

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 TF12-03 for Sterile Protective Gloves

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

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 725270 and CE CE 275273. 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 :



August 31, 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>