

MANAGE YOUR CLEANROOM RISKS WITH HALYARD* PUREZERO*



Cleanroom Nitrile Gloves

Because you're responsible for managing risks in your cleanroom operation, choosing the right cleanroom glove is critical.

Your gloves play an important role: protecting your workers as well as your products and processes. Plus you need a reliable supply to avoid operations disruption. That's why we created HALYARD* **PURE**ZERO* Cleanroom Gloves.

PUREZERO* Cleanroom Gloves are ideal for applications that involve handling delicate equipment in microelectronics, semiconductors, optics, pharmaceutical and medical device manufacturing applications. In fact, they are specifically designed to meet the stringent requirements of contamination controlled environments.

As the name implies, **PURE**ZERO* gloves are designed to meet standards, to help you:

- manage user comfort and protection
- manage product contamination
- manage supply chain



Cleanroom Nitrile Gloves

USER COMFORT AND PROTECTION

The accelerator-free¹ formulation of PUREZERO* Nitrile Cleanroom Gloves is the solution. It reduces the risk of allergies and skin irritation associated with accelerator chemicals in other nitrile gloves. As a result, PUREZERO* gloves are comfortable to wear, allowing workers to focus on their delicate tasks rather than their gloves.

PUREZERO* Cleanroom Nitrile Gloves are designed to protect workers with effective barrier protection against chemical splash, micro-organisms and contaminations.

Our Cleanroom Gloves are certified as PPE category III per the Regulation (EU) 2016/425 EEC. The applicable standards are:

- EN ISO 374-1: 2016 Type C K dangerous chemicals and micro-organisms (Permeation time)
- EN ISO 374-2: 2019 Dangerous chemicals and microorganisms (Determining resistance to penetration holes/defects)
- EN ISO 374-4: 2019 Resistance to Degradation by Chemicals
- EN ISO 374-5:2016 Micro-organism and Virus Protection
- EN 420:2003 +A1:2009 General Requirements for Protective Gloves
- EN 16523-1:2015+A1:2018 Permeation of chemicals (+IPA 70%)
- ISO 16604:2004 contact with blood and body fluids
- ASTM D6978 Permeation testing on chemotherapy drugs (14 drugs)

PRODUCT CONTAMINATION

A consistent quality of PUREZERO* Cleanroom Gloves ensures low particle and endotoxin levels. HALYARD* PUREZERO* Gloves are manufactured and packaged at our ISO 9001 and ISO 13485 certified facility in state-of-the-art cleanrooms and are recommended for ISO Class 4/5/6/7 and Grade A/B/C/D + aseptic cleanrooms or cleanzones. Our gloves are clean processed (washed repeatedly in deionized water) to ensure consistent control of low particles, extractables and endotoxin levels.

- Low Particle Levels max $950 \ge 0.5 \mu m/cm^2$ for white gloves, max $1200 \ge 0.5 \mu m/cm^2$ for blue gloves
- \bullet Sterility Assurance Levels (SAL) of $10^{\text{-}6}$ and an endotoxin level of 20 units/pair maximum
- AQL of 1 for pinholes
- Triple layer packaging (poly pouch and poly bag plus case liner).
- HALYARD* **PURE**ZERO* HG3 light blue sterile nitrile gloves: 300 hand specific pairs per case: two gloves/ poly wallet & pouch X30 sealed pouches per PE bag x 10 PE bags per lined carton.
- HALYARD** **PURE**ZERO* HG3 white sterile nitrile gloves: 200 hand specific pairs per case: 2 gloves/poly wallet & pouch x20 sealed pouches per bag x10 PE bags per lined carton



You can rely on consistent quality, with Certificates of Analysis (CoA), and Certificates of Irradiation (CoI) easily accessible online for every production lot. You can also find the Declaration of Conformity (DoC) documents showing compliance to applicable regulations and standards, all at www.halyardhealth.com/information.

