

# 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 DERMACARE GLOVES, LATEX FREE, POWDER FREE

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| PRODUCT DESCRIPTION                                                                                                                   | C = MP Class<br>R = Rule | UMDNS | Personal<br>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 | DAWN BLUE | UDI-DI        |
|------|-----------|---------------|
| XS   | 7900DC    | 3800234841878 |
| S    | 8000DC    | 3800234840000 |
| M    | 8100DC    | 3800234841885 |
| L    | 8200DC    | 3800234841892 |
| XL   | 8300DC    | 3800234841908 |

|                                               |                                                                                                                                                                                              |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Harmonised standards and normative documents: | EN 420:2003+A1:2009; EN ISO 374-1:2016+A1:2018; EN 374-2:2014; EN 16523-1:2015; EN 374-4:2013; EN ISO 374-5:2016; EN 421:2010 (excluding clause 4.3); EN 455-1; EN 455-2; EN 455-3; EN 455-4 |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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. 2777/17920-03/E03-01**

Version: 4  
Date: June 2023  
Valid until: August 2026

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'.