HALYARD
Part of the Owens & Minor Family

EC Declaration of Conformity

Name of Products:	Medical Exam 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: **UDI-DI: (device level)**	N/A N/A
Start of CE:	9 July 2020
Conformity Assessment Route:	Annex VIII of Regulation (EU) 2017/745
Risk Classification, Rules:	Class I NS per Rule 1, Annex VIII Regultion (EU) 2017/745
CE certificate number:	N/A

O&M Halyard, Inc.
5405 Windward Parkway
Alpharetta, Georgia 30004

1-844-HALYARD

halyardhealth.com

Translation of this document will be available upon request

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Notified Body:	BSI-NL
Quality System Certificate:	FM 697013

COMMON SPECIFICATIONS: **NOT APPLICABLE**

STATEMENT: I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Regulation (EU) 2017/745 concerning Medical Devices.

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:

Angela L Bunn

On behalf of O&M Halyard, Inc

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

Date: 09 July 2020

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

Global SKU	Description	UDI-DI
13938	STERLING* NITRILE Powder-Free Exam Gloves, XS	
13940	STERLING* NITRILE Powder-Free Exam Gloves, S	
13941	STERLING* NITRILE Powder-Free Exam Gloves, M	
13942	STERLING* NITRILE Powder-Free Exam Gloves, L	
13943	STERLING* NITRILE Powder-Free Exam Gloves, XL	
31197	Kirkland Nitrile Exam Gloves – Small	
31200	Kirkland Nitrile Exam Gloves – Medium	
31210	Kirkland Nitrile Exam Gloves – Large	
44286	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, XS	
44287	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, S	
44288	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, M	
44289	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, L	
44290	STERLING* NITRILE-XTRA* Powder-Free Exam Gloves, XL	
45256	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, XS	
45257	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, S	
45258	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, M	
45259	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, L	
45260	BLACK-FIRE* Powder-Free Nitrile Exam Gloves, XL	
47195	PURPLE NITRILE* MAX Powder-Free Exam Gloves, S, 16" Extended Cuff	
47196	PURPLE NITRILE* MAX Powder-Free Exam Gloves, M, 16" Extended Cuff	
47197	PURPLE NITRILE* MAX Powder-Free Exam Gloves, L, 16" Extended Cuff	
47198	PURPLE NITRILE* MAX Powder-Free Exam Gloves, XL, 16" Extended Cuff	
47471	STERLING ZERO* Nitrile Powder-Free Exam Gloves, XS	
47472	STERLING ZERO* Nitrile Powder-Free Exam Gloves, S	
47473	STERLING ZERO* Nitrile Powder-Free Exam Gloves, M	
47474	STERLING ZERO* Nitrile Powder-Free Exam Gloves, L	
47475	STERLING ZERO* Nitrile Powder-Free Exam Gloves, XL	
50601M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, S	
50602M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, M	
50603M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, L	
50604M	PURPLE NITRILE-XTRA* Powder-Free Exam Gloves, XL	
52000M	PURPLE NITRILE* Powder-Free Exam Gloves, XS	
52001M	PURPLE NITRILE* Powder-Free Exam Gloves, S	
52002M	PURPLE NITRILE* Powder-Free Exam Gloves, M	
52003M	PURPLE NITRILE* Powder-Free Exam Gloves, L	
52004M	PURPLE NITRILE* Powder-Free Exam Gloves, XL	