment:

Respiratory Protection: None required.

Protective Gloves: None required.

Eye Protection: None required.



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

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.

Chemical Stability: Stable at ambient temperature and pressure.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: Avoid heat and flames.

Incompatible Materials: None known.

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

SAFETY DATA SHEET



HALYARD* PUREZERO* HG3 Nitrile Gloves

11. TOXICOLOGICAL INFORMATION

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

Inhalation: Not applicable.

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

Eye contact: None expected.

Ingestion: Not applicable.

Chronic toxicity: None expected.

Carcinogenicity Data: None of the components of this product is listed as a carcinogen

by IARC, NTP, US OSHA or the EU CLP Annex VI.

Reproductive Toxicity: None known.

Numerical Measures of Toxicity:

Not acutely toxic.

12. ECOLOGICAL INFORMATION

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

Persistence and Degradability: Not degradable.

Bioaccumulative Potential: Not bioaccumulative.

Mobility in Soil: Not mobile.

Other Adverse Effects: None currently known.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

US DOT Shipping Description: Not regulated
IATA Shipping Description (Air): Not regulated
IMDG Shipping Description (Vessel): Not regulated

15. REGULATORY INFORMATION

US Regulations

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





SARA 302 Listed Chemicals: None.

SARA 311/312 Hazard Categories: Not applicable to articles

SARA 313 This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under the SARA Section 313 (40

CFR 372): Not applicable to articles.

16. OTHER INFORMATION

Date Prepared: 6/24/2021

HMIS Rating: Health 0 Fire 1 Physical Hazard 0

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



July 11, 2023

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

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

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

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

Sincerely,

Caitlin Senter

Director

Global Regulatory Affairs

O&M Halyard, Inc.

^{*}Registered Trademark or Trademark of O&M Halyard or its affiliates. ©2023. All rights reserved. COPY-04686







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 Effective Date: 2021-08-12 Latest Revision Date: 2021-07-16 Expiry Date: 2024-08-11

Page: 1 of 2





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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 Effective Date: 2021-08-12 Latest Revision Date: 2021-07-16 Expiry Date: 2024-08-11

Page: 2 of 2

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

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.

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.

bsi.



Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number:

MD 735497

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

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-11-25

Latest Revision Date: 2023-01-05

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

Page: 1 of 2

bsi.



...making excellence a habit∑

ISO 13485:2016 (continued)

Certificate No: MD 735497 Location Registered Activities O & M Halyard, Inc. Headquarter management activities. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA O & M Halyard, Inc. The design and development of sterile and non-sterile medical examination gloves. 1 Edison Drive Alpharetta Georgia 30005 USA Design, development, manufacture and distribution of sterile Safeskin Medical & Scientific and non-sterile medical examination gloves. (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand

Original Registration Date: 2020-11-25 Effective Date: 2023-01-09 Latest Revision Date: 2023-01-05 Expiry Date: 2026-01-08

Page: 2 of 2

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







Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that: Safeskin Medical & Scientific

(Thailand) Ltd.

200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao,

Sonakhla 90120 Thailand

Holds Certificate Number: EMS 772160

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

The Manufacturing of Medical and Scientific Gloves.

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2022-10-27 Effective Date: 2022-10-27 Latest Revision Date: 2022-10-27 Expiry Date: 2025-10-26

Page: 1 of 1





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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 14001:2015 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.



May 4, 2023

RE: HALYARD* PUREZERO* HG3 and HG5 Nitrile Gloves

Dear Valued Customer,

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

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

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

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

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

Sincerely,

Shannon Smith

Shannon SmithAssociate Product Manager
O&M Halyard, Inc.

COPY-04632

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

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HG3 Nitrile Cleanroom Gloves

