

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): Halyard Health, Inc.
5405 Windward Parkway
Alpharetta, Georgia (GA) 30004, USA

EU Authorized Representative: Halyard Belgium BVBA
Leonardo Da Vincilaan 1
1930 Zaventem
Belgium

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

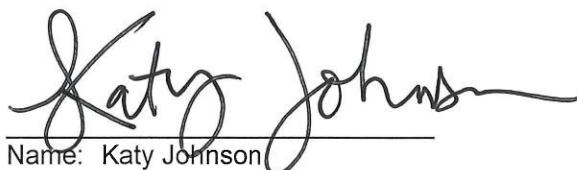
Notified Body: N/A

ISO certificate number: ISO 13485:2012 No. Q1N 15 01 90627 002 (TUV)

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 Halyard Health, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:



Name: Katy Johnson
Title: Regulatory Affairs Technical Leader
Halyard Health, Inc.
Date: 3-Nov-2017

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
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
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

Product Code	Alternative Code	Product Description	Start of CE mark
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