

UKCA DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer :

Manufacturer:	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, VA 23116 The United States of America
Authorized Representative:	Arc Royal Virginia Road Kells, Co Meath, Ireland
UK Responsible Person:	RLD Quality Limited Centenary House Peninsula Park Rydon Lane Exeter, EX2 7XE United Kingdom

Technical File TF-003 PPE Respirators

Product Code	Product Description	Color
62408	FFP2 NR Filtering Half Mask, Fluidshield* 3 Surgical Respirator	Yellow
62354	FFP1 NR Filtering Half Mask	White

The object of the declaration is in conformity with Regulation 2016/425 on personal protective equipment as brought into UK law and amended. Conformity is declared with the following standards:

Standards:
EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles- Requirements, testing, marking

The filtering half mask is category III PPE.

The approved body, BSI Assurance UK Ltd, Approved Body Number 0086 (Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom) performed the UKCA Examination (Module B) set out in Annex V and issued the UKCA Type Examination Certificate **UKCA 750168**.

The PPE are subject to the conformity assessment procedure 'UKCA conformity to type based on quality assurance of the production process' under the requirements of The Product Safety and Metrology etc (Amendment etc)(EU Exit) Regulations 2020 (SI 2020/676) relating to Personal Protective Equipment Regulation (PPE) 2016/425 Annex VIII (Module D), under surveillance of the notified body BSI Assurance UK Ltd, Approved Body Number 0086 (Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom) which issued the certificate **UKCA 750170**.

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: halyardhealth.com/information



Authorized Signature :

Angela L. Bunn

Angela L. Bunn (Sep 16, 2022 06:28 EDT)

Angela L. Bunn
Director, Global Regulatory Affairs
O&M Halyard, Inc.
9120 Lockwood Blvd., Mechanicsville, VA, 23116

Date: **Sep 16, 2022**