




**REIGN PRODUCTION COMPANY
NITRILE MEDICAL EXAM GLOVES
SPECIFICATIONS / SAFETY DATA SHEET**

SECTION 1: IMPORTER'S DETAILS

Company Name (ODM) 	Reign Production Company, a wholly owned subsidiary of Reign International Portfolio Holdings Corporation, chartered in Texas, USA (collectively referred to as "REIGN GROUP")
Legal Representative	Dr. Pepe JD Colón, Chief Executive Officer
Registered Address	17250 Dallas Parkway, Dallas, Texas 75248 USA
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Email Address	PJC@reigngroup.co
Website	www.reigngroup.co
FDA Owner Operator No.	10083394
D&B D-U-N-S No.	118568279
NAICS Code	325212
SIC Codes:	2822, 28220102

SECTION 2: PRODUCT INFORMATION

Trade Name	Reign Gloves™
Type	Nitrile Examination Glove – Disposable
Material	Nitrile Butadiene Rubber (NBR)
Classifications	Class 1 Medical Device (FDA Product Code LZA)
Life Expectancy	One time use only (Under recommended storage conditions, the product has a 5-year minimum shelf life.)
Color	Blue
Design Features	Ambidextrous, Powder Free, Non-Latex, Non-Sterile, Textured Fingers
Cuff	Beaded Cuff
Manufacturing Practices	ISO 9001:2015, ISO 13485:2016, ISO 21420:2020
Regulatory/Compliance	ASTM D6319, USA FDA 510(K) Full Statement
Origin	Vietnam



SECTION 3: PHYSICAL DIMENSION – 3 MILS, 240 MM/ 9”

Size Differentiations	Small (S)	Medium (M)	Large (L)	Extra Large (XL)
Lot Batch Code	6001	6002	6003	6004
Reference SKU Number	8001	8002	8003	8004
Width Average (mm)	85 ± 5	95 ± 5	105 ± 5	115 ± 5
Weight Average (gm)	3.4 ± 0.3	3.8 ± 0.3	4.0 ± 0.3	4.3 ± 0.3
Length (mm)	Minimum 240			
Thickness of Cuff (mm)	0.06± 0.2			
Thickness of Palm (mm)	0.07 ± 0.2			
Thickness of Finger (mm)	0.080 ± 0.2			

SECTION 4: PHYSICAL PROPERTIES

Tensile Strength before aging (MPa)	18 – 28 (Inspection Level S-2, AQL 4.0)
Tensile Strength after aging (MPa)	14 – 18 (Inspection Level S-2, AQL 4.0)
Elongation @ break psi before aging (%)	650 – 750 (Inspection Level S-2, AQL 4.0)
Elongation @ break psi after aging (%)	500 - 650 (Inspection Level S-2, AQL 4.0)
Penetration (free from holes)	Level 3 AQL 1.5, G-1 performance level for water leak/air leak test
Ph	7.35
Odor	Odorless
Physical State	Solid, film
Powder Free Glove Composition	Nitrile latex, potassium hydroxide, aquawax, ZDBC, ZDEC, zinc oxide, Polymeric hindered phenol, Sulphur, titanium dioxide and color pigment.
Powder residue content	< 2.0 mg as per ASTM D6124-06 Test Method
Aqueous soluble protein content	Meets ASTM D5712-10, Resulting tests generated values below 200µg/dm ² of aqueous extractable protein content
Extractable antigenic protein content	< 10 µg/dm ²



SECTION 5: CHEMICAL RESISTANCE

Penetration resistance to viral	ASTM F1671 compliant
Permeation by continuous contact	ASTM F739 compliant
Permeation by intermittent contact	ASTM F1383 compliant
Human repeat insult patch testing – allergens	ASTM D6355 compliant
Resistance to chemotherapy drugs	ASTM D6978 compliant
Primary skin irritation	ISO 10993 compliant
Skin sensitization	ISO 10993 compliant

SECTION 6: PACKAGING DETAILS

Box Capacity & Weight (kg)

100 glove pieces per Box dispensers | 200g

Illustration & Dimensions of Small glove size Box (cm)