Cleanroom Nitrile Gloves

RELIABLE SUPPLY CHAIN THROUGH VERTICAL INTEGRATION

PUREZERO* Cleanroom Gloves ensure reliable supply, regulatory compliance and consistent quality.

HALYARD* has manufactured leading private label cleanroom gloves for more than 20 years at our Safeskin Medical & Scientific (Thailand) Ltd. manufacturing facility, which holds ISO 9001 and ISO 13485 certifications.

We control the materials and design while adhering to strict quality standards and product specifications in our own facilities, with our own teammates. Quality and sterility assurance levels are guaranteed, with all raw materials and components traceable to their original supplier. And with our global product codes, you can use one code/SKU from HALYARD* globally at all of your production facilities.



From raw materials to distribution, we have full control over our global supply chain.

RISK-FREE CONVERSION

With our years of glove experience, HALYARD* can provide all the support you need to easily convert from your current glove to **PURE**ZERO* Cleanroom Gloves, including:

- Technical documentation
- Validation data
- Product knowledge and expertise

To trial HALYARD* **PURE**ZERO* Cleanroom Gloves, contact your Cleanroom distributor today, or email us at info@hyh.com.



Cleanroom Nitrile Gloves

HALYARD* offers an accelerator-free¹ portfolio of three non-sterile and two sterile cleanroom gloves to address the needs of pharmaceutical, medical device, microelectronics and semi conductor manufacturing industries.

NON-STERILE

HALYARD* PUREZERO* HG3 WHITE NITRILE GLOVES





Physical Properties

AQL	1
Non-Sterile	✓
Ambidextrous	✓
Tacky Outer Glove Finish	✓
Textured Fingertips	✓
Accelerator-Free	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Tensile Strength ²	20 MPa (Target)
Ultimate Elongation ²	600%
Shelf Life	5 Years

Cleanliness Properties

Max Particle Count	≥0.5µm / cm² <950	IEST RP-CC005
Ionic Content (Extractable ions)	Max Level (μg/g)	IEST RP-CC005
Calcium	50	
Chloride	35	
Magnesium	5	
Nitrate	20	
Potassium	5	
Sodium	10	
Sulfate	10	
Zinc	25	
Ammonium	5	

For use in ISO 4/5/6/7/8, GMP Grade A/B/C/D TACKY FINISH

Ordering Information

Size	Code
XS	CLN3031XS
SM	CLN3031SM
MD	CLN3031MD
LG	CLN3031LG
XL	CLN3031XL
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HALYARD* PUREZERO* HG3 LIGHT BLUE NITRILE GLOVES

Recommended for use in ISO 4/5/6/7/8 and GMP Grade B/C/D cleanrooms or cleanzones. **PURE**ZERO* HG3 Light Blue Nitrile Cleanroom Gloves are non-sterile, ambidextrous, and 12 inches (305mm) long with a high tack/grip surface and feature a beaded cuff to aid in donning and help prevent roll down.



Physical Properties

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AQL	1
Non-Sterile	✓
Ambidextrous	✓
Tacky Outer Glove Finish	✓
Textured Fingertips	✓
Accelerator-Free	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Tensile Strength ²	20 MPa (Target)
Ultimate Elongation ²	600%
Shelf Life	5 Years

Cleanliness Properties

Max Particle Count	≥0.5µm / cm² <1200	IEST RP-CC005
Ionic Content (Extractable ions)	Max Level (μg/g)	IEST RP-CC005
Calcium	50	
Chloride	35	
Magnesium	5	
Nitrate	20	
Potassium	5	
Sodium	10	
Sulfate	10	
Zinc	25	
Ammonium	5	

For use in ISO 4/5/6/7/8, GMP Grade A/B/C/D TACKY FINISH

Ordering Information

Size	Code
XS	CLN9031XS
SM	CLN9031SM
MD	CLN9031MD
LG	CLN9031LG
XL	CLN9031XL

Cleanroom Nitrile Gloves

NON-STERILE (Continued)

HALYARD* PUREZERO* HG3 SMOOTH WHITE NITRILE GLOVES

Recommended for use in ISO Class 4/5/6/7/8 and GMP Grade B/C/D cleanrooms or cleanzones. **PURE**ZERO* HG3 SMOOTH White Nitrile Cleanroom Gloves are non-sterile, ambidextrous, and 12 inches (305mm) long with a smooth finish and feature a beaded cuff to aid in donning and help prevent roll down.



