

# THD FACE MASK THD F3 whitebarrier

Made in Italy

CE

FN









NOTE: The image has the sole purpose of presenting the product; please refer to the table of product codes for available variants

#### CLASSIFICATION:

Class I Medical Device according to Regulation (EU) 2017/745

## TYPE

Face Mask for medical use, Type II, single-use, non-sterile, latex free

## INTENDED USE

**THD Face Mask – THD F3 whitebarrier** is a non-sterile, single-use medical device intended to reduce the emission of infectious agents from the nose and mouth of healthcare personnel and/or an asymptomatic carriers or patients with clinical symptoms.

## DESCRIPTION

THD F3 whitebarrier is classified as a type II surgical mask according to EN 14683 technical standard, suitable for covering the wearer's mouth, nose and chin ensuring tight adhesion to the sides.

THD F3 whitebarrier it is specifically designed to limit the transmission of infectious agents from the nose and mouth of healthcare personnel and/or an asymptomatic carrier or a patient with clinical symptoms with a Bacterial Filtration Efficiency (BFE) greater than 99%, thanks to a polypropylene and polyester non-woven fabric multi-layer with internal filtering layer.

The efficient filtering properties and the good fit of the THD F3 whitebarrier surgical mask provide a valid solution in terms of:

- **Comfort**: the layer in contact with the skin is soft and non-abrasive. The soft elastic bands ensure that the mask adheres tightly to the sides of the wearer's face with maximum comfort.
- **Protection**: the inner layer guarantees the filtering properties by blocking more than 99% of the penetration of infectious agents.
- High breathability: the material allows an easy air flow in both directions.

#### FEATURES:

- Excellent resistance to bacterial penetration with filtering power BFE > 99%
- Good air porosity which guarantees high breathability
- Excellent fit and comfortable elastic bands
- Composed of three layers of non-woven fabric (NW)
- Conformable edge, useful for reducing fogging of glasses
- Good tensile strength, both in longitudinal and in transversal way
- Ultralight
- Hypoallergenic
- Contamination degree (bioburden): less than 30 CFU / g

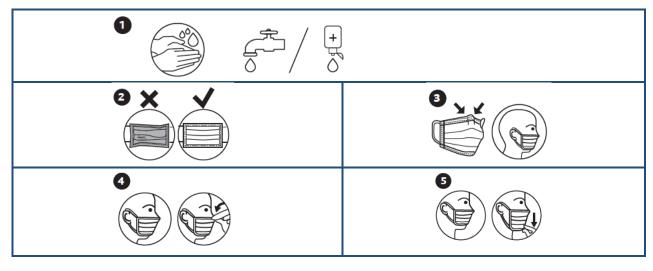
MATERIALS: Non-woven fabric (NW) - Spunbond/Meltblown

CHEMICAL COMPOSITION: polypropylene, polyester

THD S.p.A. Via dell'Industria, 1 42015 Correggio (RE), Italy – Tel +39 0522 634311 Fax +39 0522 634371 – www.thdlab.com



# OPERATING SCHEME/WAY OF USE:



**MAINTENANCE:** Not necessary, single-use device.

STORAGE AND HANDLING OF THE DEVICE: Store at room temperature, without exposing to moisture or direct heat.

**PRECAUTIONS FOR USE:** Do not use in case of evident defects such as damaged, laundry or unstitched tissue.

CONTRAINDICATIONS: There are no particular contraindications in the use of this medical device.

**TRANSPORT AND DISPOSAL METHODS:** There are no particular observances to be followed during transport. Disposal must be carried out in solid waste containers if the mask is not used.

In case of use, the mask must be disposed of:

- At home, in the unsorted collection
- In the hospital/professional environment, in the appropriate containers of hazardous waste at infection risk.

Features THD Face Mask – THD F3 whitebarrier					
Sizes	Regular Fit	Small Fit	Junior		
Dimensions – Length	17,5 cm 14,5 cm		14,5 cm		
Dimensions – Height (pleated mask)	9,5 cm	9,5 cm	9,5 cm		
Elastic bands - Length	Standard	Standard	Junior		
Material	3 layers made of non-woven fabric in Polypropylene/Polyester: - outer layer and skin contact layer in Spunbond NW - internediate layer with filtering properties in Meltblown NW				
Colour	White outside / inside				
Sterilization	Not Sterile				
Applied Standards	EN14683 / ISO10993-1				
Product Classification	Class I Medical Device according to Regulation (EU) 2017/745				
EN14683 Classification	Face mask for medical use, Type II				
Bacterial Filtration Efficiency (BFE)	> 99%				
Differential pressure (Pa/cm <sup>2</sup> )	< 40				
Contamination degree	≤ 30 CFU/g				

REF	Trade Name	Description	Size	Q.ty
800247	THD FACE MASK F3 50 B M R	THD F3 whitebarrier - 50 pcs - Regular	Regular Fit	50 pcs
800243	THD FACE MASK F3 20 B M R	THD F3 whitebarrier - 20 pcs - Regular	Regular Fit	20 pcs
800248	THD FACE MASK F3 20 B M S	THD F3 whitebarrier - 20 pcs - Small	Small Fit	20 pcs
800259	THD FACE MASK F3 20 B M J	THD F3 whitebarrier - 20 pcs - Junior	Junior	20 pcs

THD S.p.A. Via dell'Industria, 1 42015 Correggio (RE), Italy – Tel +39 0522 634311 Fax +39 0522 634371 – www.thdlab.com