

Novolab NV		Date: 23-09-2021
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Diebeke 7 (IZ) 9500 Geraardsbergen (Belgium)		Version: 1.7
Author: B. Gernaey	Declaration of conformity CE	Documentn°: C2-1

ROLL-O-GLOVE® Neo - Extended

Authorised representative: Novolab NV Diebeke 7(IZ) 9500 Geraardsbergen Belgium	Product: ROLL-O-GLOVE® Neo - Extended	References & size: A29535 (XS-6) A29536 (S-7) A29537 (M-8) A29538 (L- 9) A29539 (XL-10)
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Classification: PPE CAT III (complex design)

Applicable norms:

EN ISO 21420: 2020 – EN ISO 374 – EN455 – MDR (EU) 2017/745 (compliant with PPE Regulation (EU) 2016/425)

Additional standards: Meets or exceeds EN455-1:2000, EN455-2:2009+A1:20011, EN455-3:2006 and EN455-4:2009 relating to MDR (EU) 2017/745 for medical devices (class 1).

Novolab NV declares that *ROLL-O-GLOVE® Neo - Extended* disposable powder free chloroprene gloves are personal protective equipment(PPE) in conformity with PPE Regulation (EU) 2016/425 and with the harmonized standards EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN 16523:2015, EN ISO 374-5:2016, EN ISO 21420: 2020 (General requirements for gloves) and EN421:2010 (for radioactive contamination only). The gloves are non-sterile gloves with a typical length of 290mm with green color. This device is identical to the PPE which is the subject of EC Type certificate 2777/10838-02/E00-00 issued by the notified body SATRA TECHNOLOGY EUROPE LTD, Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland (N.B. 2777).

This device has been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product under the supervision of notified body: SATRA TECHNOLOGY EUROPE LTD, Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland (N.B. 2777).

Intended use:

Store the gloves in a cool and dry place for maintaining the best quality. Do not store above 40°C. Gloves should be protected in any case from direct sunlight, UV light exposure, X-ray devices or other ozone sources during storage. Disposal of the gloves should be in accordance with local authority regulations and with industry best practices. Chloroprene gloves are not biodegradable and thus should be disposed properly. Chloroprene disposable gloves are not intended for applications involving direct exposure to harsh chemicals, use heavy duty protective gloves instead. Disposable gloves should only be used for brief contact or splash protection and are intended for single use. Chloroprene disposable gloves are not suitable for thermal, cryo- or mechanical protection. Immediately discontinue use if damaged.

This declaration is valid for *ROLL-O-GLOVE® Neo - Extended*, only in its unopened, undamaged package.

For Novolab NV:

Bram Gernaey
General Manager
Novolab NV

