TECHNICAL DOCUMENTATION FOR PPE TYPE FP5 SAFECOMFORT REF 88001-88002 ACCORDANCE WITH STANDARDS PPE-R/02.075 VERSION 2

0. PURPOSE

THE PPE TYPE FP5 SAFECOMFORT REF 88001-88002, designed for repiratory protection only SARS-CoV-2 of the user, is manufactured by AXELMED S.R.L Via della Liberazione 58 - 20098 San Giuliano Milanese (MI) / Italy with the general health and safety requirements specified in Regulation (EU) 2016/425, in particular, the specifications contained in standards PPE-R/02.075 published by the Respitartory Protection Vertical Group assigned by the European Committee for Standardisation, as Category III PPE.

1. GENERAL REQUIREMENTS

1.1 Design principles

This PPE is a filter masks used as respiratory protection against only SARS-CoV-2. According to Commission Recommendation (EU) 2020/403 of 13 March 2020 paragraph 3 and 4 and actual WHO recommendations, FFP2 or equivalent filtering half-masks can be used for protection against SARS-CoV-2.

The ergonomic design takes into consideration the activities that the wearer might perform under normal conditions of use without exposure to additional risks, except in the event of the user's individual hypersensitivity.

1.2 Innocuousness

The materials and components of the PPE DO NOT adversely affect the wearer under normal conditions of use, nor do they produce known toxic or allergenic effects as they are made from commonly-used materials.

All parts that are in contact with the wearer are free of roughness, sharp edges and/or protrusions that could cause harm, because they are made with patterns that fit the morphology of the human body.

1.3 Comfort and effectiveness

It provides the highest level of comfort possible to ensure appropriate protection against hazards due to its ability to adapt to cutting patterns.

Its design enables it to be correctly fitted and to remain in place during the period of foreseeable use.

It can be used with other PPE worn by the user.

2. ADDITIONAL REQUIREMENTS

THE PPE TYPE FP5 SAFECOMFORT REF 88001-88002 complies with the general design requirements and fitting systems, comfort, ageing, sizing and marking defined below.

2.1 Design and fitting systems

The PPE's design and fitting systems enable it to adapt to the morphology of the user as shown in the following documents:

- Description of the PPE in accordance with Annex I.
- Specification of materials and components in accordance with Annex I.

2.2 Comfort

Sweat is eliminated through the use of natural breathable materials.

3 SCOPE OF APPLICATION OF RECOMENDATION FOR USE PPE-R/02.075 VERSION 2

A respiratory protection device can only be approved when its individual components satisfy the requirements of the test specifications which may be a complete standard or part of it, and practical behavior tests have been carried out satisfactorily on the complete equipment, as specified in the appropriate standard.

A filter masks used as filtering half mask to protect against COVID-19.

4 GENERAL REQUIREMENTS OF RECOMENDATION FOR USE PPE-R/02.075 VERSION 2

4.1 Design:

A filter half mask covers the nose, mouth, and chin. The half mask consists entirely, or for the most part, of filter material or includes a face adapter in which the main filter (s) constitute an inseparable part of the equipment. The half filter mask must guarantee a tight fit, against the ambient atmosphere, to the face of the wearer, regardless of whether the skin of the wearer is dry or wet and that his head is in motion. Air enters the filter half mask and passes directly to the nose and mouth areas of the face adapter. The exhaled air exits directly into the outside atmosphere through the filter material.

These devices are designed to ensure protection against COVID-19

5 SPECIFIC REQUIREMENTS OF RECOMENDATION FOR USE PPE-R/02.075 VERSION 2

5.1 Packaging

Filter half masks are supplied for sale packed in such a way that they are protected against mechanical damage and contamination before use.

5.2 Material

The materials used is suitable to withstand handling and use during the period of time for which the filter half mask has been designed.

After being subjected to the conditioning test described in section 8.3.1 of EN 149, no filter half mask shows mechanical damage to the face adapter or straps.

After the conditioning described in sections 8.3.1 and 8.3.2 of EN 149, the filter half mask is not crushed.

Any material in the filter media that is released by the action of the flow of air through the filter does not constitute a danger or damage to the wearer.

