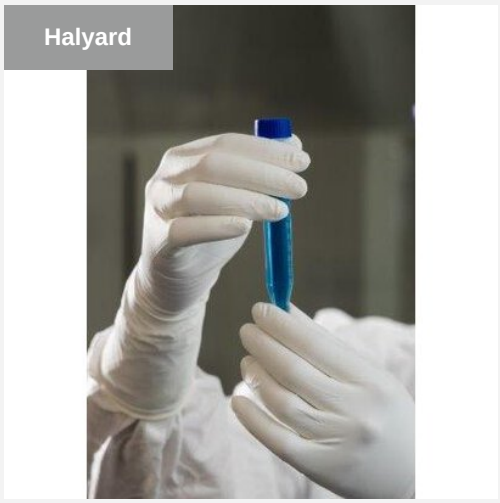


Empfohlene Reinraumklassen

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

GMP C | D

Nitril-Handschuhe PUREZERO HG3 SGX (white) #CLN3231SM

pure[11]-Nr.: 1105044, Marke: Halyard

Eigenschaften

- Marke: Halyard
- Handschuhtyp: Dünnfilm
- Länge in cm: 30,5 cm
- Chemikalienbeständigkeit - Typ: Typ C
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Lebensmittelkonformität
- Silikonfrei
- Vulkanisationsbeschleunigerfrei
- Verpackungsform: Beutel
- Antistatisch
- AQL (Acceptable Quality Level)-Wert: 0,65
- Chemikalienbeständig gegen Isopropanol (70%): Level 0 (<10min)
- Länge in Inches: 12 In
- Latexfrei
- Materialzusammensetzung: Reinmaterial
- Oberflächenbeschaffenheit: glatt
- Reißfestigkeit EN 455-2 ASTM in MPa: 20-30

pure[11] GmbH
Bavariafilmplatz 7 | D-82031 Grünwald
Geschäftsführung: Julian Kropp, Linda Vereycken, Lars Engeler
AG München HRB 171307

T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

- Schutz vor Blut und Körpersekreten 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

pure[11]-Nr.: 1105044WHS, Nitril-Handschuhe PUREZERO HG3 SGX (white) #CLN3231SM

Farbe: Weiß; Größe: S / VE: 1000STK

pure[11]-Nr.: 1105044WHL, Nitril-Handschuhe PUREZERO HG3 SGX (white) #CLN3231LG

Farbe: Weiß; Größe: L / VE: 1000STK

pure[11]-Nr.: 1105044WHM, Nitril-Handschuhe PUREZERO HG3 SGX (white) #CLN3231MD

Farbe: Weiß; Größe: M / VE: 1000STK

pure[11]-Nr.: 1105044WHXL, Nitril-Handschuhe PUREZERO HG3 SGX (white) #CLN3231XL

Farbe: Weiß; Größe: XL / VE: 1000STK

pure[11]-Nr.: 1105044WHXS, Nitril-Handschuhe PUREZERO HG3 SGX (white) #CLN3231XS

July 14th, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding EN 1149 testing on **HALYARD* PUREZERO* HG3 Nitrile Gloves.**

The data provided on the following pages reflect the test results of **HALYARD* PUREZERO* HG3 Nitrile Gloves** for electrostatic properties in accordance with **EN 1149-1:2006** *"Protective Clothing - Electrostatic Properties - Part 1: Test Method for Measurement of Surface Resistivity"* and **EN 1149-3:2004 (Method 2)** *"Protective Clothing - Electrostatic Properties - Part 3: Test Method for Measurement of Charge Decay".*

The tests were performed at Intertek Testing Services in the UK with a report issuance of 05.07.2021.

Description of the Tested Gloves:
SAMPLE A - HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves

SAMPLE B - HALYARD* PUREZERO* HG3 White Nitrile Gloves

SAMPLE C - HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves

SAMPLE D - HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

SAMPLE E - HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves

SAMPLE A - HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample A

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	1.1×10^{12}	2.2×10^{13}
Face	1.7×10^{12}	3.4×10^{13}
Face	1.9×10^{12}	3.8×10^{13}
Face	1.0×10^{12}	2.0×10^{13}
Face	1.4×10^{12}	2.8×10^{13}
Mean	1.4×10^{12}	2.7×10^{13}
Reverse	1.3×10^{12}	2.6×10^{13}
Reverse	1.9×10^{12}	3.8×10^{13}
Reverse	2.4×10^{12}	4.8×10^{13}
Reverse	2.1×10^{12}	4.2×10^{13}
Reverse	1.8×10^{12}	3.6×10^{13}
Mean	1.9×10^{12}	3.7×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	21.50
2	0.00	20.15
3	0.00	>30.00
Mean	0.00	≥23.88

