UK 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

UK Responsible Person

RLD Quality Limited
Centenary House
Peninsula Park
Rydon Lane
Exeter, EX2 7XE
United Kingdom

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

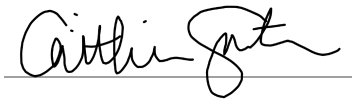
The object of the declaration is in conformity with the Regulation 2016/425 on Personal Protective Equipment, as amended to apply in GB. Conformity is declared with the following standards :

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; UKCA 750144, UKCA 750142, UKCA 750140: EN 421:2010 Protective gloves against ionizing radiation and radioactive contamination

This declaration confirms that the approved body, BSI Assurance UK Ltd, Approved Body Number 0086 (Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom) performed the UKCA-Type Examination (Module B) set out in Annex V and issued the UKCA Type Examination Certifcate UKCA 750144, UKCA 750142, UKCA 750140, UKCA 773147, UKCA 773148, UKCA 773149 and UKCA 815814**.** Cleanroom gloves are classified as Category III under the PPE Regulation 2016/425 on personal protective equipment as brought into UK law and amended.

The PPE are subject to the conformity assessment procedure conformity described in Regulation 2016/425 on personal protective equipment, as amended to apply in GB based on internal production control plus supervised product checks at random intervals (Module C2) set out in Annex VII under surveillance of the approved body BSI Assurance UK Ltd, Approved Body Number 0086, (Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom), which issued the certificate UKCA 750172.

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