EU DECLARATION OF CONFORMITY

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

Manufacturer:

O&M Halyard, Inc.
1220 Old Alpharetta Rd.,
Ste. 320, Alpharetta, GA 30005

EU Authorized Representative:

Arc Royal
Virginia Road Kells, Co
Meath, Ireland

Technical File TF12-02 for Synthetic Gloves (PPE)

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 WHITE SGX* NITRILE GLOVES NON-STERILE AMBI (SLICK)	WHITE
CLN3231SM	HALYARD PUREZERO HG3 WHITE SGX* NITRILE GLOVES NON-STERILE AMBI (SLICK)	WHITE
CLN3231MD	HALYARD PUREZERO HG3 WHITE SGX* NITRILE GLOVES NON-STERILE AMBI (SLICK)	WHITE
CLN3231LG	HALYARD PUREZERO HG3 WHITE SGX* NITRILE GLOVES NON-STERILE AMBI (SLICK)	WHITE
CLN3231XL	HALYARD PUREZERO HG3 WHITE SGX* 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
CLN30512XS	HALYARD* PUREZERO* HG5 WHITE NITRILE GLOVES, NON-STERILE, AMBI, TACKY	WHITE

CLN30512SM	HALYARD* PUREZERO* HG5 WHITE NITRILE GLOVES, NON-STERILE, AMBI, TACKY	WHITE
CLN30512MD	HALYARD* PUREZERO* HG5 WHITE NITRILE GLOVES, NON-STERILE, AMBI, TACKY	WHITE
CLN30512LG	HALYARD* PUREZERO* HG5 WHITE NITRILE GLOVES, NON-STERILE, AMBI, TACKY	WHITE
CLN30512XL	HALYARD* PUREZERO* HG5 WHITE NITRILE GLOVES, NON-STERILE, AMBI, TACKY	WHITE
CLN305122XL	HALYARD* PUREZERO* HG5 WHITE NITRILE GLOVES, NON-STERILE, AMBI, TACKY	WHITE
CLN92512XS	HALYARD* PUREZERO* HG5 BLUE SGX* NITRILE GLOVES, NON-STERILE, AMBI, SMOOTH	BLUE
CLN92512SM	HALYARD* PUREZERO* HG5 BLUE SGX* NITRILE GLOVES, NON-STERILE, AMBI, SMOOTH	BLUE
CLN92512MD	HALYARD* PUREZERO* HG5 BLUE SGX* NITRILE GLOVES, NON-STERILE, AMBI, SMOOTH	BLUE
CLN92512LG	HALYARD* PUREZERO* HG5 BLUE SGX* NITRILE GLOVES, NON-STERILE, AMBI, SMOOTH	BLUE
CLN92512XL	HALYARD* PUREZERO* HG5 BLUE SGX* NITRILE GLOVES, NON-STERILE, AMBI, SMOOTH	BLUE
CLN90511XS	HALYARD* PUREZERO* HG5 BLUE NITRILE 10 IN. GLOVES, NON-STERILE, AMBI, TACKY	BLUE
CLN90511SM	HALYARD* PUREZERO* HG5 BLUE NITRILE 10 IN. GLOVES, NON-STERILE, AMBI, TACKY	BLUE
CLN90511MD	HALYARD* PUREZERO* HG5 BLUE NITRILE 10 IN. GLOVES, NON-STERILE, AMBI, TACKY	BLUE
CLN90511LG	HALYARD* PUREZERO* HG5 BLUE NITRILE 10 IN. GLOVES, NON-STERILE, AMBI, TACKY	BLUE
CLN90511XL	HALYARD* PUREZERO* HG5 BLUE NITRILE 10 IN. GLOVES, NON-STERILE, AMBI, TACKY	BLUE
CLN8231XS/ CLN82318XS	HALYARD* PUREZERO* HG3 CREAM* LATEX GLOVES	CREAM
CLN8231SM/ CLN82318SM	HALYARD* PUREZERO* HG3 CREAM* LATEX GLOVES	CREAM
CLN8231MD/ CLN82318MD	HALYARD* PUREZERO* HG3 CREAM* LATEX GLOVES	CREAM
CLN8231LG/ CLN82318LG	HALYARD* PUREZERO* HG3 CREAM* LATEX GLOVES	CREAM
CLN8231XL/ CLN82318XL	HALYARD* PUREZERO* HG3 CREAM* LATEX GLOVES	CREAM

The object of the declaration is in conformity with Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment. Conformity is declared with the following standards :

Standards:
EN ISO 21420:2020 Protective gloves - General requirements and test methods.
EN ISO 374-1:2016+A1:2018 Protective Gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration.
EN ISO 374-4:2019 Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals
EN ISO 374-5:2016 Protective gloves against dangerous 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 potentially hazardous liquid chemicals under conditions of continuous contact.
ISO 16604:2004 Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens - Test method using Phi-X174 bacteriophage.
Below standard only applicable for HG3 Nitrile gloves with certificate number; CE 725272, CE 725275, CE 725276: EN 421:2010 Protective gloves against ionizing radiation and radioactive contamination

This declaration confirms that the notified body, BSI Group The Netherlands B.V., 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 certificates CE 725272, CE 725275, CE 725276, CE 773144, CE 773145, CE 773146 and CE 815812. Cleanroom gloves are classified as Category III under the PPE Regulation 2016/425 and Cleanroom 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 :

Caitlin Senter
Director, Global Regulatory Affairs
O&M Halyard, Inc.
1220 Old Alpharetta Rd., Ste. 320, Alpharetta, GA 30005
Date : 08 May 2025

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**