EN 14683 " SURGICAL MASKS " INSPECTION AND TEST REPORT

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MANUFACTURER TITLE AND ADDRESS :FAS ESTINTORI SRL

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1. PURPOSE:

This protocol, TS EN 14683 + AC / SEPTEMBER 2019 Medical Face Masks - Requirements and Test methods, ISO 22609/2004 Medical Facial Mask Test Resistance Method, Penetration Through Synthetic Blood, EN ISO 11737-1 / 2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of the microorganism population on the products, It has been prepared to test the masks using current standard methods and to verify their performance according to their class and intended use.

2. SCOPE:

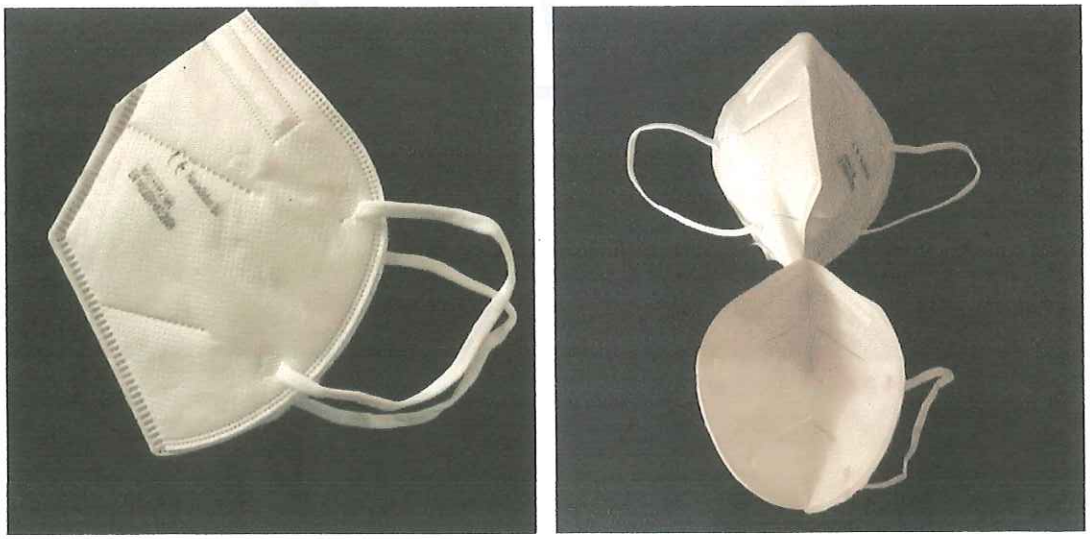
This protocol, TS EN 14683 + AC / SEPTEMBER 2019 Medical Facial Masks - Requirements and Test methods, ISO 22609/2004 Medical Facial Masks Test Resistance Method, Penetration through Synthetic Blood and sterilization of EN ISO 11737-1 / 2018 Healthcare products - Microbiological methods - Part 1: Covers the following testing activities specified in the identification of the microorganism population on products.

3. DESCRIPTION OF THE MASK TO BE TESTED

3.1 Brand of the Product : FAS ESTINTORI

3.2 Description of the Product : FAS M20 FFP2 NR

3.2 Single Picture of the Product :



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4. REQUIREMENTS

4.1 GENERAL

4.1.1 Design :

Requirement:

Wearing a medical face mask; nose, mouth, chin to fit the side area of the face.

Medical face masks can be produced in different shapes and structures. In face masks; The face shield with or without anti-fog function (to protect the user against splashes and droplets) or the bridge of the nose (to improve compliance by adapting to the nose lines).

Assessment:

Mask Weight	4.7 g

Result:

When the produced mask was produced in the above dimensions and evaluated on 3 different subjects; It was observed that the product fits well on the face and there is no gap on the edges.

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4.2 PERFORMANCE CONDITIONS:

4.2.1 Bacterial Filtration Efficiency (BFE):

Requirement:

Test Flow Rate	: 28,3 L/dk
Total Test Flow Time	: 2 minutes
Sample Size	: 9 x 9 cm
Test Microorganism	: *Staphylococcus aureus* ATCC 6538
Bacteria Concentration	: 5 x 10^5 kob/ml
Incubation Time, Temperature	: 37 ± 2 °C, 20 - 52 h
Test Condition	:(21±5)°C, (85±5)% relative humidity, 4 hours

Average of Positive Control Bacteria: 2.76x10^3 kob/ml

For bacterial filtration efficiency, when tested according to TS EN 14683 + AC APPENDIX B, the bacterial filtration efficiency (BFE) of the medical face mask should comply with the minimum value given for the relevant type specified in the table below.

TEST	TYPE I	TYPE II	TYPE IIR
BACTERIAL FILTRATION EFFICIENCY (BFE)%	≥ 95	≥ 98	≥ 98

Result:

TEST SAMPLE NUMBER	EXPERIMENT SAMPLE NUMBER OF BACTERIA (cfu) (T)	BACTERIAL FILTRATION EFFICIENCY (BFE%)
1	21	99.2%
2	20	99.3%
3	17	99.4%
4	24	99.1%
5	28	98.9%
Average	-	99.2%

BFE = (C-T) / C x 100

The average filtration efficiency (BFE) of the two samples taken in the manufactured medical face mask was calculated as **99.2 %.**

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4.2.2 Respirability :

Requirement:

The differential pressure of medical face masks tested according to TS EN 14683 + AC ANNEX C has been tested on 5 different products.

