Messrs
MAREMOD SA
Str. Scarlatescu nr. 17-19, Sector 1
011158 BUCHAREST ROMANIA

Zola Predosa, 10/07/2020

Ref. Your Order del 2020

Test Report N°20-0812-01

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description

Denomination: Mask
Code: MMC1-MM01
Lot: 0011905
Sterilization: No
Receipt number: 16805
Receipt date: 01/07/2020
Sampling carried out by: MAREMOD SA

Further information about the sample

Number of tested samples: 5
Size of the area of the specimens: 50 cm^2
Side of the test sample facing the challenge aerosol: the internal part

Test date

The test was started on 08-07-2020 and was completed on 09-07-2020

Test method

EN 14683:2019 Annex B

Equipments and reagents

Vacuum pump "GEO Air Plus"
Modified Andersen Cascade Impactor "TE-20-830"
MMAD nebulizer 3,0 ± 0,3 µm
Colture plates containing TSA

Summary of method

A negative control is performed by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 minutes.

Then the bacterial challenge of Staphylococcus Aureus ATCC 6538, with a concentration of 1,7 x 10^3 to 3,2 x 10^3 UFC/ml, is delivered to the aerosol chamber.

A first positive control is performed, by passing the bacterial challenge through the cascade impactor at a flow rate of 28,3 ± 0,5 l/min for 1 minute. The airflow is maintained through the cascade impactor for 1 additional minute, for a total test time of 2 minutes.

The control plates are removed from the cascade impactor and fresh plates are placed in order to perform the test on the test samples.

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The specimen is clamped in place between the first stage of the cascade impactor and the inlet cone of the nebulization collector and the procedure used for the positive control is repeated for each of the 5 specimens to be tested.
After the last specimen has been tested, a further positive control run is performed.
Then all the plates are incubated at 37 ± 2℃ for a lenght of time between 24 and 72 hours.
After the incubation, for each specimen and control run, the number of colonies is counted in order to give the total number of CFU collected by the cascade impactor.
The Bacterial Filtration Efficiency (BFE) is calculated for each test specimen, as a percentage, using the following formula:

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

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

Results

Determination	Collected CFU	BFE (%)	BFE (%) Type I limit	Compliance to Type I limit	BFE (%) Type II and IIR limit	Compliance to Type II and IIR limit
Negative control	0.0					
Positive control run 1	2788.0					
Positive control run 2	2684.0					
Positive control average	2736.0					
Test 1	6.0	99.8	≥ 95	Compliant	≥ 98	Compliant
Test 2	9.0	99.7	≥ 95	Compliant	≥ 98	Compliant
Test 3	8.0	99.7	≥ 95	Compliant	≥ 98	Compliant
Test 4	7.0	99.7	≥ 95	Compliant	≥ 98	Compliant
Test 5	2.0	99.9	≥ 95	Compliant	≥ 98	Compliant
Sample average	**6.4**	**99.8**	≥ 95	Compliant	≥ 98	Compliant

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(#) Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorized by:
Head of Laboratory, Giovanni Bassini, Ch. Eng.

END OF TEST REPORT

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Messrs.
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Zola Predosa, 09/11/2020

Ref. Your Order /

Test Report N°20-1443-02

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

Sample description

Denomination: MASK
Code: MFMT1-MM001
Lot: 1-2020
Sterilization: No
N°of tested samples: 5
Receipt number: 18614
Receipt date: 02/11/2020
Sampling carried out by: MAREMOD SA

The test was started on 04/11/2020 and was completed on 09/11/2020.

Test method

ISO 11737-1:2018

Summary of practice

Samples were aseptically treated. Micro-organisms were extracted from samples using sterile physiological saline containing 0.05 % of Tween 80 in mechanical agitation. The extract was collected and filtered through a 0.45 µm sterile membrane filter. One half of the filter was incubated on Triptone Soya Agar (TSA) culture medium for 72 hours at 32 ± 2℃ in order to evaluate non-selective aerobic bac teria. The other half was incubated on Potato Dextrose Agar (POT) culture medium for 5 days at 22 ± 2℃ in order to evaluate yeasts and moulds. Results were multiplied by correction factor (1.7 – 1.66) obtained from the method validation (see test report N°20-0 816-03).