5.3 Practical performance test

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

During the practical performance test, the test subject pay particular attention to the ability of the product to maintain a good faceseal. If the wearer observes that a good faceseal is not maintained, they shall be instructed to readjust the filtering half mask according to the user instructions. Should the test subject experience further difficulties with maintaining a good faceseal during the practical performance test, the filtering half mask shall be considered unsatisfactory.

5.4 Finishing of the parts

The parts of the device that will be in contact with the wearer have not sharp edges or burrs.

5.6 Filter material penetration

The penetration of the filter of the filtering half mask according to PPE-R/02.075 meet the requirements FFP2

Classification	Sodium chloride test 95 l/min % Max.
FFP1	20
FFP2	6
FFP3	1

A total of 3 samples of filtering half masks shall be tested.

for device without cleaning and disinfection process on:
3 samples as received;

Exposure test with a specified mass of test aerosol of 120 mg according to EN 13274-7, shall be performed:

- for device without cleaning and disinfection process on:
3 sample as received;

5.7 Skin compatibility
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

5.8 Carbon dioxide content in inhalation air
The carbon dioxide content in the inhalation air (dead space) does not exceed an average of 1.0% (by volume).

5.9 Head harness
The head harness shall be designed so that the filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the filtering half mask firmly in position

5.10 Field of vision
A field of view is acceptable, as determined in the practical behavior test.

5.12 Resistance to breathing

The breathing resistances apply to valveless filtering half masks and shall meet according to PPE-R/02.075 the requirements FFP2.

Classification	Maximum resistance permitted (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

for device without cleaning and disinfection process on:
3 samples as received;

6 SAMPLES SUBMITTED

The following were submitted:

- 30 (thirty) FP5 SAFECONFORT 88001-88002

7 MEANS OF CONTROL

The model FP5 SAFECOMFORT REF 88001-88002 is subject to the following control mechanisms:

-Attached the internal production protocol.

8 ESSENTIAL REQUIREMENTS

Annex II Regulation 2016/425	Clauses of Standard PPE-R/02.075 VERSION 2 version 1
1.1.1 Ergonomics	3.7; 3.9
1.1.2.1. Optimum level of protection	3.7; 3.9; 3.11
1.1.2.2. Classes of protection appropriate to different levels of risk	3.9
1.2.1. Absence of inherent risks and other nuisance factors.	3.6; 3.11; 3.13; 3.15
1.2.1.1. Suitable constituent materials	3.5; 3.6; 3.7; 3.10
1.2.1.2. Satisfactory Surface condition of all PPE in contact with the user	3.7; 3.8
1.2.1.3. Maximum permissible user impediment.	3.7;3.13
1.3.1 Adaptation of PPE to user morphology	3.7
1.3.2. Lightness and strength	3.4; 3.5; 3.7
1.4. Manufacturer's instructions and information	5
2.1. PPE incorporating adjustment systems.	3.12
2.3. PPE for the face, eyes and respiratory system.	3.13
2.4. PPE subject to ageing	3.6; 4; 5
2.6. PPE for use in potentially explosive atmospheres.	5
2.8. PPE for intervention in very dangerous situations.	5
2.9. PPE incorporating components wich can be adjusted or removed by the user.	3.12; 3.16
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety.	4
3.10.1. Respiratory protection.	3.6; 3.7; 3.8; 3.9; 3.11; 3.15; 4; 5

9 RISK ASSESMENT

Risk assessment according to Spanish Law 31/1995 Prevention of occupational hazards.

RISK AGAINST WHAT IT PROTECTS	TYPE OF WORK	PROBABILITY OF A DANGER / INJURY HAPPENING	QUALIFY THE SERIOUSNESS OF THE DANGER/INJURY	GENERAL CALIFICATION	PROTECTION DEGREE	STANDARD FOR EVALUATING THE LEVEL OF PROTECTION	SOURCE THAT CONTRIBUTES TO THE EXHIBITION
Filtering half mask to protect against COVID-19	Sanitary ambient, hospitals, contact with infected COVID 19 patients	Very high	High	IMPORTANT RISK	Against solid aerosols of sodium clhoride (FFP2)	7.9, 7.16; 7.17 EN 149	Inadequate risk assessment
						10 EN 149	Inappropriate use as indicated in the information leaflet
						7.7; 7.9; 7.13; 10 EN 149	Bad placement
						10 EN 149	Inappropriate use as indicated in the information leaflet
						7.7; 7.9; 7.13; 10 EN 149	Bad placement

