

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Name of Products:	Medical Exam Gloves, Non-Sterile Protective Gloves, Non-Sterile
Product Codes:	See Attachment A
UMDNS Code:	N/A
GMDN Code:	56286 (Nitrile examination/treatment glove, non-powdered, non-sterile)
CND Code:	T01020204: Examination/Treatment Gloves, Nitrile
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
Manufacturer SRN :	N/A
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN:	IE-AR-0000003110
UDI-DI: (device level)	06806517MEG001A3
Start of CE:	04 February 2014
Conformity Assessment Route:	Annex VIII of Regulation (EU) 2017/745 MDR 2017/745

	<p>It concerns a self-certified medical device in accordance with the MDR and that the DoC was drawn up in accordance with annex IV and the technical documentation in accordance with annex II and III.</p> <p>PPER 2016/425 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) set out in Annex V and issued the EU-Type Examination Certificates: CE 708072, CE 708074, CE 708076, CE 708077, CE 708078, CE 707079, CE 708080, CE 708081, CE 698766</p> <p>The PPE are subject to the conformity assessment procedure conformity to type based on internal production controls and supervised product checks at random intervals (Module C2) set out in Annex VII under surveillance of the notified body BSI Group Netherlands, Notified Body Number 2797 (John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands), which issued the certificate CE 708082. Module B EU Type Examination of Regulation (EU) 2016/42</p>
Risk Classification, Rules:	<p>Class I NS per Rule 1, Annex VIII Regulation (EU) 2017/745 Category III PPE per Regulation (EU) 2016/425</p>
CE certificate number:	<p>EU Type Examination Certificates (Module B): CE 708072, CE 708074, CE 708076, CE 708077, CE 708078, CE 707079, CE 708080, CE 708081, CE 698766</p> <p>EU Internal Production Controls and Supervised Product Checks at Random Intervals (Module C2): CE 708082</p>
Notified Body:	BSI-NL (2797)
Quality System Certificate:	FM 697013

COMMON SPECIFICATIONS: **NOT APPLICABLE**

The object of the declaration is in conformity with the PPE Regulation 2016/425 in addition to Medical Device Regulation (EU) 2017/745. Conformity to Regulation 2016/425 is declared with the following standards:

Applicable 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 374-2:2014 Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.
EN 374-4:2013. 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 Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.
EN 455-1:2001 Medical gloves for single use . Requirements and testing for freedom from holes.
EN 455-2:2015 Medical gloves for single use. Requirements for physical properties.
EN 455-3:2015 Medical gloves for single use. Requirements and testing for biological evaluation.
EN 455-4:2009 Medical gloves for single use. Requirements and testing for shelf life determination.

This declaration confirms that the notified body, BSI Group, 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 698766, 708074, 708072, 708078, 708080, 708077, 708081, 708076, 708079). 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) and issued CE 708082.

STATEMENT: I, the undersigned, hereby declare that the specified medical device(s) and personal protective equipment (PPE) meet(s) the applicable provisions of Regulation (EU) 2017/745 concerning Medical Devices and Regulation (EU) 2016/425 concerning Personal Protective Equipment.

All supporting documentation that contains proof of compliance to the aforementioned Regulation(s) is retained under the premises of O&M Halyard, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:



On behalf of O&M Halyard, Inc

Name: Steven Dowdley
 Title: Director, Regulatory Affairs
 Address: O&M Halyard, Inc.
 9120 Lockwood Blvd.
 Mechanicsville, Virginia (VA) 23116
 United States of America

Date: **30 November 2021**

ATTACHMENT A: Product Codes and Descriptions for Medical Exam Gloves & Personal Protective Gloves (Non-Sterile)