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Results

Sample	1	2	3	4	5
Weight (g)	3.16	3.16	3.16	3.16	3.16
Mesophilic aerobic (CFU/sample)	27.2	17.0	10.2	10.2	3.4
Moulds (CFU/sample)	3.3	3.3	13.3	<3.3	<3.3
Yeasts (CFU/sample)	<3.3	<3.3	<3.3	<3.3	<3.3
Sum of microorganism (CFU/sample)	<33.8	<23.6	<26.8	<16.8	<10.0
CFU/g	<10.7	<7.5	<8.5	<5.3	<3.2
Compliance (*)	Y	Y	Y	Y	Y

Legenda
Y = Compliant
N = Not compliant

OPINIONS AND INTERPRETATIONS - Not included in ACCREDIA accreditation

(*) Compliance with EN 14683:2019 5.2.5 Microbial cleanliness (Bioburden) / Conformità alla EN 14683:2019 5.2.5 Microbial cleanliness (Bioburden).

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(#) Data provided by the Customer. The laboratory declines responsability for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorised by:
Head of Laboratory Dr. Giovanni Bassini

END OF TEST REPORT

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TESTS FOR IN VITRO CYTOTOXICITY

Test Substance

MASK

Test Report N°20-1443-01

Test performed for

MAREMOD SA
Str. Scarlatescu nr. 17-19, Sector 1
011158 BUCHAREST ROMANIA

by

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QUALITY ASSURANCE

Quality Assurance Manager: Alessandra Marchesi, PhD

GENERAL MANAGEMENT

Giovanni Bassini, Ch.Eng.

TIME SCHEDULE OF TEST

The test was started on 06/11/2020 and was completed on 12/11/2020.

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Ref. Your Order /

Sample description

Denomination: MASK
Code: MFMT1-MM001
Lot: 1-2020
Sterilization: No
Receipt number: 18613
Receipt date: 02/11/2020
Sampling carried out by: MAREMOD SA

Part of the sample to be tested: The whole sample
Pretreatment: /

Test Method

ISO 10993-5: 2009
ISO 10993-12: 2012

Other references

Cytotoxicity Test Protocol - /

Summary of practice

Cell cultures are grown to a near-confluent monolayer in cultures dishes. Three dishes for each sample are prepared. Moreover, three dishes are prepared for the Negative control, for the Positive control and for the Extraction solvent control. In the dishes to be treated with the sample, the medium is aspirated and replaced with test extract. Cell cultures are examined microscopically after 24 and 48h-contact to assess the presence or absence of cytotoxic effects due to the test extract.

Target cells: BSCL 56 /L 929 (Mouse connective tissue)

Culture medium: Minimum Essential Medium (MEM) with Earle's salts added with 5 % of foetal bovine serum, 1 % of L-glutamine, 0,6 % of penicillin/streptomycin and 0,3 % of fungizone (complete MEM).

Extraction conditions: 3,18 grams were extracted with 31,8 ml of complete Cell Culture Medium MEM (ratio 1 g / 10 ml) at 37℃ for 72 hours. The extra ct was tested undiluted, 1:5 and 1:10 diluted. (Ref. ISO 10993-12)

Positive control: 6 cm^2 of latex were extracted with 1 ml of complete Cell Culture Medium MEM under the same conditions of the sample.

Negative control: 0,2 grams of polycarbonate were extracted with 1 ml of complete Cell Culture Medium MEM under the same conditions of the sample.

Extraction vehicle control: complete Cell Culture Medium MEM.
Incubation: The dishes treated with the Test extract, with the Positive and Negative controls and with the Extraction solvent control are incubated for 48 h at 37 ± 1 ℃ in a 5% CO_2 atmosphere.

