

PUREZERO* Life Science Gloves Validation Guide

I. Quality

O&M Halyard has been designing and manufacturing quality nitrile exam gloves for over 20 years. The Safeskin facility is owned by O&M Halyard and our employees control all aspects of the facility and have many years of knowledge when it comes to manufacturing gloves.

HALYARD* **PUREZERO*** MARIN*, MARIN-XTRA*, LIMON*, LIMON-XTRA* AND ULTRA VIOLET* Nitrile Exam Gloves are manufactured and rigorously tested to the highest international standards to ensure performance in various Life Science settings, including working with various chemicals, viruses, bacteria, fungi and bloodborne pathogens, pharmaceuticals, food processing, or electronics.

PUREZERO* Life Science Nitrile Exam Gloves are manufactured at the Safeskin Medical & Scientific Manufacturing facility¹ which complies with:

- **ISO 9001:2015** Quality management systems - Requirements standard
- **ISO 13485:2016** - Medical Devices - Requirements for regulatory purposes
- **ISO 14001:2015** - Environmental management systems

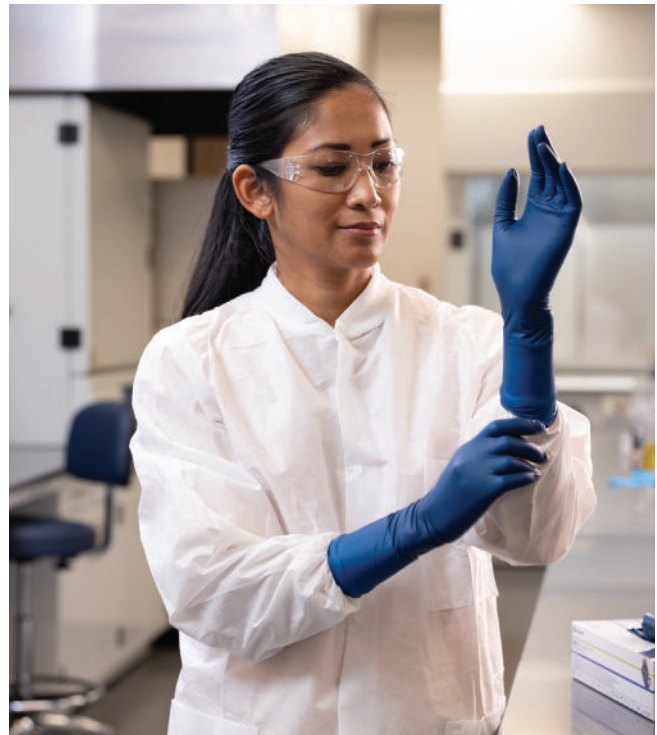
PUREZERO* Life Science Nitrile Exam Gloves meet all requirements for compliance to the following standards for gloves:

General Requirements

- **REGULATION (EU) 2016/425** "Requirements for personal protective equipment"
- **EN ISO 21420:2020**: "Protective gloves — General requirements and test methods"
- **ASTM D6319-2019**: "Standard Specification for Nitrile Examination Gloves for Medical Application"
- **REGULATION (EU) 2017/745 on Medical Devices**

Shelf Life/Aging

- **ASTM D7160-16**: "Standard Practice for Determination of Expiration Dating for Medical Gloves"
- **EN 455-4:2009**: "Medical gloves for single use - Part 4: Requirements and testing for shelf-life determination."





Manufactured at OUR OWN
Safeskin Facility in Thailand.†

Freedom from Holes

- **ASTM D5151-19:** "Standard Test Method for Detection of Holes in Medical Gloves."
- **EN 455-1:2020+A1:2022:** "Medical gloves for single use - Part 1: Requirements and testing for freedom from holes."
 - Industry Standard is 2.5 AQL for Medical Exam Gloves and 1.5 AQL for Laboratory Gloves
 - **PUREZERO* Life Science Nitrile Exam Gloves have a 1.0 AQL**

Physical Properties

- **ASTM D412-16 (2021):** "Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension." Measures the elasticity of a material while under tensile strain, as well as its behavior after testing when the material is no longer being stressed.
 - **Minimum Requirement (before aging): 14 MPa**
 - **MARIN* and MARIN-XTRA*: 42 MPa**
 - **LIMON* and LIMON-XTRA*: 42 MPa**
 - **ULTRA VIOLET*: 20 MPa**
- **EN 455-2:2015:** "Medical gloves for single use - Part 2: Requirements and testing for physical properties."

II. Environmental

The manufacturing site for **PUREZERO*** Life Sciences gloves† complies with ISO 14001:2015 "Environmental Management Systems - Requirements with Guidance for Use" which helps organizations improve their environmental performance through efficient use of resources and reduction of waste.

