

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the :

Manufacturer:

O&M HALYARD, Inc.
9120 Lockwood Blvd
Mechanicsville, VA. 23116

EU Authorized Representative:

Arc Royal
Virginia Road Kells, Co
Meath, Ireland

Technical File TF12-02 for Non-Sterile Protective Gloves

| Product Code | Product Description | Color |
|--------------|---|------------|
| CLN3031XS | HALYARD PUREZERO HG3 WHITE NITRILE GLOVES NON-STERILE AMBI (TACKY) | WHITE |
| CLN3031SM | HALYARD PUREZERO HG3 WHITE NITRILE GLOVES NON-STERILE AMBI (TACKY) | WHITE |
| CLN3031MD | HALYARD PUREZERO HG3 WHITE NITRILE GLOVES NON-STERILE AMBI (TACKY) | WHITE |
| CLN3031LG | HALYARD PUREZERO HG3 WHITE NITRILE GLOVES NON-STERILE AMBI (TACKY) | WHITE |
| CLN3031XL | HALYARD PUREZERO HG3 WHITE NITRILE GLOVES NON-STERILE AMBI (TACKY) | WHITE |
| CLN3231XS | HALYARD PUREZERO HG3 SMOOTH WHITE NITRILE GLOVES NON-STERILE AMBI (SLICK) | WHITE |
| CLN3231SM | HALYARD PUREZERO HG3 SMOOTH WHITE NITRILE GLOVES NON-STERILE AMBI (SLICK) | WHITE |
| CLN3231MD | HALYARD PUREZERO HG3 SMOOTH WHITE NITRILE GLOVES NON-STERILE AMBI (SLICK) | WHITE |
| CLN3231LG | HALYARD PUREZERO HG3 SMOOTH WHITE NITRILE GLOVES NON-STERILE AMBI (SLICK) | WHITE |
| CLN3231XL | HALYARD PUREZERO HG3 SMOOTH WHITE NITRILE GLOVES NON-STERILE AMBI (SLICK) | WHITE |
| CLN9031XS | HALYARD PUREZERO HG3 LIGHT BLUE NITRILE GLOVE, NON-STERILE, AMBI, TACKY | LIGHT BLUE |
| CLN9031SM | HALYARD PUREZERO HG3 LIGHT BLUE NITRILE GLOVE, NON-STERILE, AMBI, TACKY | LIGHT BLUE |
| CLN9031MD | HALYARD PUREZERO HG3 LIGHT BLUE NITRILE GLOVE, NON-STERILE, AMBI, TACKY | LIGHT BLUE |
| CLN9031LG | HALYARD PUREZERO HG3 LIGHT BLUE NITRILE GLOVE, NON-STERILE, AMBI, TACKY | LIGHT BLUE |
| CLN9031XL | HALYARD PUREZERO HG3 LIGHT BLUE NITRILE GLOVE, NON-STERILE, AMBI, TACKY | LIGHT BLUE |

The object of the declaration is in conformity with PPE Regulation 2016/425. Conformity is declared with the following standards :

| Standards: |
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| EN 420:2003+A1:2009 Protective Gloves. General requirements |
| EN ISO 374-1:2016 Protective Gloves Against dangerous chemicals and microorganisms. Terminology and performance requirements for chemical risks. |
| EN ISO 374-2:2019 Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration. |
| EN ISO 374-4:2019. Protective gloves against chemicals and micro-organisms. Determination of resistance by chemicals |
| EN ISO 374-5:2016. Protective gloves against chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks. |
| EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact. |

This declaration confirms that the notified body, BSI Group Netherlands, Notified Body Number 2797 (John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands) performed the EU type-examination (Module B) and issued the EU type-examination certificate CE 725272, CE 725275, and CE 725276. Protective gloves are classified as Category III under the PPE Regulation 2016/425 and Protective gloves are in conformance to type based on internal production control plus supervised product checks at random intervals (Module C2) under CE 708082.

Authorized Signature :

 2 July 2020

Steven Dowdley
Associate Director Regulatory Affairs
O&M HALYARD, Inc.
9120 lockwood blvd , Mechanicsville, VA, 23116
Date :

Note: EU DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: <http://www.halyardhealth.com/information>