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Apparatus

- Incubator, which maintains the cultures at 37℃, 5% CO_2;
- Microscope, with inverted phase contrast optics;
- Laminar Flow Cabinet;
- Sterile Disposable;
- Tissue Culture Dishes.

Interpretation of Results: The determination of the cytotoxicity is performed after a 24 and 48 h incubation period examining the cells under the microscope to assess general morphology, vacuolation, detachment, cell lysis, membrane integrity. The change from normal morphology of the Negative control is rated on a reactivity grade from 0 to 4 (see Grading system). Moreover, for the dishes treated with the Test extract the confluence of the monolayer is evaluated and the color of test medium is compared to the negative control.

Grading system

Grade	Reactivity	Reactivity description
0	None	Discrete intracytoplasmic granules; no cell lysis.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules; occasional lysed cells are present
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules; no extensive cell lysis and empty areas between cells
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed
4	Severe	Nearly complete destruction of the cell layers

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Results after 24 h incubation	Score
Positive control	4
Positive control	4
Positive control	4
Negative control	0
Negative control	0
Negative control	0
MEM control	0
MEM control	0
MEM control	0
undiluted extract	0
undiluted extract	0
undiluted extract	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control
1:5 diluted extract	0
1:5 diluted extract	0
1:5 diluted extract	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control
1:10 diluted extract	0
1:10 diluted extract	0
1:10 diluted extract	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control

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Results after 48 h incubation	Score
Positive control	4
Positive control	4
Positive control	4
Negative control	0
Negative control	0
Negative control	0
MEM control	0
MEM control	0
MEM control	0
undiluted extract	0
undiluted extract	0
undiluted extract	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control
1:5 diluted extract	0
1:5 diluted extract	0
1:5 diluted extract	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control
1:10 diluted extract	0
1:10 diluted extract	0
1:10 diluted extract	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control

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OPINIONS AND INTERPRETATIONS – Not included in ACCREDIA accreditation

The cells treated with undiluted, 1:5 and 1:10 diluted test extracts after 24 and 48 hours of incubation do not show any changes from normal morphology of the Negative control. The undiluted, 1:5 and 1:10 diluted test extracts do not show any reactivity.

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(#)Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorized by:
General Management, Giovanni Bassini Ch.Eng.

Zola Predosa, 13/11/2020

END OF TEST REPORT

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Zola Predosa, 13/07/2020

Ref. Your Order del 2020

Test Report N°20-0812-02

DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Sample description

Denomination: Mask
Code: MMC1-MM01
Lot: 0011905
Sterilization: No
Receipt number: 16806
Receipt date: 01/07/2020
Sampling carried out by: MAREMOD SA

Further information about the sample

Number of tested specimens: 5
Number of tested areas per sample: 5
General location of the chosen areas to be tested: representative areas are chosed for the test. Specimens are taken from one or more samples, depending on the available area.
Sample preparation: the test is performed on the sample lying flat, wrinkle-free.

