Test Report

UNI EN 14683: 2019

Filtranium S.r.l.

MA-2020-043 of 18/11/2020

Medical Face Masks

Model: Dr. Filtrex

Digitally signed by Șevciuc Marina
Date: 2022.02.17 12:42:31 EET
Reason: MoldSign Signature
Location: Moldova

TEST REPORT N°	MA –2020-043	ISSUED	18/11/2020	AUTHORIZED COPY FROM:	DTL LUCA BEDONNI

Test Report UNI EN 14683: 2019

Verification code:	MA-2020-043	**Date of issue:**	18/11/2020
Start of test:	12/11/2020	**Date end tests:**	17/11/2020

Applicant: **Filtranium S.r.l.**

Legal office:

Address ***Str. Matei Basarab*** *n°* ***1A***

Locality ***Ialoveni, Chisinau*** *Zip code* ***---***

District ***---*** *Country* ***Moldova (MD)***

Device:

Medical Face Mask class I - NOT STERILE, Model: Dr. Filtrex

Test performed by: **Luca Bedonni**

Test Approved by: **Antonio Bedonni**

This test report has been approved by the Test Laboratory Management (DTL).
The results are valid only for the samples to be tested and identified herein. Sampling is the responsibility of the applicant.

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1. STANDARDS

Standard	Description
UNI EN 14683: 2019	Medical face masks – Requirements and test methods
UNI EN ISO 11737-1: 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

2. TESTED DEVICE SPECIFICATION

2.1 Description

Manufacturer	Filtranium S.r.l.
Customer	Filtranium S.r.l.
Customer address	Str. Matei Basarab, 1A - Ialoveni, Chisinau - Moldova (MD)
Product manager	---
Type of product	Medical Face Mask
Model	Dr. Filtrex
Lot	---
Sterilization	NO
N° units analyzed	5

2.2 Place and date of execution of the tests

Place	Date
Ente Certificazione Macchine	12/11/2020

Measurement site parameters							
Temperature:	9°C	Pressure:	1004 mb	Relative humidity:	87%	Wind:	/

3. TEST

1.1 Bacterial filtration efficiency (BFE)

1.1.1 Equipment used

- Vacuum pump "GEO Air Plus"
- Andersen Cascade Impactor "TE-20-830" edited
- Nebulizzatore MMAD 3,0 ± 0,3 µm
- Piastre contenenti TSA

1.1.2 Test Method

Before the start of the test, the samples were conditioned at 25 ± 2 ° C in the presence of 75 ± 10% U R.
A negative control is performed by passing the air, without adding the bacterial solution, through the cascade impactor for 2 minutes.
Then the bacterial solution of Staphylococcus Aureus ATCC 6538, with a concentration of 3700 CFU / ml, is introduced into the spray chamber.
A first positive control is performed, passing the nebulized bacterial solution through the cascade impactor at a flow of 28.3 ± 0.5 l / min for 1 minute. The air flow is maintained through the cascade impactor for an additional minute, for a total test time of 2 minutes.
The control plates are removed from the cascade impactor and new plates are placed to perform the test on the samples to be tested.
The specimen is locked in position between the first plate of the cascade impactor and the inlet cone of the nebulizer collector and the procedure previously used for the positive control is repeated for each of the 5 specimens.
After the last specimen has been tested, an additional positive control test is performed.
Then all plates are incubated at 37 ± 2 ° C for a period of time between 24 and 72 hours.
After incubation, for each specimen and for each control, the number of colonies is counted in order to obtain, for each of them, the total number of CFUs collected by the cascade impactor.
The bacterial filtration efficiency (BFE) is calculated for each sample, in percentage, using the following formula:

$$\mathbf{BFE = [(C - T) / C] \times 100}$$

where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen.

1.1.3 Limit

BFE (%) LIMIT TYPE I	**≥ 95 %**
BFE (%) LIMIT TYPE II	**≥ 98 %**

1.1.4 Results

Determination	**UFC**	**BFE (%)**
Negative control	0,0	**96,0%**
Positive control	1700 ÷ 3000	
	BFE (%)	
Test 1	94,7	
Test 2	95,5	
Test 3	95,9	
Test 4	96,2	
Test 5	94,5	

1.1.5 Conclusions

The device has a bacteriological filtration efficiency of 96,0 %, therefore it can be classified TYPE I according to UNI EN 14683: 2019

Classification: TYPE I

1.2 Breathability (Differential pressure)

1.2.1 Test method

Each sample is conditioned at 22 ± 2 ° C and 80 ± 10% of relative humidity for a minimum of 4 hours before the test. A device measures the differential pressure required to suck air through a measured surface of the medical mask at a constant air flow. A digital differential pressure gauge measures the differential pressure. A mass flow meter is used to measure the air flow. A pump draws air through the test apparatus and a needle valve is used to regulate the flow. Without specimen in position, the holder is closed and the differential pressure gauge is reset. The pump is started and the air flow is regulated at 8 l / min.
The support is opened and the specimen is positioned through the 25 mm diameter orifice (total area 4.9 cm2) between the upper and lower part of the support. Then it is locked in place using a mechanical clamp with enough pressure to avoid air leaks.
With the specimen in position, the flow rate must be 8 l / min.
The procedure described is performed on 5 (or an adequate number) different areas of the mask and readings are averaged.
For each test sample the differential pressure of each tested area is calculated as follows:

DP = DP read \ 4,9

Where:
DP is the Differential Pressure per cm^2 of the sample expressed in Pa;
Dp read is the differential Pressure per specimen;
4,9 is the area (in cm^2) of the sample.

