HALYARD
Part of the Owens & Minor Family

EU DECLARATION OF CONFORMITY

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

Name of Product:	Synthetic Gloves (PPE) – Non-sterile
Product Codes:	See **Attachment A**
Technical File Number :	12-04 Rev. 04
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. 1220 Old Alpharetta Rd., Ste. 320, Alpharetta, GA 30005 United States of America
Manufacturer SRN :	US-MF-000043924
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN:	IE-AR-000003110
Basic UDI-DI:	06806517MEG001A3
Start of CE:	28 October 2022 per Regulation 2017/745 21 September 2022 per Regulation 2016/425
Conformity Assessment Route:	Annex VIII of Regulation (EU) 2017/745 **MDR 2017/745** 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. **PPER 2016/425** The PPE are subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) set out in Annex VII under surveillance of the notifed body BSI Group The

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information

	Netherlands B.V., Notified Body Number 2797 (John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands), which issued the certificate of Module C2: CE 708082 and Module B: CE 759289, CE 759290, CE 759291, CE 760576 and CE 760577.
Risk Classification, Rules:	Class I NS per Rule 1, Annex VIII Regulation (EU) 2017/745 Category III PPE per Regulation (EU) 2016/425
Notified Body:	BSI Group The Netherlands B.V., Notified Body Number 2797 John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Quality System Certificate:	FM 697013

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

Applicable Standards:	
Quality System	BS EN ISO 13485:2016 PPE Regulation (EU) 2016/425 (MODULE C2)
Risk Management	BS EN ISO 14971:2019
Biocompatibility	BS EN ISO 10993-2009 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013
Packaging	(Not Applicable)
Labeling	BS EN ISO 15223-1:2021 and BS EN 1041:2008+A1:2013
Sterilization	(Not Applicable) Non-Sterile
Clinical	MEDDEV 2.7.1
Product Specific	EN 455-1:2020+A1:2022 EN 455-2:2015 EN 455-3:2015 EN 455-4:2009 EN ISO 21420:2020 EN ISO 374-1:2016+A1:2018 EN ISO 374-2:2019 EN ISO 374-4:2019 EN ISO 374-5:2016 EN 16523-1:2015+A1:2018 ISO 16604:2004

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information

STATEMENT: I, the undersigned, hereby declare that the product listed in Attachment A meets the applicable provisions of the 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.

Authorized Signature:

On behalf of O&M Halyard, Inc

Name: Caitlin Senter
Title: Director, Global Regulatory Affairs
Address: O&M Halyard, Inc.
1220 Old Alpharetta Rd.,
Ste. 320, Alpharetta, GA 30005
United States of America
Date: 18 September 2025

ATTACHMENT A: Product List

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information

HALYARD
Part of the Owens & Minor Family

Attachment A (Product List)

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

Alternative Code	Product Code	Product Description	Start of CE mark
LFS111XS	48766	PUREZERO* MARIN* NITRILE Exam Gloves/X-Small (5,5)	21 September 2022
LFS111SM	48767	PUREZERO* MARIN* NITRILE Exam Gloves/Small (6,5)	21 September 2022
LFS111MD	48768	PUREZERO* MARIN* NITRILE Exam Gloves/Medium (7,5)	21 September 2022
LFS111LG	48769	PUREZERO* MARIN* NITRILE Exam Gloves/Large (8,5)	21 September 2022
LFS111XL	48770	PUREZERO* MARIN* NITRILE Exam Gloves/X-Large (9,0)	21 September 2022
LFS121XS	48761	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves X-Small (5,5)	21 September 2022
LFS121SM	48762	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves /Small (6,5)	21 September 2022
LFS121MD	48763	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves/Medium (7,5)	21 September 2022
LFS121LG	48764	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves /Large (8,5)	21 September 2022
LFS121XL	48765	PUREZERO* MARIN* XTRA* NITRILE* Exam Gloves /X-Large (9,0)	21 September 2022
LFS311XS	48750	PUREZERO* Limon* NITRILE Exam Gloves/X-Small (5,5)	21 September 2022
LFS311SM	48751	PUREZERO* Limon* NITRILE Exam Gloves/Small (6,5)	21 September 2022
LFS311MD	48752	PUREZERO* Limon* NITRILE Exam Gloves/Medium (7,5)	21 September 2022
LFS311LG	48753	PUREZERO* Limon* NITRILE Exam Gloves/Large (8,5)	21 September 2022
LFS311XL	48754	PUREZERO* Limon* NITRILE Exam Gloves/X-Large (9,0)	21 September 2022
LFS321XS	48797	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/X-Small (5,5)	21 September 2022
LFS321SM	48798	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/Small (6,5)	21 September 2022
LFS321MD	48799	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/Medium (7,5)	21 September 2022
LFS321LG	48800	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/Large (8,5)	21 September 2022
LFS321XL	48801	PUREZERO* Limon* XTRA* NITRILE Exam Gloves/X-Large (9,0)	21 September 2022
LFS511XS	48771	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/X-Small (5,5)	21 September 2022
LFS511SM	48772	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/Small (6,5)	21 September 2022
LFS511MD	48773	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/Medium (7,5)	21 September 2022
LFS511LG	48774	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/Large (8,5)	21 September 2022
LFS511XL	48775	PUREZERO* ULTRA VIOLET* NITRILE Exam Gloves/X-Large (9,0)	21 September 2022

Note: DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: www.halyardhealth.com/information