10 MARKING

Each half mask should be marked so that the following information is easily readable by the user and remains readable throughout its intended use:

1- Standard PPE-R/02.075 version 1
2- Manufacturer's name or brand: AXELMED
3- PPE reference: MASK FP5 SAFECOMFORT REF 88001-88002
4- CE marking: CE
5- Production control body: 0161
6- Classification: COVID-19

11 INFORMATION LEAFLET

The leaflet that accompanies each FP5 SAFECOMFORT REF 88001-88002, an example of which is attached in Annex II, is written in the official language of the Member State in which it is sold, as well as other possible languages.

ANNEX I

DESCRIPTION

The FP5 SafeComfort mask consists of five layers of non-woven polypropylene sandwich laminates. Each layer (outer facing, double meltblown, sponge, inner facing) is structured differently for the specific function for which it is intended: anti-splash protective, filtering, dissipating, hypoallergenic. It does not cause blisters or irritation. Latex-free. It does not contain phthalates.

FIELD OF USE

In the medical healthcare and microbiological fields, and in proximity to the surgical intraoperatory field, a safe and durable "barrier effect" on germs is required. Being without an exhalation valve, it is therefore also indicated to be applied to positive or symptomatic patients during rescue operations, ambulance transport, hospitalization, isolation and quarantine.

PROPERTIES AND ADVANTAGES

The FP5 SafeComfort mask is sewn in three steps: it does not contain adhesives often associated with skin irritation. The hypoallergenic inner layer (facing inwards) in contact with the soft nose-mouth systemmanaged comfort, while the fibers of which it is included avoids both maceration and irritation. The 2 coupled filters (double meltblown) are made up of high-filtration micro brews. The intermediate layer (sponge) covers the circulation of the hot air emitted by cooling it and extending the life of the mask.The nose pad in soft anatomical material is adaptable to the face and makes the FP5 comfortable and without the need to “push” continuously the metal band. The extra-long and hypoallergenic adjustable tubular laces ensure a perfect seal both with and without headgear or protective mask.

ANNEX II: INFORMATION LEAFLET

AXELMED S.R.L Via della Liberazione 58 - 20098 San Giuliano Milanese (MI) / Italy

CE **0161**

FP5 SAFECOMFORT REF 88001-88002

This product has been manufactured in compliance with Regulation (EU) 2016/425, for basic use, PPE-R/02.075 VERSION 2 Respiratory protective devices. Filtering half masks to protect only for COVID 19. Requirements, testing, marking, in compliance with certificate **nº 2020/2803/0161 by AITEX**, Plaza Emilio Sala nº 1, Alcoi, Spain, Notified Body 0161

Recommendations for use:

The PPE is manufactured in a woven material with: The FP5 SafeComfort mask consists of five layers of non-woven polypropylene sandwich laminates. Warnings: -This mask is manufactured only for protection COVID 19. -fit of filtering half mask (check prior to use); -it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; -Mask not valid in conditions of poor air quality (contaminants, oxygen deficiency); - Mask not valid in explosive atmosphere -this product is not flame resistant and must not be used in areas with open flames -The user must know the use and mask handling -Do not use risk zones of explosion -This PPE must not be used against risks other than those previously described.

USE AND MAINTENANCE INSTRUCTIONS

In order for the AXELMED FP5 SAFECOMFORT protection mask to be effective it is necessary to use it in combination with frequent hand cleaning performed with the help of disinfectant detergents, it is necessary that it is not used by several people and it is necessary to use it correctly. Specifically, it is advisable to follow the following steps:

• clean your hands with an alcohol or soap-based detergent and water before putting it on;
• when using for the first time, it is possible to adjust the two right and left cotton pads in the nose pad by pressing them or pulling them out according to the shape of the face and, if necessary, in special cases (small people, children), also tighten the width of the elastic with a knot;
• widen the lower part of the elastic and insert it around the neck, then position the upper part of the elastic on the nape;
• the elastic is sliding and adapts independently even if you wear a face protection visor and the headdress of the biological protection suit;
• cover the mouth and nose with the mask making sure that there are no spaces between the face and the mask along the entire perimeter of contact;
• it is recommended to keep the mask as high as possible and close to the eyes for perfect closure;
• avoid touching the mask externally while using it (if you do, clean your hands with an alcohol or soap and water based detergent);
• to remove the mask, free the upper elastic from the nape towards the front and then widen the sliding part behind the neck without touching the external part of the mask.

