

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 GLAMOUR 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	PINK	UDI-DI	LILAC	UDI-DI
XS	7900PG	3800234841151	7900LG	3800234841106
S	8000PG	3800234841168	8000LG	3800234841113
M	8100PG	3800234841175	8100LG	3800234841120
L	8200PG	3800234841182	8200LG	3800234841137
XL	8300PG	3800234841199	8300LG	3800234841144
SIZE	GOLD	UDI-DI	SILVER	UDI-DI
XS	7900GG	3800234841052	7900SG	3800234841205
S	8000GG	3800234841069	8000SG	3800234841212
M	8100GG	3800234841076	8100SG	3800234841229
L	8200GG	3800234841083	8200SG	3800234841236
XL	8300GG	3800234841090	8300SG	3800234841243

Harmonised standards and
normative documents:

Personal Protective Equipment of Design Category III
EN ISO 374-1:2016+A1:2018, EN ISO 374-4:2019, EN ISO 21420:2020, EN ISO 374-5:2016

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)

Issued EU Type Examination Certificate No. 2777/10648-06/E00-00

Version: 4

Date: June 2023

Valid until: June 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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