

10-August-2021

Declaration of Conformity
O&M Halyard 62408 FFP2 NR TYPE IIR Respirator

Dear Valued O&M Halyard Customer,

Thank you for your interest in our products. O&M Halyard offers a wide variety of medical facemasks and respirators to meet our customers' needs.

This communication serves to confirm that O&M Halyard product 62408, FFP2 NR Filtering Half Mask, Yellow respirator meets the requirements of EN 149:2001+A1:2009 (*Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking*) and EN 14683:2019+AC:2019 Medical (*face masks - Requirements and test methods Medical face masks. Requirements and test methods*) and is respectively CE-marked as a category III PPE in accordance with the requirements of Regulation (EU) 2016/425 and as a class I non-sterile medical device in accordance with the requirements of Regulation (EU) 2017/745.

FFP2 NR

BSI Netherlands (2797) is responsible for both EC type examination (CE 711883) and quality assurance assessment (CE 711886) under the requirements of the Regulation (EU) 2016/425. Performance includes the following:

- ≥94% NaCl and paraffin oil filtration at 95 l/min flowrate
- ≤1% CO₂ buildup
- ≤11% Total Inward Leakage
- ≤0,7 mbar inhalation resistance at 30 l/min
- ≤2,4 mbar inhalation resistance at 95 l/min
- ≤3,0 mbar exhalation resistance at 160 l/min
- ≤ 5 second burn flammability

TYPE IIR

The surgical mask has been CE marked on O&M Halyard's self-declaration (class I non-sterile device).

Performance testing in the scope of the EN 14683 was performed by accredited laboratories.

TYPE IIR Criteria	Report Reference	Result
BFE≥98%	Centexbel 20.07539.01	All results >99.9% BFE
MICROBIAL CLEANLINESS <30 CFU/g	Centexbel 20.07539.01	All samples had less than 30 CFU/g
BREATHABILITY (EXEMPT)	N/A	Code 62408 exempt from meeting the breathability requirement in EN14683 as it is an approved EN149 FFP2 NR respirator and is intended for medical use. This product does meet the breathability requirements for FFP2.
SPLASH RESISTANCE 16,0kPa	SGS/IPS 74357	No penetration failures were noted out of 52 splashes at 16,0kPa (120mmHg).

ASTM F1862 Level 3 Splash resistance

62408 FFP2 respirator also achieves Level 3 splash resistance (160mm Hg / 21,3 kPa), reference SGS/IPS 74407 & 74437.

For more information please contact your O&M Halyard representative.



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