Physical Properties

AQL	1
Non-Sterile	✓
Ambidextrous	✓
Smooth Outer Glove Finish	✓
Textured Fingertips	✓
Accelerator-Free	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Tensile Strength ²	20 MPa (Target)
Ultimate Elongation ²	600%
Shelf Life	5 Years

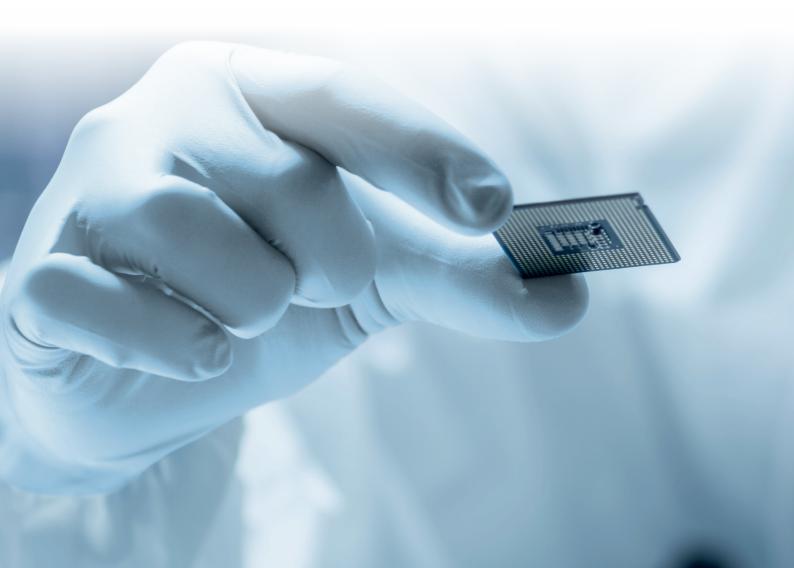
Cleanliness Properties

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Max Particle Count	$\geq 0.5 \mu \text{m} / \text{cm}^2 < 950$	IEST RP-CC005
Ionic Content (Extractable ions)	Max Level (μg/g)	IEST RP-CC005
Calcium	50	
Chloride	35	
Magnesium	5	
Nitrate	20	
Potassium	5	
Sodium	10	
Sulfate	10	
Zinc	25	
Ammonium	5	

For use in ISO Class 4/5/6/7/8, GMP Grade A/B/C/D SMOOTH FINISH

Ordering Information

Size	Code
XS	CLN3231XS
SM	CLN3231SM
MD	CLN3231MD
LG	CLN3231LG
XL	CLN3231XL



Cleanroom Nitrile Gloves

STERILE

HALYARD* PUREZERO* HG3 LIGHT BLUE STERILE NITRILE GLOVES

Recommended for use in ISO Class 4/5 and GMP Grade A/B + aseptic. **PURE**ZERO* HG3 Light Blue Sterile Nitrile Cleanroom Gloves have a hand specific shape, 4-mil fingertip thickness, 12 inches (305mm) long with a smooth finish, and a beaded cuff to aid in donning and help prevent roll down.



