

## UKCA Declaration of Conformity

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

<b>Name of Product:</b>	Nitrile Exam Gloves – Non-sterile
<b>Product Codes:</b>	See <b>Attachment A</b>
<b>Technical File Number:</b>	012-02 Rev.00
<b>GMDN Code:</b>	56286 (Nitrile examination/treatment glove, non-powdered, non-sterile)
<b>CND Code:</b>	T01020204: Examination / Treatment Gloves, Nitrile
<b>Legal Manufacturer (Place of Issue):</b>	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
<b>Authorized Representative:</b>	ArcRoyal Virginia Road Kells, Co Meath, Ireland
<b>UK Responsible Person:</b>	RLD Quality Limited Centenary House Peninsula Park Rydon Lane Exeter, EX2 7XE United Kingdom
<b>Start of UKCA:</b>	02 February 2024 per UK MDR 2002 31 October 2023 per Regulation 2016/425 on personal protective equipment, as amended to apply in GB
<b>Conformity Assessment Route:</b>	<p><b>UK MDR 2002</b></p> <p>It concerns a self-certified medical device in accordance with the UK MDR 2002 and that the DoC was drawn up in accordance with annex VII and the technical documentation in accordance with section III.</p> <p><b>PPER 2016/425, as amended to apply in GB</b></p> <p>The PPE are subject to the conformity assessment procedure conformity to type based on quality assurance of the production process' (Module B) set out in Annex V under surveillance of the notified body SATRA Technology Centre, (Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, UK). which issued the certificate CE AB0321/17717-01/E07-01.</p>

<b>Risk Classification, Rules:</b>	Class I NS per Rule 1, Annex IX [as modified by Part II of Schedule 2A to the UK MDR 2002]  Category III PPE per Regulation 2016/425 on personal protective equipment, as amended to apply in GB
<b>Notified Body:</b>	SATRA Technology Centre Notified Body Number 0321 Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, UK
<b>Quality System Certificate:</b>	FM 697013

The object of the declaration is in conformity with Regulation 2016/425 on personal protective equipment, as amended to apply in GB and UK MDR 2002. Conformity is declared with the following standards:

<b>Applicable Standards:</b>	
<b>Quality System</b>	BS EN ISO 13485:2016 Regulation 2016/425 on personal protective equipment, as amended to apply in GB (PPE) Annex V (Module B)
<b>Risk Management</b>	BS EN ISO 14971:2019
<b>Packaging</b>	(Not Applicable)
<b>Labeling</b>	BS EN ISO 15223-1:2021 and BS EN 1041:2008+A1:2013
<b>Sterilization</b>	(Not Applicable) Non-Sterile
<b>Clinical</b>	MEDDEV 2.7.1
<b>Product Specific</b>	EN 455-1:2022 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

STATEMENT: I, the undersigned, hereby declare that the product listed in Attachment A meets the applicable provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB (PPE) and UK MDR 2002.

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, MS, RAC

Title: Director, Global Regulatory Affairs

Address: O&M Halyard, Inc.

9120 Lockwood Blvd.

Mechanicsville, Virginia (VA) 23116

United States of America

Date: 02 February 2024

**ATTACHMENT A: Product Codes**

**Attachment A (Product List)**

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

<b>Product Code</b>	<b>Product Description</b>
47373	SKYBREEZE* Powder-Free Nitrile Exam Gloves, XS
47374	SKYBREEZE* Powder-Free Nitrile Exam Gloves, S
47375	SKYBREEZE* Powder-Free Nitrile Exam Gloves, M
47376	SKYBREEZE* Powder-Free Nitrile Exam Gloves, L
47377	SKYBREEZE* Powder-Free Nitrile Exam Gloves, XL