

# ROSENBERG – NITRILE GLOVES

## DESCRIPTION

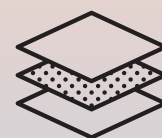
STABLE, TEAR-RESISTANT DISPOSABLE GLOVES

MADE OF NITRILE FOR PROFESSIONAL USE.

(SINGLE USE) AS DISPOSABLE MEDICAL GLOVES, CHEMICAL PROTECTIVE GLOVES, FOOD AND RESTAURANTS, COSMETICS



Layer Thickness: 5 mil approx. 0.13mm, this is thicker than many other nitrile gloves (approx. 0.09 mm), therefore more tear-resistant. With thinner gloves, 2 gloves are often used in practice dressed on top of each other (double consumption = double costs), which is not necessary with Rosenberg.



Reinforced fingertips and cuff for improved grip and higher stability (do not tear as quickly)



Nitrile, natural latex free, phthalate free



Powder-free, minimizes particle contamination, if products must not be contaminated



Medical use according to EN455 (PPE), but not sterile for surgical use



Protects against contact for a short time with chemicals and chemical splashes



Can be used with both hands




Tight fitting



Length: Size S = approx. 230 mm



Color blue 



Rolled Edge



Food suitable for contact allowed with food



CE certified (Europe)



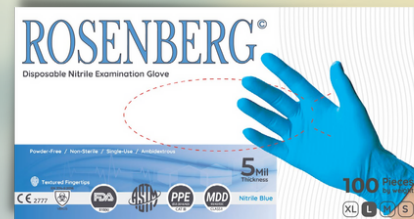
FDA-certified (USA, Canada, Latin America)



Available sizes: S M L XL

1 box contains 100 pieces (50 pairs)





## CERTIFICATES:

- ✓ CE 2777 Risk Class - Category III (Europe)
- ✓ FDA-certified (USA, Canada, Latin America)
- ✓ EN374-5: 2016 (Protective gloves against dangerous chemicals and microorganism Anti-Virus)
  - ✓ EN374-1:2016
  - ✓ EN374-2:2019 Level 3
- ✓ EN374-2:2003 Level 3 and/ or equivalent: ASTM D6319; All stock PPE
- ✓ Category III Certified (Covid – 19 approved AQLI 05 or AQL0.65)
  - ✓ EN374-4:2019
- ✓ EN420 / PPE Regulation (EU) 2016/425 -Annex II
- ✓ EN455.1 :2000 or equivalent BS EN ISO374
  - ✓ EN455.2:2015
  - ✓ EN455.3:2015
- ✓ EN455.4:2009 or equivalent ANSI/ ISEAI 05 or equivalent ASTM D6319
  - ✓ EN14683:2019
  - ✓ EN149:2001 + A1:2009
  - ✓ EN14126.2003
  - ✓ EN455 1-2-3-4
  - ✓ CE + FDA/ 510K-USA

**Protection against dangerous chemicals and microorganisms:**  
 These gloves are made of 95.8% nitrile and offer an excellent biological barrier and good resistance to bacteria, fungi, viruses and a variety of chemicals, found in typical medical and industrial environments.

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**WARNING:** The information does not reflect the actual duration of protection at the workplace and the differentiation between mixtures and pure chemicals. The chemical resistance was tested under laboratory conditions using samples assessed from the palm of the hand only and relates only to the chemical tested.

It may be different when used in a mix. It is recommended to check whether the gloves for are suitable for the intended use, since the conditions at the workplace depend on temperature, abrasion and deterioration may deviate from the type test. When using protective gloves due to of physical property changes provide less resistance to the hazardous chemical. Movement, snagging, rubbing, chemical contact deterioration, etc., may affect the actual use time significantly shorten. With corrosive chemicals, degradation can be the most important factor when choosing chemical resistant gloves.





BELOW ARE THE STANDARDS AND CERTIFICATIONS THAT OUR ROSENBERG DISPOSABLE NITRILE GLOVES MEET:

