# EU Declaration of Conformity

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

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| **Name of Product:** | Facial Protection: FFP2 Respirator |
| **Product Codes:** | See **Attachment A** |
| **UMDNS Code:** | N/A |
| **GMDN Code:** | 66199 (Surgical/medical face mask, non-antimicrobial, single-use)<br>57794 (Surgical/medical respirator, non-antimicrobial, single-use) |
| **CND Code:** | T020699: Surgical Face Masks: Other |
| **Legal Manufacturer (Place of Issue):** | O&M Halyard, Inc.<br>1220 Old Alpharetta Rd., Suite 320<br>Alpharetta, Georgia (GA) 30005<br>United States of America |
| **Manufacturer SRN :** | US-MF-000043924 |
| **Authorized Representative:** | ArcRoyal<br>Virginia Road Kells, Co<br>Meath, Ireland |
| **AR SRN:** | IE-AR-000003110 |
| **Basic UDI-DI:** | 06806517FP001AH |
| **Start of CE:** | 5 May 2021 per Regulation 2017/745<br>7 May 2019 per Regulation 2016/425 |
| **Conformity Assessment Route:** | Annex VIII of Regulation (EU) 2017/745<br>**MDR 2017/745**<br>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.<br>**PPER 2016/425**<br>The notified body, BSI Group Netherlands, Notified Body Number 2797 (John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands) performed the EU-type Examination (Module B) set out in Annex V and issued the EU-Type Examination Certifate CE 711883. |



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| | The PPE are subject to the conformity assessment procedure conformity to type based on quality assurance of the production process' (Module D) set out in Annex VIII under surveillance of the notifed body BSI Group Netherland, Notified Body Number 2797 (John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands), which issued the certificate CE 711886. |
| **Risk Classification, Rules:** | Class I NS per Rule 1, Annex VIII Regulation (EU) 2017/745<br>Category III PPE per Regulation (EU) 2016/425 |
| **Notified Body:** | BSI Group Netherlands<br>Notified Body Number 2797<br>John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands |
| **Quality System Certificate:** | FM 697013 |

COMMON SPECIFICATIONS: **NOT APPLICABLE**

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

| **Applicable Standards:** |
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| EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles-Requirements, testing, marking |
| EN 14683:2019 Medical face masks. Requirements and test methods |

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., Suite 320
Alpharetta, Georgia (GA) 30005
United States of America

Date: 28-Jul-2025



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ATTACHMENT A: Product Codes

| Product Code | Product Description | Color |
|---|---|---|
| 62408 | PFR P2 Filtering Half Mask / Yellow | Yellow |



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