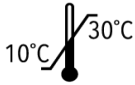










L x W x H = 20cm x 12cm x 6cm

Labeling

Compliant with GMP requirements and ISO 10282 and ISO 11193

SECTION 7: HANDLING AND STORAGE

Humidity Range	Product shall maintain its properties when stored in dry condition and prolonged storage <50% relative humidity.								
Temperature Range	Product shall maintain its properties when stored at temperatures between 10°C to 30°C: 								
Heat Effects	Exposure to heat accelerates ozone damage and degradation, and the product should always be stored away from radiators, air outlets or other heat sources and should not be stored long term in areas with temperatures above 90°F/32.2°C								
Storage Life & Tracking	<p>Product strategically placed in storage on a first-in-first-out basis. Each Box and Carton is marked with the Manufactured Date, Expiry Date, Reference Number and Lot Code:</p> <table border="1" data-bbox="532 982 1555 1224"> <tr> <td data-bbox="532 982 789 1066"></td> <td data-bbox="789 982 1045 1066"></td> <td data-bbox="1045 982 1302 1066">REF</td> <td data-bbox="1302 982 1555 1066">LOT</td> </tr> <tr> <td data-bbox="532 1066 789 1224">Indicates the date when Product is manufactured.</td> <td data-bbox="789 1066 1045 1224">Indicates the date after which Product is not to be used.</td> <td data-bbox="1045 1066 1302 1224">Indicates Product's catalogue number to identify Product.</td> <td data-bbox="1302 1066 1555 1224">Indicates Product's batch code to identify Product's batch or lot.</td> </tr> </table>			REF	LOT	Indicates the date when Product is manufactured.	Indicates the date after which Product is not to be used.	Indicates Product's catalogue number to identify Product.	Indicates Product's batch code to identify Product's batch or lot.
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Indicates the date when Product is manufactured.	Indicates the date after which Product is not to be used.	Indicates Product's catalogue number to identify Product.	Indicates Product's batch code to identify Product's batch or lot.						
Effects of Sunlight & Ultraviolet Light Source	Keep away from sunlight. Sunlight could cause discoloration, and long exposure could severely reduce physical properties of product. Also, to prevent product degradation, protection against oxidizing agents and from ultraviolet light sources is required, including weak UV from fluorescent lamps and ozone that may be generated by motors and electrical devices.								
Exposure Avoidance Symbols	<p>In order avoid adversely impacting storage life, the below symbols are on both the box and carton:</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>								



SECTION 8: HAZARDS IDENTIFICATION (Potential Health Effects)

Hazardous Properties	Product is not hazardous
Routes of Exposure	Skin Contact
Signs and Symptoms	No adverse health effects are anticipated from the reasonable use of Product
Eyes	Non-hazardous
Skin	Not a Primary Skin Irritant. Not a Derma Sensitizer
Ingestion	Product not been tested for hazards related to ingestion

SECTION 9: FIRST AID MEASURES (Steps to be Taken in Event of Mishap)

Eyes	Non-hazardous
Inhalation	Not Applicable
Skin	Wash with soap and water
Ingestion	Seek medical attention if a significant quantity is swallowed

SECTION 10: FIRE FIGHTING MEASURES

Flammability Classification	Non-classified. Product will burn but is not easily ignited
Extinguishing Media	Water spray, carbon dioxide, foam or dry chemical.
Firefighting Precautions	Wear self-contained breathing apparatus and full fire-fighting turn-out gear

SECTION 11: ACCIDENTAL RELEASE MEASURES

Release Response	Retain for recycle or disposal
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SECTION 12: EXPOSURE CONTROLS & PERSONAL PROTECTION REQUIREMENTS

Engineering Control	Use local exhaust in confined spaces where product is heated
Eyes	No PPE is required. Use goggles if product is heated
Inhalation	Not Required
Skin	Not required. Use heat resistant gloves if product is heated to melting state

SECTION 13: STABILITY & REACTIVITY

Chemical Stability	Product is stable
Conditions to Avoid	Avoid contact with excessive heat, sparks or open flame. Avoid dust accumulation
Hazardous Circumstances	A variety of toxic of gases may be formed when decomposition of gloves is due to burning which may further cause respiratory irritation



SECTION 14: TOXICOLOGICAL INFORMATION

Acute Effects	Non-toxic
Sub-chronic and Chronic Effects	Non-toxic

SECTION 15: ECOLOGICAL INFORMATION

Product of Biodegradation	Non-biodegradable
Ecotoxicity	Product considered as inert

SECTION 16: DISPOSABLE CONSIDERATION & RECOMMENDED METHOD OF DISPOSAL

Incineration	<p>Put appropriate amount of Product into an incinerator or furnace to destroy Product following the requirements shown below:</p> <ol style="list-style-type: none">1) Burning temperature exceeds 850°C2) Combustion retention time is not less than 2 seconds <p><u>Note:</u> Product should not be destroyed by open burning at low temperature nor disposed of at normal disposal areas</p>
Other Disposal Considerations	<p>Check with local, provincial and national authorities before discarding. The information offered here is for Product as shipped. Use and/or alterations to Product such as mixing with other materials may significantly change the characteristics of the material and alter the proper disposal method</p>

SECTION 17: TRANSPORT INFORMATION

Possesses no threat or dangers while in transit

SECTION 18: REGULATORY INFORMATION

Not Applicable



SECTION 19: DISCLAIMER NOTICE

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