Result:

TEST SAMPLE		AIR FLOW RATE	TEST AREA	DIFFERENTIAL PRESSURE VALUE	CALCULATED VALUE
NUMBER	AREA				
1	1	8 l/min	5,0 cm^2	249 Pa	49.8 Pa/cm^2
	2	8 l/min	5,0 cm^2	226 Pa	45.2 Pa/cm^2
	3	8 l/min	5,0 cm^2	203 Pa	40.6 Pa/cm^2
	Average			**226 Pa**	**45.2 Pa/cm^2**
2	1	8 l/min	5,0 cm^2	191 Pa	38.2 Pa/cm^2
	2	8 l/min	5,0 cm^2	193 Pa	38.6 Pa/cm^2
	3	8 l/min	5,0 cm^2	195 Pa	39.0 Pa/cm^2
	Average			**193 Pa**	**38.6 Pa/cm^2**
3	1	8 l/min	5,0 cm^2	331 Pa	66.2 Pa/cm^2
	2	8 l/min	5,0 cm^2	234 Pa	46.8 Pa/cm^2
	3	8 l/min	5,0 cm^2	207 Pa	41.4 Pa/cm^2
	Average			**187 Pa**	**51.5 Pa/cm^2**
4	1	8 l/min	5,0 cm^2	248 Pa	49.6 Pa/cm^2
	2	8 l/min	5,0 cm^2	222 Pa	44.4 Pa/cm^2
	3	8 l/min	5,0 cm^2	224 Pa	44.8 Pa/cm^2
	Average			**231 Pa**	**32.9 Pa/cm^2**
5	1	8 l/min	5,0 cm^2	203 Pa	40.6 Pa/cm^2
	2	8 l/min	5,0 cm^2	241 Pa	48.2 Pa/cm^2
	3	8 l/min	5,0 cm^2	231 Pa	46.2 Pa/cm^2
	Average			**225 Pa**	**45.0 Pa/cm^2**

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4.2.3 Splash Resistance :

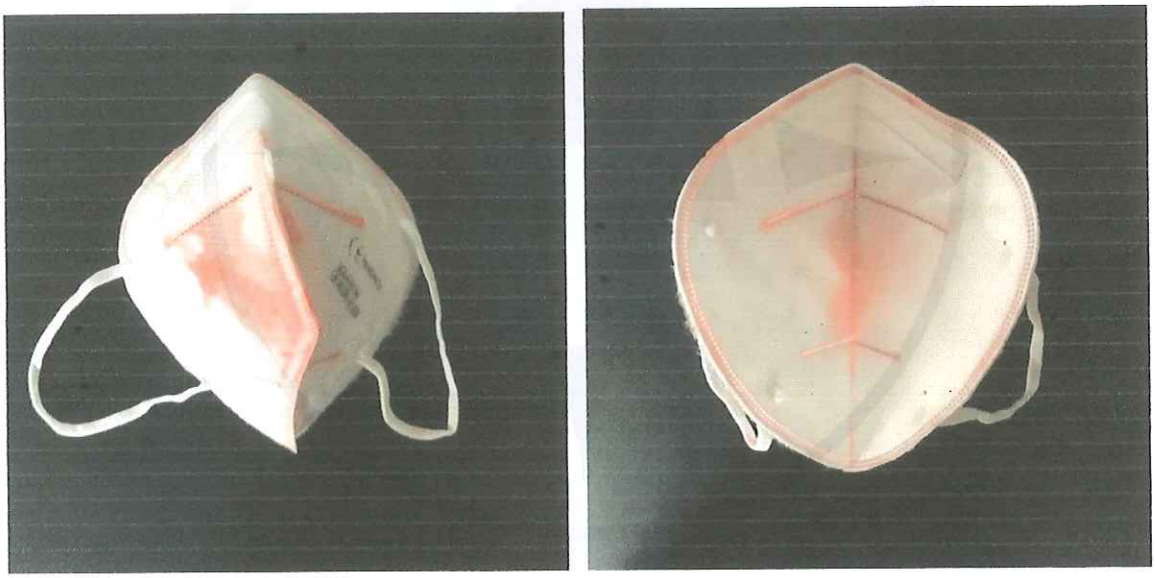
Requirement:

TS EN 14683 + AC Standard (5.2.4) clause test refers to ISO 22609: 2004 standard. The resistance of medical face masks to splashing liquid must comply with the values given for the relevant type indicated in the table below.

TEST	REQUIREMENT
SPLASH RESISTANCE kPa	≥16.0

Result:

In the artificial blood splashes with 16.0 kPa pressure on the produced masks.



Artificial blood has not passed into the inner surface of the mask.

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4.2.4 Microbial Cleaning:

Requirement:

TS EN 14683 + AC Standard (5.2.5) clause test refers to EN ISO 11737-1 2018 standard. Microbial cleansing of medical face masks should comply with the values given for the relevant type indicated in the table below.

TEST	REQUIREMENT
MICROBIAL CLEANING (cfu/g)	≤30

Result:

Microbial cleaning test was performed on a total of 5 samples from the masks produced and the following results were obtained.

TEST SAMPLE	READ-OUT (cfu/g)
1	2
2	3
3	1
4	3
5	1
AVERAGE	**2**

The average of **2 cfu / g** of the five samples taken from the masks produced was calculated.

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