62408

FFP2 Filtering Half Mask Respirator and Type IIR Surgical mask

TECHNICAL DATA SHEET

MD CE 2797

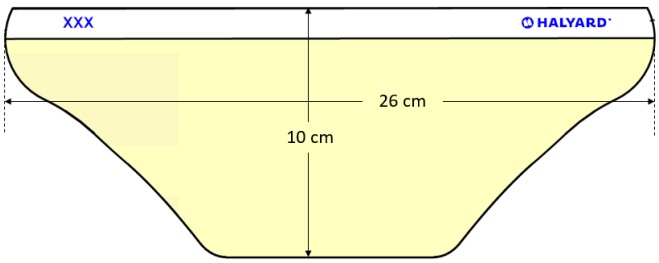
Description

The HALYARD 62408 FFP2 Filtering Half Mask is a flat folded yellow pouch-style respirator with polyurethane headbands and polyethylene film gasket. This model does not have an exhalation valve. The 62408 respirator meets the requirements as an EN149 FFP2 NR respirator and an EN14683 TYPE IIR surgical mask. It exceeds the TYPE IIR requirements by providing 21,3 kPa splash resistance.

Intended Use
The 62408 particulate respirator is designed for healthcare workers. It filters solid and non-volatile liquid particles and resists penetration from fluid splashes. The mask is a single shift device as denoted by the classification symbol NR.
See instruction for use for important additional warnings.

Materials
Components are ultrasonically welded together.
Outside layer: Polypropylene Spunbond, Yellow /White
Filter Media: Electret Polypropylene Meltblown
Inside: Clear Polyethylene/Polyester Bicomponent Nonwoven
Nose piece: Flat Aluminum Wire
Bindings: Polypropylene Spunbond
Gasket: Clear Polyethylene Film
Headbands: Polyurethane, Blue
Does not contain Natural Rubber Latex.
Does not contain DEHP.

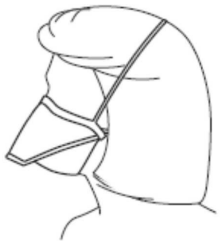
Dimensions
Headstrap length: 22 cm, unstretched



Packaging

Shipping case of 300 respirators.
50 respirators per dispenser and 6 dispensers per shipping case.
Bar coding: GS1-128 on shipping case and dispenser boxes.

Performance



FFP2 NR Performance per EN149:2001 + A1:2009
≤6% Penetration (NaCl, oil @ 95 lpm)
≤8% Total Inward Leakage
≤0,7 mbar inhalation resistance @ 30 lpm
≤2,4 mbar inhalation resistance @ 95 lpm

Type IIR Performance per EN 14683:2019
Bacterial filtration efficiency ≥ 98%
Microbial cleanliness <30 cfu/g
Splash Resistance:21,3 kPa/160 mmHg
(This exceeds the TYPE IIR requirement of 16,0 kPa)

Sterilisation

These products are non-sterile. These products cannot be sterilized.

Manufacturing

Materials manufactured in the USA.
Product assembled in Mexico.
The products are manufactured in an ISO 13485 certified plant.

Regulatory Information

Products meet the specifications of EN 149:2001+A1:2009 and are CE marked as category III PPE per Regulation (EU) 2016/425 on personal protective equipment. BSI Netherlands (2797) carried out the EU-type examination procedure (module B of annex V) and the quality assurance assessment (module D of annex VIII).

Products meet the specifications of EN 14683:2019 for medical face masks and are CE marked as a class I non-sterile medical device per Medical Device Regulation (EU) 2017/745.

Storage Information

Store in a dry and cool place (between -17°C and 32°C, relative humidity <85%), away from sources of light and radiation.
Keep the masks as much as practicably possible in their dispenser box.
Keep dispenser boxes as much as practicably possible in their shipper box.

Shelf Life

5 years, from date of manufacture.

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.

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