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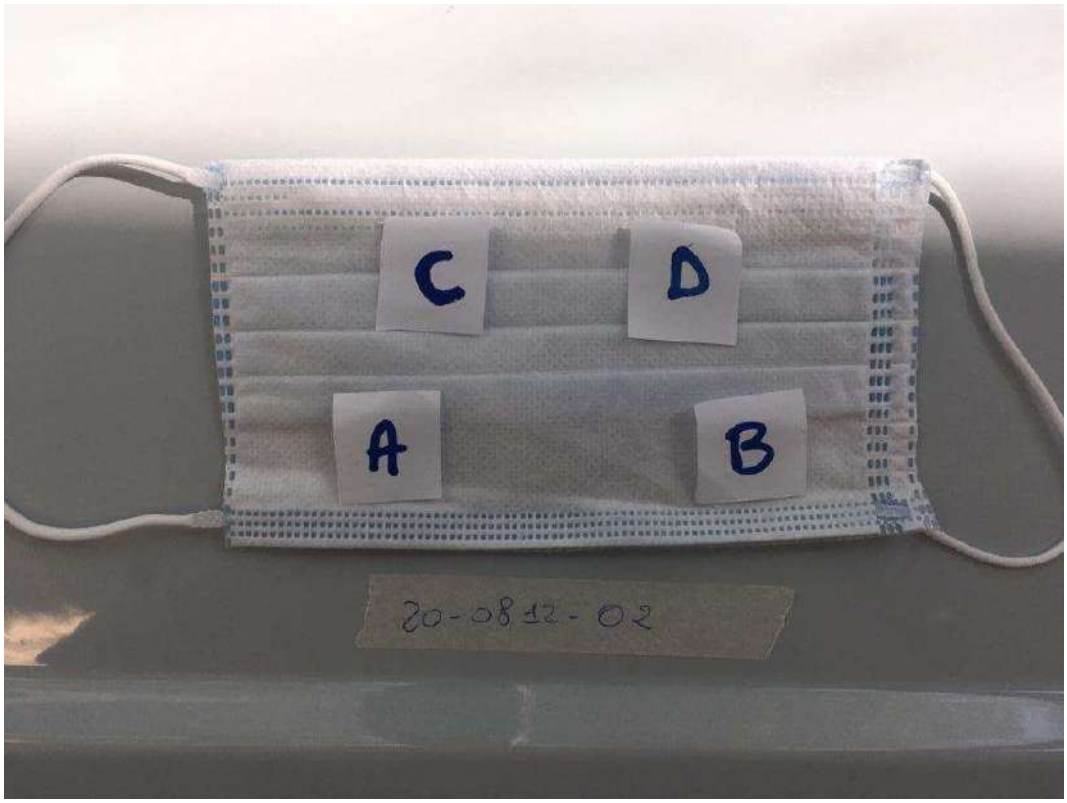
Picture of the sample:



Test date

09-07-2020

Test method

EN 14683:2019 Annex c

Summary of method

Each specimen is conditioned at 22 ± 2℃ and 80 ± 1 0% relative umidity for a minimum of 4 hours before the test.
A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material. A digital differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.
Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 l/min.
The holder is opened and the test specimen is placed across the 25 mm diameter orifice (total area 4,9 cm2) between the top and the bottom parts of the holder. Then it is clamped in place using a mechanical clamp with sufficient pressure to avoid air leaks. Due to the presence of an allignment system the tested area of the specimen should be perfectly in line and across the flow air.With the specimen in place the flow rate shall be 8 l/min.
The procedure described is carried out on 5 (or appropriate number) different areas of the mask and the readings averaged.

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For each test specimen the differential pressure of each tested area is calculated as follows:

DP = DP read \ 4,9

where

DP is the Differential Pressure for cm2 of test material expressed in Pa;
Dp read is the Differential Pressure for specimen;
4,9 is the area (in cm2) of the test material.

Results

Determination	DP Read (Pa)	DP (Pa/cm2)	DP (Pa/cm2) Type I and II limit	Compliance to Type I and II limit	DP (Pa/cm2) Type IIR limit	Compliance to Type IIR limit
Specimen 1 – Pos. A	149	30.4	< 40	Compliant	< 60	Compliant
Specimen 2 – Pos. B	119	24.3	< 40	Compliant	< 60	Compliant
Specimen 3 – Pos. C	146	29.8	< 40	Compliant	< 60	Compliant
Specimen 4 – Pos. D	175	35.7	< 40	Compliant	< 60	Compliant
Specimen 5 – Pos. A	143	29.2	< 40	Compliant	< 60	Compliant
Total average of specimens		**29.9**	**< 40**	**Compliant**	**< 60**	**Compliant**

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(#) Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorized by:
Head of Laboratory, Giovanni Bassini, Ch. Eng.