Physical Properties

AQL	1
Sterile	✓
Hand Specific Pairs	✓
Smooth Outer Glove Finish	✓
Textured Fingertips and palms	1
Accelerator-Free	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Tensile Strength ²	20 MPa (Target)
Ultimate Elongation ²	600%
Sterility Assurance Level (SAL)	10-6
Shelf Life	5 Years

Cleanliness Properties

Max Particle Count	≥0.5µm / cm² <1200	IEST RP-CC005
Max Endotoxin Level	<20 EU	
Ionic Content (Extractable ions)	Max Level (µg/g)	IEST RP-CC005
Calcium	50	
Chloride	35	
Magnesium	5	
Nitrate	20	
Potassium	5	
Sodium	10	
Sulfate	10	
Zinc	25	
Ammonium	5	

For use in ISO Class 4/5, GMP Grade A/B + aseptic SMOOTH FINISH SAL 10⁻⁶

Ordering Information

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

HALYARD* PUREZERO* HG3 WHITE STERILE NITRILE GLOVES

Recommended for use in ISO Class 4/5 and GMP Grade A/B + aseptic. **PURE**ZERO* HG3 White Sterile Nitrile Cleanroom Gloves have a hand specific shape, 6-mil fingertip thickness, 12 inches (305mm) long with a smooth finish, and beaded cuff to aid in donning and help prevent roll down.



Physical Properties

AQL	1
Sterile	✓
Hand Specific Pairs	✓
Smooth Outer Glove Finish	✓
Textured Fingertips and palms	✓
Accelerator-Free	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Tensile Strength ²	20 MPa (Target)
Ultimate Elongation ²	600%
Sterility Assurance Level (SAL)	10-6
Shelf Life	5 Years

Cleanliness Properties

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Max Particle Count	≥0.5µm / cm² <950	IEST RP-CC005
Max Endotoxin Level	<20 EU	
Ionic Content (Extractable ions)	Max Level (μg/g)	IEST RP-CC005
Calcium	50	
Chloride	35	
Magnesium	5	
Nitrate	20	
Potassium	5	
Sodium	10	
Sulfate	10	
Zinc	25	
Ammonium	5	

For use in ISO Class 4/5, GMP Grade A/B + aseptic SMOOTH FINISH SAL 10⁻⁶

Ordering Information

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

PRODUCT SELECTION GUIDE

	Description	Designed for	Max Particle Count	ISO Class	Finish	Double Donning	Size Range	Fingertip Thickness	Case Count
NON-STERILE	HALYARD* PURE ZERO* HG3 White Nitrile Gloves	semiconductor pharmaceutical medical device manufacturing	<950	ISO Class 4/5/6/7/8, GMP Grade B/C/D cleanrooms or cleanzones	Tacky	Recommended for outer glove	XS-XL	.16mm (6 mil)	1000/cs
	HALYARD* PURE ZERO* HG3 Light Blue Nitrile Gloves	semiconductor pharmaceutical medical device manufacturing	<1200	ISO Class 4/5/6/7/8, GMP Grade B/C/D cleanrooms or cleanzones	Tacky	Recommended for outer glove	XS-XL	.10mm (4 mil)	1500/cs
	HALYARD* PURE ZERO* HG3 SMOOTH White Nitrile Gloves	semiconductor pharmaceutical medical device manufacturing	<950	ISO Class 4/5/6/7/8, GMP Grade B/C/D cleanrooms or cleanzones	Smooth (SGX)	outer or under	XS-XL	.16mm (6 mil)	1000/cs
STERILE	HALYARD* PURE ZERO* HG3 Light Blue Sterile Nitrile Gloves	pharmaceutical biotechnology sterile compounding aseptic processing	<1200	ISO Class 4/5, GMP Grade A/B + aseptic cleanrooms	Smooth	outer or under	6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0	.10mm (4 mil)	300 pairs/cs
	HALYARD* PURE ZERO* HG3 White Sterile Nitrile Gloves	pharmaceutical biotechnology sterile compounding aseptic processing	<950	ISO Class 4/5, GMP Grade A/B + aseptic cleanrooms	Smooth	outer or under	6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0	.16mm (6 mil)	200 pairs/cs
Арр	olies to all PUREZERO* Gloves:	Textured Fingertips	Accelerator-Fi	ee¹ AQL1 C	€ 2797 (PPE Cat. III)	ISO 374-5:2016 VIRUS	(:2016/Type C	7

For more information or samples, contact your distributor orcontact us at: info@hyh.com