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 TF12-03 for Synthetic Gloves (PPE)

Product Code	Product Description	Color
CLN323260	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323265	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323270	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323275	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323280	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323285	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323290	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323210	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN923260	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923265	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923270	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923275	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923280	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923285	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923290	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923210	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN823260/ CLN8232860	HALYARD* PUREZERO* HG3 CREAM* STERILE LATEX GLOVES	CREAM

CLN823265/ CLN8232865	HALYARD* PUREZERO* HG3 CREAM* STERILE LATEX GLOVES	CREAM
CLN823270/ CLN8232870	HALYARD* PUREZERO* HG3 CREAM* STERILE LATEX GLOVES	CREAM
CLN823275/ CLN8232875	HALYARD* PUREZERO* HG3 CREAM* STERILE LATEX GLOVES	CREAM
CLN823280/ CLN8232880	HALYARD* PUREZERO* HG3 CREAM* STERILE LATEX GLOVES	CREAM
CLN823285/ CLN8232885	HALYARD* PUREZERO* HG3 CREAM* STERILE LATEX GLOVES	CREAM
CLN823290/ CLN8232890	HALYARD* PUREZERO* HG3 CREAM* STERILE LATEX GLOVES	CREAM
CLN823210/ CLN8232810	HALYARD* PUREZERO* HG3 CREAM* STERILE 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 725270, CE 725273 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 725270, CE 725273 and CE 815813. 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**