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE B - HALYARD* PUREZERO* HG3 White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample B

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	5.3×10^{11}	1.0×10^{13}
Face	5.1×10^{11}	1.0×10^{13}
Face	5.9×10^{11}	1.2×10^{13}
Face	5.9×10^{11}	1.2×10^{13}
Face	6.4×10^{11}	1.3×10^{13}
Mean	5.7×10^{11}	1.1×10^{13}
Reverse	7.6×10^{11}	1.5×10^{13}
Reverse	7.4×10^{11}	1.5×10^{13}
Reverse	6.8×10^{11}	1.3×10^{13}
Reverse	6.4×10^{11}	1.3×10^{13}
Reverse	6.6×10^{11}	1.3×10^{13}
Mean	6.9×10^{11}	1.4×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.01	12.50
2	0.01	6.96
3	0.00	8.86
Mean	0.01	9.42

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE C - HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample C

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	2.4×10^{12}	4.8×10^{13}
Face	2.1×10^{12}	4.2×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	2.6×10^{12}	5.1×10^{13}
Face	2.5×10^{12}	5.0×10^{13}
Mean	2.3×10^{12}	4.5×10^{13}
Reverse	1.7×10^{12}	3.4×10^{13}
Reverse	2.1×10^{12}	4.2×10^{13}
Reverse	2.8×10^{12}	5.5×10^{13}
Reverse	2.0×10^{12}	4.0×10^{13}
Reverse	2.4×10^{12}	4.8×10^{13}
Mean	2.2×10^{12}	4.3×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	>30.00
2	0.00	>30.00
3	0.00	>30.00
Mean	0.00	>30.00

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE D - HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample D

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	1.2×10^{12}	2.4×10^{13}
Face	1.4×10^{12}	2.8×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	1.1×10^{12}	2.2×10^{13}
Mean	1.4×10^{12}	2.8×10^{13}
Reverse	1.0×10^{12}	2.0×10^{13}
Reverse	1.6×10^{12}	3.2×10^{13}
Reverse	1.1×10^{12}	2.2×10^{13}
Reverse	1.5×10^{12}	3.0×10^{13}
Reverse	1.9×10^{12}	3.8×10^{13}
Mean	1.4×10^{12}	2.7×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	9.37
2	0.00	7.85
3	0.00	13.05
Mean	0.00	10.09

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE E - HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample E

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	5.6×10^{11}	1.1×10^{13}
Face	5.0×10^{11}	9.9×10^{12}
Face	5.5×10^{11}	1.1×10^{13}
Face	5.3×10^{11}	1.0×10^{13}
Face	5.1×10^{11}	1.0×10^{13}
Mean	5.3×10^{11}	1.0×10^{13}
Reverse	7.0×10^{11}	1.4×10^{13}
Reverse	6.8×10^{11}	1.3×10^{13}
Reverse	6.7×10^{11}	1.3×10^{13}
Reverse	6.4×10^{11}	1.3×10^{13}
Reverse	7.2×10^{11}	1.4×10^{13}
Mean	6.8×10^{11}	1.3×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.02	6.09
2	0.01	5.57
3	0.00	7.74
Mean	0.00	6.47

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

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,

Steven Dowdley
Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

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

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number: CE 725275

In respect of:

Nitrile Protective Gloves for Personal Protection.
Model CLN3231LG powder free gloves.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

First Issued: 2020-11-17
Latest Issue: 2020-11-17

Effective Date: 2020-11-17
Expiry Date: 2025-11-17

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 725275

Product Specification

Range:	Halyard Purezero HG3 Smooth White Nitrile Gloves Non-Sterile Ambi (SLICK)
Models:	CLN3231XS CLN3231SM CLN3231MD CLN3231LG CLN3231XL
Classification:	Protective gloves for use against chemical and micro-organism hazards.
Description:	A five fingered, ambidextrous, single use powder free, non-sterile, Nitrile with textured finger surface with smooth grip. Gloves are 310mm in length available coloured White.
PPE Category:	Complex
Product sizes:	XS, S, M, L, XL
Applicable Standards:	The following Harmonized European Standards: EN 420:2003+A1:2009 Protective gloves. General requirements. EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks. EN 374-2:2019. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration. EN 374-4:2019 Determination of resistance to degradation by chemicals. EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks. EN 16523-1:2015. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact. ISO 16604:2004 Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by blood-borne pathogens.