Global SKU	Description	Color	UDI-DI
13938	STERLING* NITRILE Powder-Free Exam Gloves, XS	grey	06806517MEG001A3
13940	STERLING* NITRILE Powder-Free Exam Gloves, S	grey	06806517MEG001A3
13941	STERLING* NITRILE Powder-Free Exam Gloves, M	grey	06806517MEG001A3
13942	STERLING* NITRILE Powder-Free Exam Gloves, L	grey	06806517MEG001A3
13943	STERLING* NITRILE Powder-Free Exam Gloves, XL	grey	06806517MEG001A3
44286	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, XS	grey	06806517MEG001A3
44287	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, S	grey	06806517MEG001A3
44288	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, M	grey	06806517MEG001A3
44289	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, L	grey	06806517MEG001A3
44290	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, XL	grey	06806517MEG001A3
44740	BASICS* White Powder-Free Nitrile Exam Gloves, XS	White	06806517MEG001A3
44741	BASICS* White Powder-Free Nitrile Exam Gloves, S	White	06806517MEG001A3
44742	BASICS* White Powder-Free Nitrile Exam Gloves, M	White	06806517MEG001A3
44743	BASICS* White Powder-Free Nitrile Exam Gloves, L	White	06806517MEG001A3
44744	BASICS* White Powder-Free Nitrile Exam Gloves, XL	White	06806517MEG001A3
44749	BASICS* Blue Powder-Free Nitrile Exam Gloves, XS	Blue	06806517MEG001A3
44750	BASICS* Blue Powder-Free Nitrile Exam Gloves, S	Blue	06806517MEG001A3
44751	BASICS* Blue Powder-Free Nitrile Exam Gloves, M	Blue	06806517MEG001A3
44752	BASICS* Blue Powder-Free Nitrile Exam Gloves, L	Blue	06806517MEG001A3
44753	BASICS* Blue Powder-Free Nitrile Exam Gloves, XL	Blue	06806517MEG001A3
45256	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, XS	orange inner layer with black outer layer (can be reversed)	06806517MEG001A3
45257	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, S	orange inner layer with black outer layer (can be reversed)	06806517MEG001A3
45258	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, M	orange inner layer with black outer layer (can be reversed)	06806517MEG001A3
45259	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, L	orange inner layer with black outer layer (can be reversed)	06806517MEG001A3
45260	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, XL	orange inner layer with black	06806517MEG001A3

		outer layer (can be reversed)	
47195	PURPLE NITRILE* MAX Powder-Free Exam Gloves, S, 16" Extended Cuff	Purple	06806517MEG001A3
47196	PURPLE NITRILE* MAX Powder-Free Exam Gloves, M, 16" Extended Cuff	Purple	06806517MEG001A3
47197	PURPLE NITRILE* MAX Powder-Free Exam Gloves, L, 16" Extended Cuff	Purple	06806517MEG001A3
47198	PURPLE NITRILE* MAX Powder-Free Exam Gloves, XL, 16" Extended Cuff	Purple	06806517MEG001A3
47471	STERLING ZERO* Nitrile Powder-Free Exam Gloves, XS	Grey	06806517MEG001A3
47472	STERLING ZERO* Nitrile Powder-Free Exam Gloves, S	Grey	06806517MEG001A3
47473	STERLING ZERO* Nitrile Powder-Free Exam Gloves, M	Grey	06806517MEG001A3
47474	STERLING ZERO* Nitrile Powder-Free Exam Gloves, L	Grey	06806517MEG001A3
47475	STERLING ZERO* Nitrile Powder-Free Exam Gloves, XL	Grey	06806517MEG001A3
50600M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, XS	Purple	06806517MEG001A3
50601M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, S	Purple	06806517MEG001A3
50602M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, M	Purple	06806517MEG001A3
50603M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, L	Purple	06806517MEG001A3
50604M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, XL	Purple	06806517MEG001A3
52000M	PURPLE NITRILE* Powder-Free Exam Gloves, XS	Purple	06806517MEG001A3
52001M	PURPLE NITRILE* Powder-Free Exam Gloves, S	Purple	06806517MEG001A3
52002M	PURPLE NITRILE* Powder-Free Exam Gloves, M	Purple	06806517MEG001A3
52003M	PURPLE NITRILE* Powder-Free Exam Gloves, L	Purple	06806517MEG001A3
52004M	PURPLE NITRILE* Powder-Free Exam Gloves, XL	Purple	06806517MEG001A3