

EC - VERKLARING VAN OVEREENSTEMMING

Conform Richtlijn (EU) 2017/745 van de Raad betreffende medische hulpmiddelen en Verordening (EU) 2016/425 betreffende persoonlijke beschermingsmiddelen.

SOFT NITRIL HANDSCHOENEN DERMACARE, LATEXVRIJ, POEDERVRIJ

Pagina 1 van 2

PRODUCTBESCHRIJVING	K = MP Klasse R = Regel	UMDNS	Pers. Besch. middel Cat.	Aangemeld orgaan
Wegwerp medische handschoenen bedoeld om zowel de drager als de patiënt te beschermen tegen kruisbesmetting door micro-organismen.	KI - R1, R5	11882	III	CE 2777

MAAT	DAWN BLUE	UDI-DI
XS	7900DC	3800234841878
S	8000DC	3800234840000
M	8100DC	3800234841885
L	8200DC	3800234841892
XL	8300DC	3800234841908

Geharmoniseerde normen, andere normen of normatieve documenten:

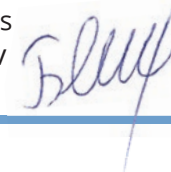
EN 420:2003+A1:2009; EN ISO 374-1:2016+A1:2018; EN 374-2:2014; EN 16523-1:2015; EN 374-4:2013; EN ISO 374-5:2016; EN 421:2010 (uitsluitende clause 4.3); EN 455-1; EN 455-2; EN 455-3; EN 455-4

Nr. aangemeld orgaan 2777
SATRA Technology Europe Ltd., Bracetown Business Park,
Dublin D15 YN2P Ireland, dat verantwoordelijk is voor
het EU-typeonderzoek en de permanente conformiteit (module C2)

Afgegeven EU-certificaat van typeonderzoek nr. 2777/17920-03/E03-01

Versie: 4
Datum: Juni 2023
Geldig t/m: August 2026

Afdeling: Regulatory Affairs
Naam: Borislav Stoyanov
Handtekening:



Hoofdkantoor:

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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'.

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WARNING

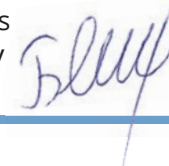
Examination and disposable protective glove made of nitrile butadiene rubber, powderfree, non-sterile, ambidextrous, for single use. Store in original packaging in a dry and out of the sun at 5°C to 40°C. Dispose of in accordance with valid local regulations. Degradation levels indicate the change in 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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