THE EU COMPLIANCE AND MARKET																
	<p><b>Manufacturer</b> Leping Shengde Medical Technology Company Limited No. 17, Yubao Village, Lingang Village Committee, Lingang Town, Leping City, Jingdezhen City, Jiangxi Province, China Postcode: 333300</p>															
	<p><b>Product Reference</b> SD001</p>															
	<p><b>PPE Regulation (EU) 2016/425 – Annex II</b> Notified Body: CE 2777 - SATRA Technology Europe Ltd EU Type-Examination Certificate (Module B) Certificate Number: 2777/17436-01/E00-00</p>															
	<p><b>Risk Class - Category III</b> Date of Issue: 15/07/2021; Expiry Date: 15/07/2026</p>															
	<p><b>EN 374</b> <i>Protective gloves against dangerous chemicals and micro-organisms</i></p>															
	<p>EN ISO 374 -1:2016+A1:2018 <b>Part 1: Terminology and performance requirements for chemical risks - Type C</b></p> <table border="1"> <thead> <tr> <th>EN ISO 374-1:2016+A1:2018 / Type C</th> <th>Level</th> <th>EN ISO 374-4:2019 % Degradation</th> </tr> </thead> <tbody> <tr> <td>40% Sodium Hydroxide (K)</td> <td>6</td> <td>-60.5</td> </tr> </tbody> </table>	EN ISO 374-1:2016+A1:2018 / Type C	Level	EN ISO 374-4:2019 % Degradation	40% Sodium Hydroxide (K)	6	-60.5									
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	<p>EN ISO 374-2:2019 <b>Part 2: Determination of resistance to penetration</b></p> <table border="1"> <thead> <tr> <th>Clause 4.1</th> <th>Air Leak Test</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td>Clause 4.2</td> <td>Water Leak Test</td> <td>Pass</td> </tr> </tbody> </table>	Clause 4.1	Air Leak Test	Pass	Clause 4.2	Water Leak Test	Pass									
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	<p>EN ISO 374-4:2019 <b>Part 4: Determination of resistance to degradation by chemicals</b></p> <p>EN ISO 374-5:2016 <b>Part 5: Terminology and performance requirements for micro-organisms risks</b> Protection against Bacteria and Fungi - <b>Pass</b> Protection against Viruses - <b>Pass</b></p>															
	<p>EN 16523-1:2015+A1:2018 <b>Part 1: Determination of material resistance to permeation by liquid chemical under conditions of continuous contact</b></p> <table border="1"> <thead> <tr> <th>Chemical</th> <th>Performance Level</th> <th>Observation</th> </tr> </thead> <tbody> <tr> <td>40% Sodium Hydroxide</td> <td>-6</td> <td>No Change</td> </tr> </tbody> </table>	Chemical	Performance Level	Observation	40% Sodium Hydroxide	-6	No Change									
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	<p><b>EN 21420:2020</b> <i>Protective gloves - General requirements and test methods</i> Determination of pH value 6.6 (Requirement: 3.5-9.5)</p> <p>Dexterity Performance Level 5 (Minimum pin diameter / mm: 5.0)</p> <p>Sizing</p> <table border="1"> <thead> <tr> <th>Size</th> <th>Measure (mm)</th> <th>Minimum length requirements (mm)</th> </tr> </thead> <tbody> <tr> <td>S</td> <td></td> <td>230</td> </tr> <tr> <td>M</td> <td></td> <td>240</td> </tr> <tr> <td>L</td> <td></td> <td>250</td> </tr> <tr> <td>XL</td> <td></td> <td>260</td> </tr> </tbody> </table>	Size	Measure (mm)	Minimum length requirements (mm)	S		230	M		240	L		250	XL		260
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	<p><b>Medical Devices Regulation (EU) 2017/745 Class I</b> Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices – Review Report EC Declaration of Conformity – MDR and PPE Regulations</p> <p><b>EC Representative</b> MedPath GmbH (<b>EU market</b>) Mies-van-der-Rohe-Straße 8, 80807 München, Germany</p>															
																
	<p><b>EU Declaration of Conformity of the Manufacturer</b> EU Declaration of Conformity: MDR, PPE, FCM Regulations and Standards</p>															







### EN 455 - Medical gloves for single use

BS EN 455-1:2000

Part 1, Clause 5.1: Requirements and testing for freedom from holes AQL 1.5

BS EN 455-2:2015

Part 2, Clauses 4.2, 4.3, 5.2, 5.3: Requirements and testing for physical properties

Size	Test Items	Median Value	Minimum requirements
L	Dimensions	Length	248 mm
		Width	105 mm
L	Tensile Strength	Force at Break Before Ageing	≥ 7.4 N
L		Force at Break After Ageing	≥ 7.4 N

BS EN 455-3:2015

Part 3, Clause 4.4: Requirements and testing for biological evaluation

Test Item*	Test Result	Requirement
Removable surface powder	0.18 mg	≤ 2 mg

\*Testing in accordance with EN ISO 21171:2006)

 Regulation (EC) 1935/2004

Council of Europe Resolution AP (2004)

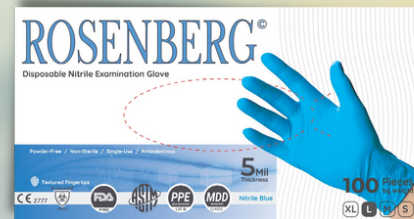
Commission Regulation (EU) No. 10/2011

Test Method	Test	Result
EN 1186-1:2002	Overall Migration	Pass
EN 1186-9:2002		Pass
DIN 10955:2004	Sensorial examination odour and taste test	Pass
EN 13130-1:2004 Analysis performed by UV-Vis	Specific Migration of primary aromatic amine	Pass
EN 13130-1:2004 Analysis performed by GC-MS	Specific Migration of nitrosamine and nitrosatable substances	Pass

 Description and Instructions for Storage

High quality disposable nitrile gloves provide an excellent biological barrier, preventing the skin's contact with contamination and other external materials and fully protecting the hands. Our gloves guarantee superior levels of security, dexterity, and comfort to help reduce the risk of fatigue when in use for extended periods of time. Our gloves are not made with natural rubber latex and they are





		<p>powder free, also reducing the risk of allergies, dermatitis, and contamination.</p> <p>Store in a cool, dry place and avoid excessive heat (30°C, 88°F). Opened box should be shielded from exposure to direct sun or fluorescent lighting.</p>
	<p><b>CAUTION</b></p>	<p>To Prevent injury, we recommend:</p> <ol style="list-style-type: none"> <li>1. Use these gloves for their intended purpose only.</li> <li>2. Inspect before use, do not use if the gloves have holes, excessive wear, or other damage.</li> <li>3. After use, wearer should check the glove and remove any contamination from the outer surface before removing the glove from the hand. Alternatively, carefully peel the glove off the hand so that the contaminated glove outer does not touch your skin.</li> </ol>

**To summarise the Norms & Standards:**

- ✓ EN 455; EN374; EN420/ PPE Regulation (EU) 2016/425
  - ✓ EN 455.1:2000 or equivalent BS EN ISO374
  - ✓ EN 455.2:2015; EN 455.3:2015; EN 455.4:2009
    - or equivalent ANSI/ ISEA105 or equivalent ASTM D6319
- ✓ EN 374-2:2003 Level 3 EN14683:2019; EN 149:2001 + A1:2009
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