

Declaration of Conformity

Product description :	Synthetic Gloves – Sterile
Product Codes :	See attached Annex (product list)
UMDNS Code:	11882 (Gloves Examination / Treatment)
GMDN Code:	61631 (Nitrile examination/treatment glove, non-powdered, sterile)
Legal Manufacturer (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 455-4:2009
Start of CE:	See attached Annex (product list)
Conformity Assessment Route:	Annex V and VII
Device Classification:	Class I Sterile, per Rule 1 of Annex IX
CE certificate number:	CE 698961
Notified Body:	BSI (2797)
Quality Certificate Number:	FM 697013

We hereby declare that the above mentioned devices comply with the provisions of the European 93/42/EEC Council Directive on Medical Devices.

All supporting documentation is retained at the premises of O&M Halyard, Inc. This declaration of conformity is issued under the sole responsibility of O&M Halyard, Inc. and is valid for the products listed on the attached product list in their original, unmodified packaging.

Authorized Signature:

 23 June 2020

Name: Steven Dowdley
Title: Associate Director, Regulatory Affairs
O&M Halyard, Inc.

Annex (Product List)

This declaration of conformity is issued under the sole responsibility of Halyard Health, Inc. and is valid for the products listed on the attached product list in their original, unmodified packaging.

Product Code	Alternative Code	Description	Start of CE mark
50494	52201M	PURPLE NITRILE* Sterile Powder-Free Exam Gloves / S (6-6,5)	04-Feb-2015
50495	52202M	PURPLE NITRILE* Sterile Powder-Free Exam Gloves / M (7-7,5)	04-Feb-2015
50496	52203M	PURPLE NITRILE* Sterile Powder-Free Exam Gloves / L (8-8,5)	04-Feb-2015

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:

 23 June 2020

Name: Steve Dowdley
Title: Associate Director, Regulatory Affairs
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