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IRRITATION TESTS - ANIMAL IRRITATION TEST

Test Sample

MASK

Test Report N°20-1285-03

Test performed for

MAREMOD SA
Str. Scarlatescu nr. 17-19, Sector 1
011158 BUCHAREST ROMANIA

by

BIOCHEM S.r.l.
Via Benini 13
40069 ZOLA PREDOSA BO

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QUALITY ASSURANCE

Quality Assurance Manager: Alessandra Marchesi, PhD.

TEST DIRECTOR

Giovanni Bassini, Ch.Eng.

TIME SCHEDULE OF TEST

The test was started on 30/11/2020 and was completed on 04/12/2020.

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Ref. Your Order /

Test Substance

Denomination: MASK
Code: MFMT1-MM001
Lot: 1-2020
Sterilization: No
Receipt number: 18178
Receipt date: 08/10/2020
Sampling carried out by: MAREMOD SA

Part of the sample to be tested: the whole sample
Pretreatment: /

Test Method

- ISO 10993-10:2010
- ISO 10993-12:2012

Reference document

- ASTM F 719-81: Standard practice for Testing biomaterials in rabbits for primary skin irritation.

Other references

IrritationTest Protocol - /

Summary of practice: Exposure of skin to the extracts of the test material are accomplished by means of a patch test technique employing cutaneous sites on the back of each of 3 albino rabbits. The animals are observed at regular intervals for 72 h evaluating the skin reactions for erythema and oedema.

Extraction conditions

The extraction was performed by Biochem in the following way:
– 3 g were extracted with 30 ml of PHYSIO (ratio 1 g / 10 ml) at 37℃ for 72 hours;
– 3 g were extracted with 30 ml of OIL (ratio 1 g / 10 ml) at 37℃ for 72 hours.

Positive control: : 10 % sodium dodecyl sulfate. Test performed on May 2020: primary irritation index (total PII) of 3,78 corresponding to a MODERATE irritation response.

Negative controls

– PHYSIO;
– OIL.

Animals: Healthy thin-skinned albino rabbits, female, 2 to 4 Kg; three animals are used to test the sample.

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Procedure: Approximately 24 h before the test beginning, closely clip the fur on the backs of the animals on both sides of the spinal column over a sufficiently large test area. Place the test and control material on skin test sites of each animal's back and occlude the sites by placing gauze flats for at least 4 h. After 24, 48 and 72 h after removal of the patches score test sites for erythema and oedema in accordance with the following Grading System.

Grading system

Erythema	Score	Oedema	Score
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Well-defined oedema (edges of area well defined by definite raising)	2
Moderate erythema	3	Moderate oedema (raised approximately 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond exposure area)	4

Then, calculate the Primary Irritation Index. This Index is characterized by number (score) and description (Irritation response Category) in accordance with the following scheme:

Irritation Response Categories	**Score**
Negligible	from 0 to 0,4
Slight	from 0,5 to 1,9
Moderate	from 2 to 4,9
Severe	from 5 to 8

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Results

Extraction vehicle for Test material and Control sites 1: PHYSIO
Extraction vehicle for Test material and Control sites 2: OIL

Rabbit N.	164	Test material sites		Negative control sites	
Time	Reaction	**1**	**2**	**1**	**2**
24 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
48 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
72 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
Primary Irritation Score		0.0		0.0	
		0.0			

Rabbit N.	177	Test material sites		Negative control sites	
Time	Reaction	**1**	**2**	**1**	**2**
24 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
48 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
72 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
Primary Irritation Score		0.0		0.0	
		0.0			

Rabbit N.	163	Test material sites		Negative control sites	
Time	Reaction	**1**	**2**	**1**	**2**
24 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
48 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
72 h	Erythema	0	0	0	0
	Oedema	0	0	0	0
Primary Irritation Score		0.0		0.0	
		0.0			

Primary Irritation Index (Total PII) **0.0**

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Conclusions

Under the experimental conditions the test sample showed a Negligible Irritation Response

The present test report exclusively refers to the referenced test sample.
If the sample has been sampled by the Customer, the results are referred to the sample as received.
The present test report may not be partially reproduced without Biochem authorization.