1.2.2 Limit

DP (Pa/cm^2) LIMIT TYPE I	**≤ 40 Pa/cm^2**
DP (Pa/cm^2) LIMIT TYPE II	**≤ 40 Pa/cm^2**
DP (Pa/cm^2) LIMIT TYPE IIR	**≤ 60 Pa/cm^2**

1.2.3 Results

Determination	DP (Pa/cm^2)	DP (Pa/cm^2)
Sample 1	28,6	**30,0**
Sample 2	29,2	
Sample 3	27,3	
Sample 4	29,5	
Sample 5	30,9	

1.2.4 Conclusions

The device has a differential pressure of 30,0 Pa/cm^2, therefore it respects the minimum requirements imposed by the UNI EN 14683: 2019.

ACCORDANT

1.3 Microbial cleanliness (Bioburden)

1.3.1 Test method

The samples were treated aseptically. The microorganisms were extracted from the samples using a sterile physiological solution containing 0.05% of Tween 80 under stirring. The extract obtained from each sample was collected and filtered on a 0.45 µm sterile filter. Each filter was cut in half, one half was placed on a soybean triptone plate (TSA) and incubated for 72 hours at 32 ± 2 ° C to search for mesophilic aerobic bacteria, the other half on a plate. of potato dextrose agar (POT) and incubated at 22 ± 2 ° C for 5 days to look for mold and yeast. The results obtained were multiplied by the correction factor (1.85 - 1.64) obtained from the validation of the method (see point 3.3.5.).

1.3.2 Limit

LIMIT TYPE I	**≤ 30 (UFC/g)**
LIMIT TYPE II	**≤ 30 (UFC/g)**

1.3.3 Results

N° sample	**(UFC / g)**
Sample 1	24
Sample 2	22
Sample 3	26
Sample 4	32
Sample 5	28
Average value	28,5
Correction factor	1,08
Correct value	**28**

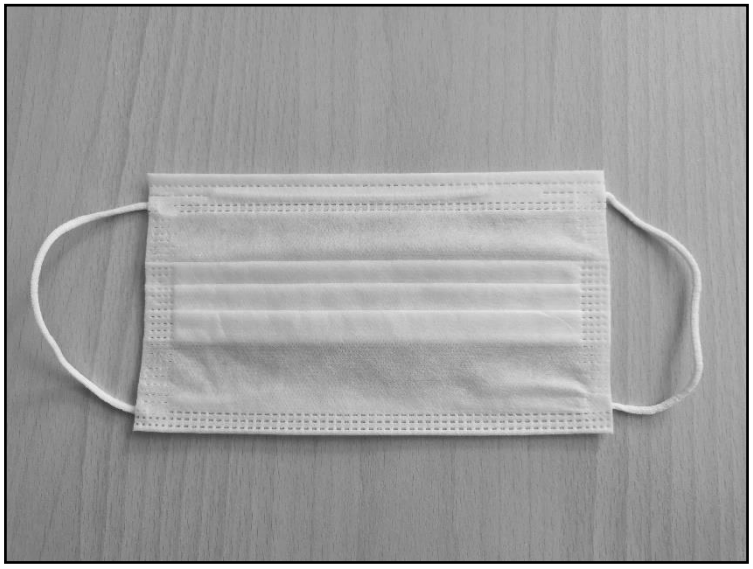
1.3.4 Conclusions

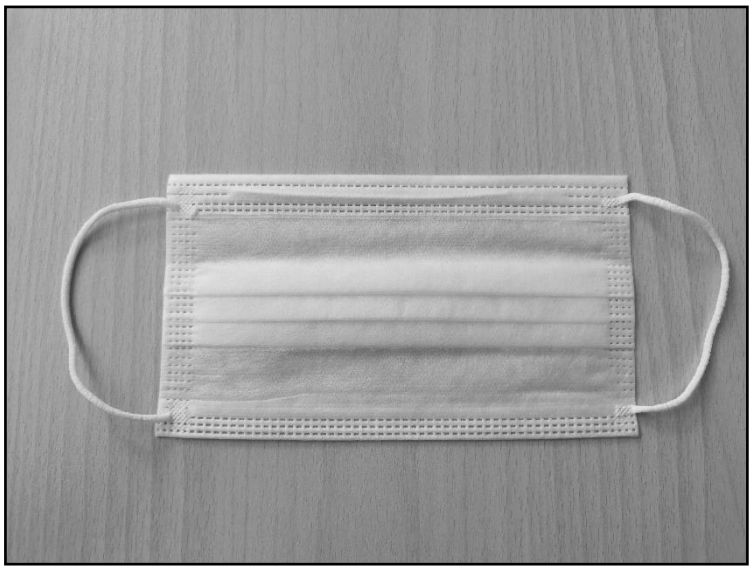
The device is subject to microbial contamination <30 (UFC / g), therefore it respects the minimum requirements imposed by the UNI EN 14683: 2019.

ACCORDANT

4. ATTACHMENTS

1.4 Images of the device





Technician in charge

(Luca Bedonni)

Laboratory manager

(Antonio Bedonni)