ADDED PROTECTION FROM THE RISK OF CHEMICAL EXPOSURE

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

CHEMOTHERAPY DRUG RESISTANCE GUIDE⁴

Chemotherapy Agent (Concentration in mg/ml)	HALYARD* PURE ZERO* HG3 White Nitrile Gloves	
	Minimum Breakthrough Detection Time (minutes)	Average Steady State Perm. Rate (µg/cm²/min)
Carmustine (BCNU) (3.3)	55.4	0.50
Cisplatin (1.0)	>240	N/A
Cyclophasphamide (20.0)	>240	N/A
Dacarbazine (10.0)	>240	N/A
Doxorubicin HCL (2.0)	>240	N/A
Etoposide (20.0)	>240	N/A
Fluorouracil (50.0)	>240	N/A
Ifosfamide (50.0)	>240	N/A
Methotrexate (25.0)	>240	N/A
Mitomycin C (0.5)	>240	N/A
Mitoxantrone (2.0)	>240	N/A
Paclitaxel (6.0)	>240	N/A
Thiotepa (10.0)	48.8	0.23
Vincristine (1.0)	>240	N/A
Additional Tests		
Fentanyl Citrate Injection, 100 mcg/2mL	>240	N/A

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

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

CAUTION:

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

DEFINITION OF TERMS

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

Meets USP <800> Guidelines,

against Fentanyl

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

Permeation rate: The flowrate of the chemical after the chemical breaks through the inside of the glove. It is measured in amount per surface area of the glove per time (µg/cm²/min).

PUREZERO*

HG3 Nitrile Cleanroom Gloves CHEMICAL RESISTANCE GUIDE⁵

	HALYARD* PURE ZERO HG3 White Nitrile Gloves	
Chemical (Concentration %)	Minimum Breakthrough Detection Time (minutes)	Average Steady State Perm. Rate (µg/cm²/min)
1-Butanol (99)	173.0	1.5
Acetic Acid (30)	388.9	4.5
Acrylamide (40)	>480	<1.0
Benzalkonium Chloride (1)	>480	<1.0
Chloroform (70)	0	-
Citric Acid (30)	>480	N/A
Citric Acid (70)	>480	<1.0
Cyclohexane (99)	261.6	1.7
Didecyldimethylammonium Chloride (0.04)	>480	<1.0
Dimethylformamide (99)	0	N/A
Dimethyl Sulfoxide (99)	10.1	3.6E+01
Ethanol (70)	42.2	12.5
Ethanol (99)	14.5	9.4E+01
Ethidium Bromide (1)	>480	<1.0
Glycolic Acid (10)	>480	<1.0
Glutaraldehyde (50)	>480	<1.0
Hydrazine Monohydrate (55)	>480	0.1
Hydrochloric Acid (30)	>480	<1.0
Isopropyl Alcohol (70)	125.7	1.7
Isopropyl Alcohol (99)	102.2	4.3
Methanol (99)	4.2	4.5E+01
Nitric Acid (65)	16.0	2.0E+02
Peracetic Acid (5)	>480	<1.0
Phosphoric Acid (70)	>480	<1.0
Sodium Hydroxide (50)	>480	<1.0
Sodium Hypochlorite (10-13)	>480	<1.0
Spor-Klenz (N/A)	>480	<1.0
Sulfuric Acid (50)	>480	<1.0
Sulfuric Acid (99)	12.0	N/A

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

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

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



November 13th, 2023

RE: ESD Testing for HALYARD* PUREZERO* Nitrile Gloves

Dear Valued Customer,

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

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

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

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



HALYARD* PURE ZERO* HG3 Blue Sterile Nitrile Gloves	CLN923260
HALYARD* PURE ZERO* HG3 Blue Sterile Nitrile Gloves	CLN923265
HALYARD* PURE ZERO* HG3 Blue Sterile Nitrile Gloves	CLN923270
HALYARD* PURE ZERO* HG3 Blue Sterile Nitrile Gloves	CLN923275
HALYARD* PURE ZERO* HG3 Blue Sterile Nitrile Gloves	CLN923280
HALYARD* PURE ZERO* HG3 Blue Sterile Nitrile Gloves	CLN923285
HALYARD* PURE ZERO* HG3 Blue Sterile Nitrile Gloves	CLN923290
HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves	CLN923210

HALYARD* PUREZERO* **HG5 Cleanroom Nitrile Gloves**

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

HALYARD* PUREZERO* Nitrile Exam Gloves

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



HALYARD* PURE ZERO* LIMON* Nitrile Exam Gloves	LFS311LG
HALYARD* PUREZERO* LIMON* Nitrile Exam Gloves	LFS311XL
HALYARD* PURE ZERO* LIMON-XTRA* Nitrile Exam Gloves	LFS321XS
HALYARD* PURE ZERO* LIMON-XTRA* Nitrile Exam Gloves	LFS321SM
HALYARD* PURE ZERO* LIMON-XTRA* Nitrile Exam Gloves	LFS321MD
HALYARD* PURE ZERO* LIMON-XTRA* Nitrile Exam Gloves	LFS321LG
HALYARD* PURE ZERO* LIMON-XTRA* Nitrile Exam Gloves	LFS321XL
HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves	LFS511XS
HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves	LFS511SM
HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves	LFS511MD
HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves	LFS511LG
HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves	LFS511XL

