

UNIVERSIS Glove®



OPTIMUS Nitrile Examination Gloves

Latex free | Textured | Powder Free | Non sterile | Ambidextrous

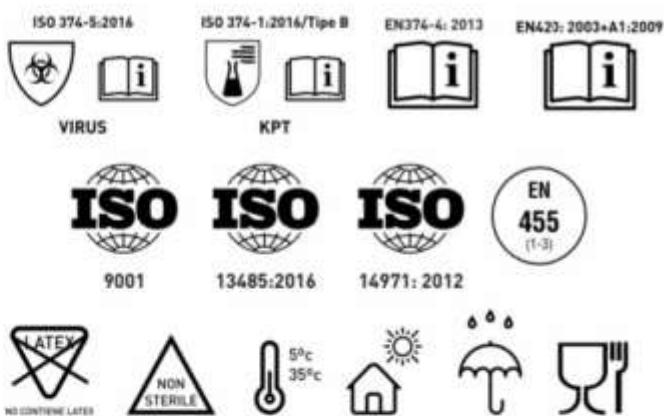
UNIVERSIS Glove®



Used



Certificated



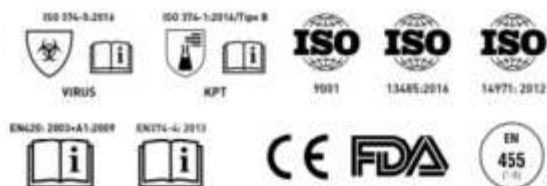
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Before the brand are introduced it is imperative to understand that:

- The product has been manufactured under strict international and European standards and conforms to FDA, 510-k, CE, EN374-1: 2016 Tipo B, EN 374-2: 2014, EN374-4: 2013, EN374-5: 2016, EN420:2003+A1:2009, EN 455-1:2000, EN 455-2: 2000, EN 455-2: 2015, EN 455-3: 1999, EN 455-3: 2015 standards. (2016/425 - MODULE C2).
- Manufactured under, EN ISO 14971: 2012, EN ISO 13485: 2016, ISO 9001.
- The product has a three-year shelf life after manufacturing warranty.
- The product will retain its properties if stored in a dry place away from sunlight.
- The company is responsible for any type of problem in the product within six months of its purchase.
- 100% Nitrile Examination Glove, Powder Free made of extruded nitrile butadiene (NBR).
- Microbe protection with enhanced comfort and fit.
- Ambidextrous with beaded cuff for easy donning (chlorinated) and prevention of roll back.
- Superior strength with puncture resistance.
- Fully textured, including fingertips, to enhance wet and dry grip.
- Thin gauge for improved tactile sensitivity.
- Allergy friendly, latex free.
- Blue, non-sterile.
- 3-year shelf life with appropriate storage conditions.
- Store in ventilated, dark, dry place, away from fire and pollution.
- Licenses, MDSA, NSF, CEMO.

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Product Information & Specs:

Product	Disposable Nitrile Exam Gloves - Powder Free
Specs	<ul style="list-style-type: none"> - Powder free - Textured surface - Not sterile - Molded cuff - With rolled edge - Straight fingers - Ambidextrous
Colour	Blue
Material	Nitrile Butadiene Rubber (NBR)
Thickness	3Mil Plus
Pieces per box	100 pieces
Certifications / Compliance of all factories	<ul style="list-style-type: none"> - FDA, 510 k - CE - All the factories with which the assignment is made for this of EN374-1: 2016 Tipo B, EN 374-2: 2014, EN374-4: 2013, EN374-5: 2016, EN420:2003+A1:2009, EN 455-1:2000, EN 455-2: 2000, EN 455-2: 2015, EN 455-3: 1999, EN 455-3: 2015 standards. (2016/425 - MODULE C2). - This qualifies the DEM nitrile product on offer for legal distribution and import to the United States of America, Europe and all key markets. - Manufactured under: EN ISO 14971: 2012, EN ISO 13485: 2016, ISO 9001. - Licenses, MDSA, NSF, AQL1.5.
Available sizes	S · M · L · XL
Country of manufacture	OEM China

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Technical Information:

Dimensions and Performance Comparison Table:

Technological Characteristics	Proposed Device K182156	Predicate Device K172525	Remark
Length	Minimum 230mm	Minimum 230mm	Same
Palm Width (size) (mm)			
XS	70 ± 10	70 ± 10	Same
S	80 ± 10	80 ± 10	Same
M	95 ± 10	95 ± 10	Same
L	110 ± 10	110 ± 10	Same
XL	120 ± 10	120 ± 10	Same
Thickness (mm)			
Finger	Minimum 0.05	0.10 ± 0.03	Similar
Palm	Minimum 0.05	0.08 ± 0.03	Similar

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PACKAGING



Box
100 Units per box
Dimension: 250 x 125 x 60mm

Carton
1.200 Units (12 Boxes)
Dimension: 360 x 250 x 250mm
Weight: 8Kg

