

EU - DECLARATION OF CONFORMITY

In compliance with Council Directive (EU) 2017/745 concerning medical devices of Annex VIII (Module D)
of the Personal Protective Equipment Regulation (EU) 2016/425

SOFT NITRILE GLOVES, LATEX - FREE, POWDER - FREE

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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	BLUE	UDI-DI	WHITE	UDI-DI	BLACK	UDI-DI	
XS	7900B	3800234840017	7900BW	3800234840062	7900BK	3800234841922	
S	8000B	3800234840024	8000BW	3800234840079	8000BK	3800234841939	
M	8100B	3800234840031	8100BW	3800234840086	8100BK	3800234841946	
L	8200B	3800234840048	8200BW	3800234840093	8200BK	3800234841953	
XL	8300B	3800234840055	8300BW	3800234840109	8300BK	3800234841960	
SIZE	COBALT BLUE	UDI-DI	PINK	UDI-DI			
XS	7900CB	3800234842127	7900PN	3800234842172			
S	8000CB	3800234842134	8000PN	3800234842189			
M	8100CB	3800234842141	8100PN	3800234842196			
L	8200CB	3800234842158	8200PN	3800234842202			
XL	8300CB	3800234842165	8300PN	3800234842219			
Harmonised standards and normative documents:		EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016					

Notified body No. 2777
SATRA Technology Europe Ltd., Bracetown Business Park,
Dublin D15 YN2P Ireland, Category III Personal Protective Equipment
and as such CE Marking is reliant on current compliance with Annex VIII
Module D of this Regulation.

SATRA Reference STE2005592

Version: 4
Date: May 2024
Valid until: May 2025

Department: Regulatory Affairs
Name: Borislav Stoyanov
Signature:



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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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