

EC Declaration of Conformity

Product description : Synthetic Gloves – Non-sterile

Product Codes : See **Attachment A**

UMDNS Code: 11882 (Gloves Examination/Treatment)

GMDN Code: 56286 (Nitrile Examination/Treatment Glove, Non-powdered)
47176 (Vinyl Examination/Treatment Glove, Non-powdered)

CE Manufacturer (and place of issue): O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116, USA

EU Authorized Representative: Arc Royal
Virginia Road Kells, Co
Meath, Ireland

Product Standards: BS EN 455-1:2000
BS EN 455-2:2015
BS EN 455-3:2015
BS EN 455-4:2009

Start of CE: See **Attachment A**

Conformity Assessment Route: Annex VII

Device Classification: I (as per rule One of Annex IX)

CE certificate number: N/A

Quality Systems Certificate: FM 697013 (BSI)

I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Directive(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:



Name: Angela L. Bunn, RAC *1-AUG-2019*
Title: Director, Regulatory Affairs Global Products Division
O&M Halyard, Inc.

Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity

Product Code	Alternative Code	Product Description	Start of CE mark
50600M	50481	PURPLE NITRILE-XTRA* Powder-Free Purple Nitrile* Exam Gloves/X-Small (5,5)	04-Feb-2015
50601M	50482	PURPLE NITRILE-XTRA* Powder-Free Purple Nitrile* Exam Gloves/Small (6,5)	04-Feb-2015
50602M	50483	PURPLE NITRILE-XTRA* Powder-Free Purple Nitrile* Exam Gloves/Medium (7,5)	04-Feb-2015
50603M	50484	PURPLE NITRILE-XTRA* Powder-Free Purple Nitrile* Exam Gloves/Large (8,5)	04-Feb-2015
50604M	50485	PURPLE NITRILE-XTRA* Powder-Free Purple Nitrile* Exam Gloves/X-Large (9)	04-Feb-2015
52000M	50486	PURPLE NITRILE* Powder-Free Purple Nitrile* Exam Gloves X-Small (5,5)	04-Feb-2015
52001M	50487	PURPLE NITRILE* Powder-Free Purple Nitrile Exam Gloves/Small (6,5)	04-Feb-2015
52002M	50488	PURPLE NITRILE* Powder-Free Purple Nitrile Exam Gloves/Medium (7,5)	04-Feb-2015
52003M	50489	PURPLE NITRILE* Powder-Free Purple Nitrile Exam Gloves/Large (8,5)	04-Feb-2015
52004M	50490	PURPLE NITRILE* Powder-Free Purple Nitrile Exam Gloves/X-Large (9)	04-Feb-2015
55030M	65030	Synthetic Exam PF Vinyl Multi-Lingual, XS	04-Feb-2015
55031M	65031	Synthetic Exam PF Vinyl Multi-Lingual, Small	04-Feb-2015
55032M	65032	Synthetic Exam PF Vinyl Multi-Lingual, Medium	04-Feb-2015
55033M	65033	Synthetic Exam PF Vinyl Multi-Lingual, Large	04-Feb-2015
55034M	65034	Synthetic Exam PF Vinyl Multi-Lingual, XL	04-Feb-2015
31197	570225	Kirkland Nitrile Exam Gloves - Small	15-Mar-2016
31200	570224	Kirkland Nitrile Exam Gloves - Medium	15-Mar-2016
31210	570226	Kirkland Nitrile Exam Gloves - Large	15-Mar-2016
13938	N/A	Sterling* Nitrile Powder-Free Exam Gloves, CE, XS	04-Feb-2015
13940	N/A	Sterling* Nitrile Powder-Free Exam Gloves, CE, Small	04-Feb-2015
13941	N/A	Sterling* Nitrile Powder-Free Exam Gloves, CE, Medium	04-Feb-2015
13942	N/A	Sterling* Nitrile Powder-Free Exam Gloves, CE, Large	04-Feb-2015
13943	N/A	Sterling* Nitrile Powder-Free Exam Gloves, CE, XL	04-Feb-2015
44286	N/A	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, XS (CE)	28-Aug-2015
44287	N/A	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, S (CE)	28-Aug-2015
44288	N/A	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, M (CE)	28-Aug-2015
44289	N/A	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, L (CE)	28-Aug-2015
44290	N/A	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, XL (CE)	28-Aug-2015
44740	N/A	BASICS* White Powder-Free Nitrile Exam Gloves, XS	18-May-2016
44741	N/A	BASICS* White Powder-Free Nitrile Exam Gloves, S	18-May-2016

Product Code	Alternative Code	Product Description	Start of CE mark
44742	N/A	BASICS* White Powder-Free Nitrile Exam Gloves, M	18-May-2016
44743	N/A	BASICS* White Powder-Free Nitrile Exam Gloves, L	18-May-2016
44744	N/A	BASICS* White Powder-Free Nitrile Exam Gloves, XL	18-May-2016
44749	N/A	BASICS* Blue Powder-Free Nitrile Exam Gloves, XS	18-May-2016
44750	N/A	BASICS* Blue Powder-Free Nitrile Exam Gloves, S	18-May-2016
44751	N/A	BASICS* Blue Powder-Free Nitrile Exam Gloves, M	18-May-2016
44752	N/A	BASICS* Blue Powder-Free Nitrile Exam Gloves, L	18-May-2016
44753	N/A	BASICS* Blue Powder-Free Nitrile Exam Gloves, XL	18-May-2016
45256	N/A	Black Fire* Powder-Free Nitrile Exam Gloves, XS	16-Mar-2017
45257	N/A	Black Fire* Powder-Free Nitrile Exam Gloves, Small	16-Mar-2017
45258	N/A	Black Fire* Powder-Free Nitrile Exam Gloves, Medium	16-Mar-2017
45259	N/A	Black Fire* Powder-Free Nitrile Exam Gloves, Large	16-Mar-2017
45260	N/A	Black Fire* Powder-Free Nitrile Exam Gloves, XL	16-Mar-2017
47195	N/A	PURPLE NITRILE* MAX Powder-Free Exam Gloves/Small	3-Nov-2017
47196	N/A	PURPLE NITRILE* MAX Powder-Free Exam Gloves/Medium	3-Nov-2017
47197	N/A	PURPLE NITRILE* MAX Powder-Free Exam Gloves/Large	3-Nov-2017
47198	N/A	PURPLE NITRILE* MAX Powder-Free Exam Gloves/X-Large	3-Nov-2017
47471	N/A	STERLING ZERO* Nitrile Powder-Free Exam Gloves, XS	31-July-2019
47472	N/A	STERLING ZERO* Nitrile Powder-Free Exam Gloves, S	31-July-2019
47473	N/A	STERLING ZERO* Nitrile Powder-Free Exam Gloves, M	31-July-2019
47474	N/A	STERLING ZERO* Nitrile Powder-Free Exam Gloves, L	31-July-2019
47475	N/A	STERLING ZERO* Nitrile Powder-Free Exam Gloves, XL	31-July-2019