



THD FACE MASK

THD F4 blackbarrier



Made in Italy



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 IIR**, single-use, non-sterile, latex free

INTENDED USE

THD Face Mask – THD F4 blackbarrier 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 F4 blackbarrier is classified as a **type IIR** 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 F4 blackbarrier 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 99.6% Bacterial Filtration Efficiency (BFE), thanks to a polypropylene and polyester non-woven fabric multi-layer with internal filtering layer.

THD F4 blackbarrier is also specifically tested for resistance to splashes (blood splatters or synthetic liquids) with a pressure of at least 16 kPa (ISO 22609).

The efficient filtering properties and the good fit of the **THD F4 blackbarrier** 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 the 99.6% of the penetration of infectious agents.
- **High breathability:** the material allows an easy air flow in both directions.

FEATURES:

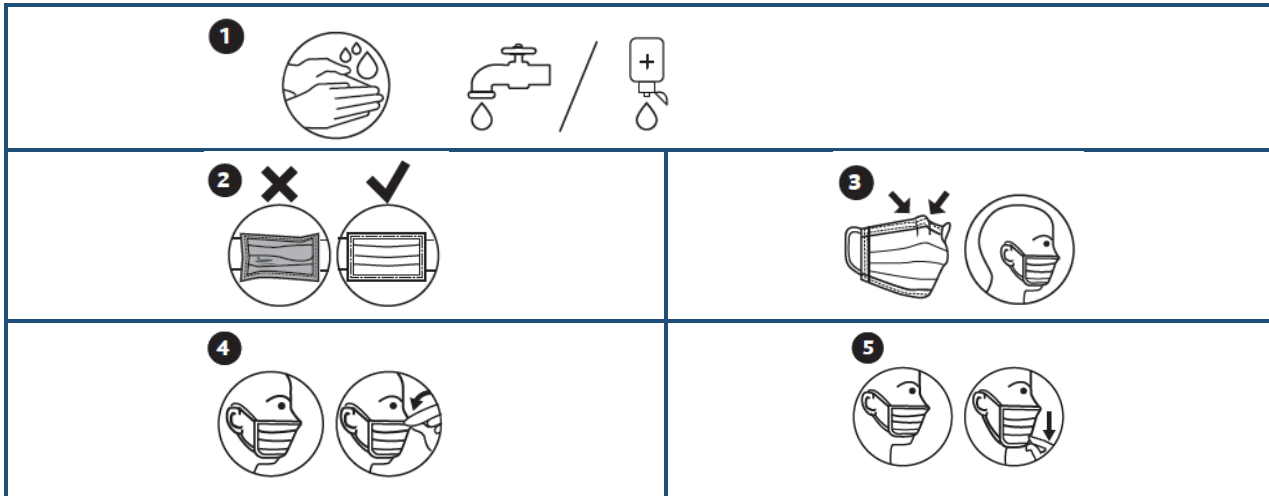
- Excellent resistance to bacterial penetration with **filtering power BFE = 99.6%**
- **Splash resistance** with a pressure of at least 16 kPa
- Good air porosity which guarantees **high breathability**
- Excellent fit and comfortable elastic bands
- Composed of **four** layers of non-woven fabric (NW)
- 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



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 F4 blackbarrier			
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	4 layers made of non-woven fabric in Polypropylene/Polyester: - 2 outer layers and 1 skin contact layer in Spunbond NW - 1 intermediate layer with filtering properties in Meltblown NW		
Colour	Black outside / inside – black elastic bands		
Sterilization	Not Sterile		
Applied Standards	EN14683 / ISO22609 / ISO10993-1		
Product Classification	Class I Medical Device according to Regulation (EU) 2017/745		
EN14683 Classification	Face mask for medical use, Type IIR		
Bacterial Filtration Efficiency (BFE)	99.6%		
Differential pressure (Pa/cm ²)	< 40		
Contamination degree	≤ 30 CFU/g		

REF	Trade Name	Description	Size	Q.ty
800255	THD FACE MASK F4 50 N M R	THD F4 blackbarrier - 50 pcs - Regular	Regular Fit	50 pcs
800252	THD FACE MASK F4 20 N M R	THD F4 blackbarrier - 20 pcs - Regular	Regular Fit	20 pcs
800253	THD FACE MASK F4 20 N M S	THD F4 blackbarrier - 20 pcs - Small	Small Fit	20 pcs
800262	THD FACE MASK F4 20 N M J	THD F4 blackbarrier - 20 pcs - Junior	Junior	20 pcs