

EU - DECLARATION OF CONFORMITY

In compliance with Council Directive (EU) 2017/745 concerning medical devices and Personal Protective Equipment Regulation (EU) 2016/425

SOFT NITRILE PREMIUM GLOVES, LATEX - FREE, POWDER - FREE

Page 1 of 2

PRODUCT DESCRIPTION	C = MP Class R = Rule	UMDNS	Personal Protection Cat.	Notified Body
Medical gloves for single use, intended to protect both the wearer and the patient from cross-contamination caused by microorganisms.	CI - R1, R5	11882	III	CE 2777

SIZE	VIOLET-BLUE	UDI-DI	WHITE	UDI-DI	BLACK	UDI-DI
XS	7900	3800234840116	7900W	3800234840161	7900BB	3800234842271
S	8000	3800234840123	8000W	3800234840178	8000BB	3800234842288
M	8100	3800234840130	8100W	3800234840185	8100BB	3800234842295
L	8200	3800234840147	8200W	3800234840192	8200BB	3800234842301
XL	8300	3800234840154	8300W	3800234840208	8300BB	3800234842318
SIZE	GREEN	UDI-DI		PINK	UDI-DI	
XS	7900G	3800234840215		7900P	3800234840260	
S	8000G	3800234840222		8000P	3800234840277	
M	8100G	3800234840239		8100P	3800234840284	
L	8200G	3800234840246		8200P	3800234840291	
XL	8300G	3800234840253		8300P	3800234840307	

Harmonised standards and normative documents:

EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016; EN 421: 2010 (excluding clause 4.3)

Issued EU Type Examination Certificate No. 2777/11578-03/E18-01

Notified body No. 2777
SATRA Technology Europe Ltd., Bracetown Business Park,
Dublin D15 YN2P Ireland, which is responsible for
EU type examination and ongoing conformity (Module C2)

Version: 4
Date: April 2024
Valid until: September 2028

Department: Regulatory Affairs
Name: Borislav Stoyanov
Signature:



Headquarters:

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WARNING

Examination and disposable protective glove made of nitrile butadiene rubber, powderfree, non-sterile, ambidextrous, for single use. Store in original packaging in a dry and out of the sun at 5°C to 40°C. Dispose of in accordance with valid local regulations. Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenged chemical. The penetration resistance has been assessed under laboratory condition and relates only to the tested specimen. **WARNING:** This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical resistance has been assessed under laboratory condition from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion, and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections. DO NOT use damaged gloves. These gloves are not made from natural rubber latex. They may contain residual chemicals used in their manufacture that can cause allergic skin reactions in some people. If skin reaction occurs, discontinue use.

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The logo for comforties.com, featuring the company name in a blue sans-serif font with a small hand icon above the 'i' in 'ties'.