III. Biological Safety

PUREZERO* Life Sciences Nitrile Exam Gloves are designed to protect against biological hazards, including viruses, bacteria, fungi, and bloodborne pathogens. These gloves are compliant with the following standards:

- **EN 455-1:2020+A1:2022** and **EN 455-3:2015** "Requirements for evaluation of biological safety for medical gloves for single use."
- **EN ISO 374-5:2016** "Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks", which measures the ability of gloves to protect users against bacteria, fungi, and viruses.

- **ASTM F1671:** "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System."
- **ISO 16604:2004** "Standard test method that tests the resistance to penetration by blood-borne pathogens." Test method using Phi-X 174 bacteriophage.

IV. Chemical Resistance

PUREZERO* Life Sciences Nitrile Exam Gloves are compliant with the following standards:

- **EN ISO 374-1:2016+A1:2018:** "Protective Gloves Against Dangerous Chemicals and Micro-organisms. Determination of Resistance to Penetration."
 - **Type B:** Protective glove with permeation resistance of at least 30 minutes each for at least 3 test chemicals.
- **EN 16523-1:2015+A1:2018:** "Protective Gloves Against Dangerous Chemicals and Micro-organisms. Determination of Resistance to Penetration."
- **EN ISO 374-2:2019:** "Protective Gloves Against Dangerous Chemicals and Micro-organisms - Determination of Resistance to Penetration."
- **EN ISO 374-4:2019:** "Protective Gloves Against Chemicals and Micro-organisms - Determination of Resistance to Degradation by Chemicals."
- **ASTM F739-12** "Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact."

V. Chemotherapy Drugs and Hazardous Drugs

PUREZERO* Life Science Nitrile Exam Gloves have been tested for use with chemotherapy drugs and fentanyl and are compliant to the following standards: **ASTM D6978-05 (2019)** Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs and **USP <800>** Standard for safe handling of hazardous drugs to minimize the risk of exposure to individuals.

VI. Pharmaceutical Compounding

PUREZERO* Life Science Nitrile Exam Gloves¹ are compliant with the standards for pharmaceutical compounding and are compliant with **USP <795>** (Non-sterile preparations) and **USP <797>** (Sterile preparations). These gloves are also compliant with the **USP <800>** Standard for safe handling of hazardous drugs to minimize the risk of exposure to individuals.

VII. Food Manufacturing

PUREZERO* Life Science Nitrile Exam Gloves are compliant with **FDA 21 CFR 177-2600** and **FDA 21 CFR 180.22** and "Food handling" claim per **Commission Regulation (EU) No 10/2011** of June 2018 which ensures that these gloves are intended to be used safely when in contact with food.

VIII. Product Safety

PUREZERO* Life Sciences Nitrile Exam Gloves are compliant with **ISO 10993-10:2010 “Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization”** and **ISO 10993-11: “Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity”**.

PUREZERO* Life Sciences Nitrile Exam Gloves are compliant with the **EU REACH Regulation** which is meant to improve the protection of human health and the environment from risks posed by chemicals. This regulation also promotes alternative methods for assessing substances to reduce the number of tests on animals.

IX. ESD (Electrostatic Discharge)

PUREZERO* Life Sciences Nitrile Exam Gloves have been tested for ESD (Electrostatic discharge) properties per **ANSI/ESD STM 15.1:2019 In-Use Resistance Testing of Gloves and Finger Cots**. All PUREZERO* Life Science Nitrile Exam Gloves are static dissipative in use.

X. Sustainability

PUREZERO* Life Sciences Nitrile Exam Gloves deliver on the following sustainability efforts:

- Our SAFESKIN manufacturing facility uses 92% renewable energy.
- Our glove dispensers are made with up to 85% recycled materials.
- Our glove cases are made with up to 99% recycled pulp.
- Our gloves are manufactured in a facility that complies with the requirements of **ISO 14001:2015 – Environmental Management System**[†]
- Our SAFESKIN manufacturing facility has been awarded the Green Industry Level 5 certification by Ministry of Thailand for 3 consecutive times since 2015.
- The innovative SMARTPULL* Dispenser[‡] reduces total waste by an average of 38.2% compared to a leading competitor. SMARTPULL* dispensing incorporates 2 separate openings on the box. This helps control dispensing to lessen waste from dropped gloves or multiple dispensing.
- Our SAFESKIN manufacturing facility has been awarded the Thailand Labour Management Excellence Award for 4 consecutive years: 2019, 2020, 2021, and 2022.

[†] Excluding ULTRA VIOLET*

[‡] PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves are only available in a 9.5" length.

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