

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:
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>