HALYARD* PUREZERO* Nitrile Gloves

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

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

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



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

Sincerely,

Caitlin Senter

Director

Global Regulatory Affairs

O&M Halyard, Inc.

Ryan Solan

Manager

Global Research and Development

O&M Halyard, Inc.

Ryan Solan

COPY-04825

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RE: Compliance statement – HALYARD* **PURE**ZERO* Nitrile Gloves

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

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

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

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

-This statement is valid unsigned -

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March 14th, 2023

RE: HALYARD* PUREZERO* Nitrile Gloves

Dear Valued Customer,

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

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

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

Sincerely,

Ryan Solan

Ryan Solan

R&D Senior Engineer Global Research and Development O&M Halyard, Inc. Theresa McCoy

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

Theresa McCoy

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September 24, 2023

RE: HALYARD* PUREZERO* HG3 and HG5 Nitrile Gloves

Dear Valued Customer,

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

According to ASTM E1252 Standard Practice for General Techniques for Obtaining Spectra for Qualitative Analysis, the results below reflect the detectable limits of silicone covering the spectral range from 4000cm⁻¹ to 50cm⁻¹- via FT-IR (Fourier Transform Infrared Anaysis). The results below indicate that the HALYARD* **PURE**ZERO* HG3 NITRILE GLOVES and HALYARD* **PURE**ZERO* HG5 NITRILE GLOVES have no silicone

detectable on the outside surface and inside surface of either gloves sampled per 3rd party testing.

The following product codes are applicable: **PURE**ZERO* HG3 White Nitrile Gloves: CLN92512XS, CLN92512SM, CLN92512MD, CLN92512LG, CLN92512XL; **PURE**ZERO* HG3 Light Blue Nitrile Gloves: CLN90511XS, CLN90511SM, CLN90511MD, CLN90511LG, CLN90511XL; **PURE**ZERO* HG3 White SGX* Nitrile Gloves: CLN3031XS, CLN3031SM, CLN3031MD, CLN3031LG, CLN3031XL; PUREZERO* HG3 Sterile White Nitrile Gloves: CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323290, CLN323210; **PURE**ZERO* HG3 Sterile Light Blue Nitrile Gloves: CLN923260, CLN923265, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210; HALYARD* **PURE**ZERO* HG5 White Nitrile Gloves: CLN30512XS, CLN30512SM, CLN30512MD, CLN30512LG, and CLN30512XL; HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves: CLN92512XS, CLN92512XS, CLN92512SM, CLN92512MD, CLN92512LG, and CLN92512LLG, and CLN92512XL.

Fourier Transform Infrared Anaysis (FT-IR) Per ASTM E1252-98(21)		
Gloves	Results	
PUREZERO* HG3 and HG5		
Nitrile Gloves	No silicon detected	

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

Sincerely

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Caitlin Senter

Director

Global Regulatory Affairs

O&M Halyard, Inc.

Nimia Maya

R&D Engineer II

Mining Mayor

Global Research and Development

O&M Halyard, Inc.

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October 2023

Owens & Minor

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

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

WHAT YOU NEED TO KNOW:

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

WHAT YOU CAN EXPECT:

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

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



PRODUCTS IMPACTED BY THIS CHANGE:

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

1 Edison Drive, Alpharetta, GA 30005 | 844.425.9273 owens-minor.com | halyardhealth.com | byramhealthcare.com



PUREZERO* HG5 White Nitrile Gloves
CODE
CLN30512XS
CLN30512SM
CLN30512MD
CLN30512LG
CLN30512XL
PUREZERO* HG5 Blue SGX* Nitrile Gloves
CODE
CLN92512XS
CLN92512SM
CLN92512MD
CLN92512LG
CLN92512XL

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

Sincerely,

Gustavo Fiallos

Director Global Quality Operations, Owens & Minor

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