VERIFICATION OF THE SEAL

• cover the front of the face mask with both hands making sure not to compromise the seal on the face;
• breathe out quickly;
• if air leaks are felt around the nose, reposition the face mask higher to eliminate the leak. Repeat the leak test as above;

"This filtering half mask is manufactured for COVID-19 protection only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same than the FFP2 nominal protection factor defined in EN 149:2001+A1:2009. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19."

Obtainen levels

OBTAINED VALUE: PASS

Maximum penetration of the filter material:

Clasification	95 l/min % Max.
FFP2	6

The level FFP2 is a guidance parameter from the standard EN 149: 2001 + A1: 2009, not applicable for RfU PPE-R/02.075 VERSION 2 since the final validity for COVID 19 certification method is according to a PASS / NOT PASS.

Storage: Keep the garment away from unnecessary exposure to sunlight, in dry places and protected against any aggressive agents.

Packaging: Plastic bag.

Web: Declaration of conformity myaxelmed.com

PICTOGRAMS EXPLANATIONS:

MM/YY
(usable shelf life 5 YEARS from date)

Maximum relativity humidityof storing 90%

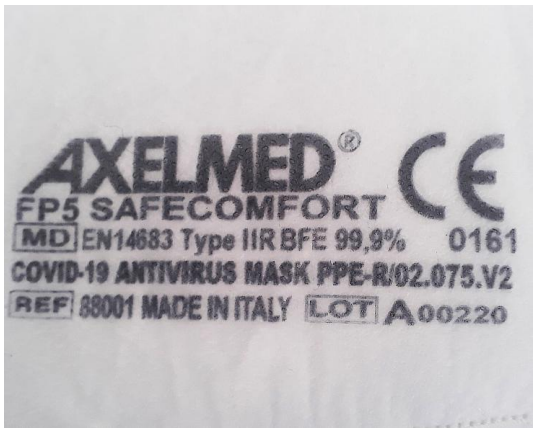
+35ºC

-10ºC
Temperature range of storing

See information supplied by the manufacturer

ANNEX III: PHOTOS OR PLANS

MARKING ON THE MASK



MARKING (PRINTED)

AXELMED®
CE
FP5 SAFECOMFORT
MD EN14683 Type IIR BFE 99,9% 0161
COVID-19 ANTIVIRUS MASK PPE-R/02.075.V2
REF 88001 MADE IN ITALY LOT A00220

ANNEX IV: MASK MARKING

FP5 SAFECOMFORT REF 88001-88002

CE **0161**

PPE-R/02.075 version 2

COVID-19

AXELMED

ANNEX V: PACKAGING

PPE-R/02. version 2
Manufacturer's name or brand: AXELMED
PPE reference: MASK FP5 SAFECOMFORT REF 88001-88002
Intended use: Filtering half mask to protect against COVID-19
CE marking: CE
Production control body: 0161

yyyy/mm

+35ºC

-10ºC

Maximum relativity humidityof storing

See information supplied by the manufacturer

AXELMED®
PRODUZIONE DISPOSITIVI MEDICI
MEDICAL DEVICES MANUFACTURING

ANNEX 4

DECLARATION OF CONFORMITY

The manufacturer established in the EC:

AXELMED S.R.L
Via della Liberazione 58 - 20098 San Giuliano Milanese (MI) / Italy

It issues this declaration of conformity, under its sole responsibility and declares that the PPE described below:

FP5 SAFECOMFORT REF 88001-88002

It complies with the provisions of the EU Regulation 2016/425 of March 9, 2016 and, in particular, with the specifications of the following RfU PPE-R/02. version 2 edited by the European Committee for Standardization

The Notified Body ASSOCIATION OF RESEARCH OF THE TEXTILE INDUSTRY, notified body nº0161, in Plaza Emilio Sala 1, 03801 Alcoy, Alicante, has carried out the EU type examination (module B) and has issued the EU type 2020/2803/00/0161 Certificate.

Made in San Giuliano Milanese, Date July 3th, 2020

AXELMED SRL
L'Amministratore Unico / CEO
Guido Ivo Tissi

Signed _____