First Issued: 2020-11-17
Latest Issue: 2020-11-17

Effective Date: 2020-11-17
Expiry Date: 2025-11-17

EU Type Examination Certificate

No. CE 725275

Product Specification

Performance

General requirements for gloves to EN 420:2003+A1:2009

Characteristic	Level
Dexterity	5

Terminology and performance requirements for micro-organism Risks EN ISO 374-5:2016

Characteristic	Level
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Resistance to chemical permeation to EN ISO 374-1:2016

Tested to the chemicals below to EN 16523-1:2015

Resistance to Degradation to chemical protection EN 374-4:2019

Tested to the chemicals below

Chemical	Permeation Level	Mean Degradation %
70% Isopropyl Alcohol	-	70.5
40% Sodium Hydroxide (K)	6	-29.3
50% Sulphuric Acid	6	-37.9
30% Hydrochloric Acid	6	9.1
1% Ethidium Bromide	6	-9.8

First Issued: 2020-11-17
Latest Issue: 2020-11-17

Effective Date: 2020-11-17
Expiry Date: 2025-11-17

EU Type Examination Certificate

No. CE 725275

Certificate Administration Details

Technical File Reference: No. 012-02 R01 Halyard Non-Sterile Cleanroom Gloves Rev02.

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
November 2020	First issue models: CLN3231XS, CLN3231SM, CLN3231MD CLN3231LG, CLN3231XL.	2797:20:3154554

Note: The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE:

The validity of the Certificate is also dependent on the maintenance of the EC quality of production by monitoring system, Module C2, as referenced on BSI Certificate CE 708082.

First Issued: 2020-11-17
Latest Issue: 2020-11-17

Effective Date: 2020-11-17
Expiry Date: 2025-11-17

HALYARD*

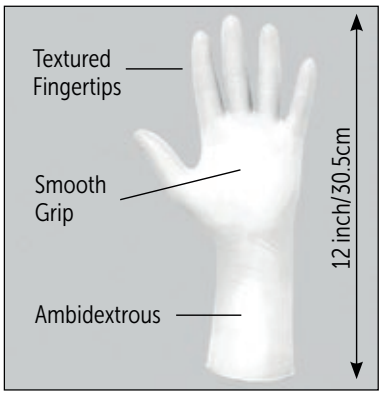
HALYARD* **PURE**ZERO* HG3 White SGX* Nitrile Cleanroom Gloves

For the Cleanroom Environment
For Industrial Use Only

TECHNICAL DATA SHEET

Description

HALYARD* **PURE**ZERO* HG3 White SGX* Nitrile Cleanroom Gloves with SMOOTH GRIP TECHNOLOGY* (SGX) 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* HG3 White SGX* Nitrile Cleanroom 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

Max Particle Count (>0.5 µm)	<950 Particles/cm^2	IEST RP-CC005
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	7	
Ammonium	5	

Physical Properties

AQL	0.65
Non-Sterile	✓
Ambidextrous	✓
Smooth 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 (6.3 mil)	0.16 mm (6.3 mil)	0.16 mm (6.3 mil)	0.16 mm (6.3 mil)	0.16 mm (6.3 mil)
Palm Thickness	0.13 mm (5.1 mil)	0.13 mm (5.1 mil)	0.13 mm (5.1 mil)	0.13 mm (5.1 mil)	0.13 mm (5.1 mil)
Cuff Thickness	0.10 mm (3.9 mil)	0.10 mm (3.9 mil)	0.10 mm (3.9 mil)	0.10 mm (3.9 mil)	0.10 mm (3.9 mil)

HALYARD*

HALYARD* PUREZERO* HG3 White SGX* Nitrile Cleanroom 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

CE 2797 (PPE Cat. III)

ISO 374-5:2016 VIRUS

ISO 374-1 / Type B KTJ

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 SGX* NITRILE CLEANROOM GLOVES, NON-STERILE, AMBIDEXTROUS, SMOOTH**

Size	Code
XS	CLN3231XS
SM	CLN3231SM
MD	CLN3231MD
LG	CLN3231LG
XL	CLN32311XL

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 per ASTM D412
This fact sheet has been created using the most recent information. In the interest of continuous improvement, the characteristics of the products may change without prior notice.

008639 COPY-04713 September 2023

Owens & Minor

HALYARD* is an Owens & Minor brand