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| Novolab NV | | Date: 23-09-2021 |
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| Diebeke 7 (IZ) 9500 Geraardsbergen (Belgium) | | Version: 1.6 |
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| Author: B. Gernaey | Declaration of conformity CE | Documentn°: C3-1 |

ROLL-O-GLOVE® Nitri - Extra Sensitive

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| Authorised representative: Novolab NV Diebeke 7(IZ) 9500 Geraardsbergen Belgium | Product: ROLL-O-GLOVE® Nitri - Extra Sensitive | References & size: A29557 (XS-6) A29558 (S-7) A29559 (M-8) A29560 (L- 9) A29561 (XL-10) |
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Classification: PPE CAT III (Complex design) - MDD

Applicable norms:

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

R-DON Technology Patent pending US 16/464,914 and PCT/MY2019/050033

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. Suitable for food contact: Tested in accordance with BS EN 1186-9/2002. (In application EC 1935/2004)

Notified body: SATRA TECHNOLOGY EUROPE LTD, Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland (N.B. 2777)

Novolab NV declares that ROLL-O-GLOVE® Nitri - Extra Sensitive disposable powder free nitrile gloves are personal protective equipment(PPE) in conformity with Council Directive 89/686/EEC 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). The gloves are non-sterile gloves with a typical length of 240mm with blue colour. ROLL-O-GLOVE® Nitri - Extra Sensitive are also in compliance with Medical Device Directive MDR (EU) 2017/745. This device is identical to the PPE which is the subject of EC Type certificate 2777/13038-02/E00-00 issued by the 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. Nitrile gloves are not biodegradable and thus should be disposed properly. Nitrile 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. Nitrile disposable gloves are not suitable for thermal, cryo- or mechanical protection. Immediately discontinue use if damaged.

Fit for special purpose – size & length: Size L-9 and XL-10 are shorter than required by EN ISO 21420: 2020.

This declaration is valid for ROLL-O-GLOVE® Nitri - Extra Sensitive, only in its unopened, undamaged package.

For Novolab NV:

Bram Gernaey
General Manager
Novolab NV