SOURCEWEB® GROUP
+44 7858 827 067
sourceweb.ag
office@sourceweb.ag

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)

SOURCEWEB® GROUP
+44 7858 827 067
sourceweb.ag
office@sourceweb.ag

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 Il
- EN455.1 :2000 or equivalent BS EN IS0374
- EN455.2:2015
- EN455.3:2015
- EN455.4:2009 or equivalent ANSI/ ISEAI 05 or equivalent ASTM D6319
- EN14683:2019
- EN149:2001 + Al: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.

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.

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.

SOURCEWEB® GROUP
+44 7858 827 067
sourceweb.ag
office@sourceweb.ag

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

THE EU COMPLIANCE AND MARKET

Manufacturer	Leping Shengde Medical Technology Company Limited No. 17, Yubao Village, Lingang Village Committee, Lingang Town, Leping City, Jingdezhen City, Jiangxi Province, China Postcode: 333300
Product Reference	SD001
PPE Regulation (EU) 2016/425 – Annex II **Risk Class - Category III**	Notified Body: CE 2777 - SATRA Technology Europe Ltd EU Type-Examination Certificate (Module B) Certificate Number: 2777/17436-01/E00-00 Date of Issue: 15/07/2021; Expiry Date: 15/07/2026
EN 374	*Protective gloves against dangerous chemicals and micro-organisms*
EN ISO 374 -1:2016+A1:2018	Part 1: Terminology and performance requirements for chemical risks - Type C

EN ISO 374-1:2016+A1:2018 / Type C	Level	EN ISO 374-4:2019 % Degradation
40% Sodium Hydroxide (K)	6	-60.5

EN ISO 374-2:2019	Part 2: Determination of resistance to penetration	
Clause 4.1	Air Leak Test	**Pass**
Clause 4.2	Water Leak Test	**Pass**
EN ISO 374-4:2019	Part 4: Determination of resistance to degradation by chemicals	
EN ISO 374-5:2016	Part 5: Terminology and performance requirements for micro-organisms risks Protection against Bacteria and Fungi - **Pass** Protection against Viruses - **Pass**	

EN 16523-1:2015+A1:2018	Part 1: Determination of material resistance to permeation by liquid chemical under conditions of continuous contact

Chemical	Performance Level	Observation
40% Sodium Hydroxide	-6	No Change

EN 21420:2020	*Protective gloves - General requirements and test methods*
Determination of pH value	6.6 (Requirement: 3.5-9.5
Dexterity	Performance Level 5 (Minimum pin diameter / mm: 5.0)
Sizing	

Size	Measure (mm)	Minimum length requirements (mm)
S		230
M		240
L		250
XL		260

Medical Devices Regulation (EU) 2017/745 Class I	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
EC Representative MedPath GmbH	**(EU market)** Mies-van-der-Rohe-Straße 8, 80807 München, Germany
EU Declaration of Conformity of the Manufacturer	EU Declaration of Conformity: MDR, PPE, FCM Regulations and Standards

SOURCEWEB® GROUP
+44 7858 827 067
sourceweb.ag
office@sourceweb.ag

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	≥ 240 mm
		Width	105 mm	95 mm +/-10
L	Tensile Strength	Force at Break Before Ageing	≥ 7.4 N	≥ 6.0 N
L		Force at Break After Ageing	≥ 7.4 N	≥ 6.0 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

SOURCEWEB® GROUP
+44 7858 827 067
sourceweb.ag
office@sourceweb.ag

		powder free, also reducing the risk of allergies, dermatitis, and contamination. 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.
	**CAUTION**	To Prevent injury, we recommend: 1. Use these gloves for their intended purpose only. 2. Inspect before use, do not use if the gloves have holes, excessive wear, or other damage. 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 hanc so that the contaminated glove outer does not touch your skin.

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

✓ EN 14126:2003

✓ EN 455 1-2-3-4 EN 374-2:2003 Level 3 and/ or equivalent: ASTM D6319; All stock PPE

✓ Category III Certified (Covid – 19 approved AQL1.5 or AQL0.65)

✓ CE + FDA/ 510K-USA