(#) Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Pesce Carla, Dr.

Issue authorized by:
Test Director Giovanni Bassini, Ch.Eng.

Zola Predosa, 06/12/2020

END OF TEST REPORT

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CLIENT	**Maremod SA,** **Scarlatescu Street 17-19, Sector 1, Cod 011158,** **Bucharest, Romania**		
LABORATORY	❒ **MaB – Applied microscopy and cell biology -** X **ToP – Toxicology and proteomics -** X **Ms² – Measurements, Sensors and Systems -**		
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Ed.	Report n°	Date	Description
01	**MS2_2020_R29**	**15/07/2020**	**First edition**

Index

1. Order Reference

TPM_2020_989_BIO6S

2. Purpose

"SPLASH RESISTANCE" analysis: evaluation of the resistance of the device to the penetration of a certain volume of synthetic blood by high-speed impact between liquid and device for a short period of time (1 second). The analysis is carried out following the guidelines of ISO 22609:2004(E).

2.1 Specimen

Maremod SA, supplied to the laboratory 32 complete face masks, from the production batch **0011905**. Mask code **MMC1-MM01**, denomination **Mask**.

2.2 Sample preparation

Samples have been tested without any modification in their geometry, whatsoever. The sample is pre-conditioned in a climatic chamber at a temperature of 21 ° C and relative humidity of 85% for 4 hours before the analysis. The measurement is made within 1 minute of removal from the climatic chamber.

3. Materials & Methods

3.1 Materials

- Demineralized H20 0.055 µS / cm
- Triton X 100 X Sigma-Aldrich cod. T8787; batch MKBR5267V
- Direct RED 80 sigma aldrich cod. 365548; batch MKBB6842V

Synthetic blood is made from a 15 mg / L solution of Triton X 100 and a Direct RED 80 red color 200 mg / L in demineralized water.

3.2 Instrumentation

- "Flower 340" climatic chamber Serial Number: 011TT29. Performance certificate valid until September 2020.
- "Winkratos 5.00" software.
- 3D-Bioplotter ENVISIONTEC, serial number ETB41507M056, (MS2_066)

3.3 Experimental method

The analysis is based on the visual observation of the sample subjected to a squirt of synthetic blood at high speed to simulate an accidental leakage of the patient's blood in the surgical site. The sample is mounted on a special support perpendicular to the direction of the liquid flow. The squirt of synthetic blood, whose speed and quantity are comparable to the excision of a large artery, takes place by pneumatic impulse through a syringe containing synthetic blood, a needle of defined section and length and a piston on which electronically regulated pressure is exerted via software. The quantity of liquid dispensed is 2.0 ml. The observation is done visually and through the use of a tissue paper, noting that the liquid does not pass through the mask or does not wet the inside after 10 seconds from performing the test. Synthetic blood is prepared using a solution of Triton X 100 in order to have a surface tension of 0.042 N / m, comparable to that of whole blood.

3.4 Experimental conditions

The experimental parameters for the test have been set as indicated below:

Sample-cannula distance	Cannula internal diameter	Cannula length	Pressure	Pulse duration
30 cm	0.84 mm	12.7 mm	21 kPa	0.7 s
30 cm	0.84 mm	12.7 mm	16 kPa	0.9 s

3.5 Acceptance criterion

The test is carried out according to ISO 22609:2004 on the samples available at the maximum designated pressure of 21kPa. In case of permeation to synthetic blood, the test is carried out at a pressure of 16kPa, corresponding to the minimum pressure allowed by UNI EN 14683:2019 for surgical masks. To have an AQL of 4% the test is considered approved if the number of samples that exceed the resistance to penetration of liquid are at least 29.

4. Results

The masks with sample code **MMC1-MM01**, denomination **Mask**, have been subjected to pre-treatment and splash resistance test. Figure 1 shows a representative image of the internal and external part of a sample template.

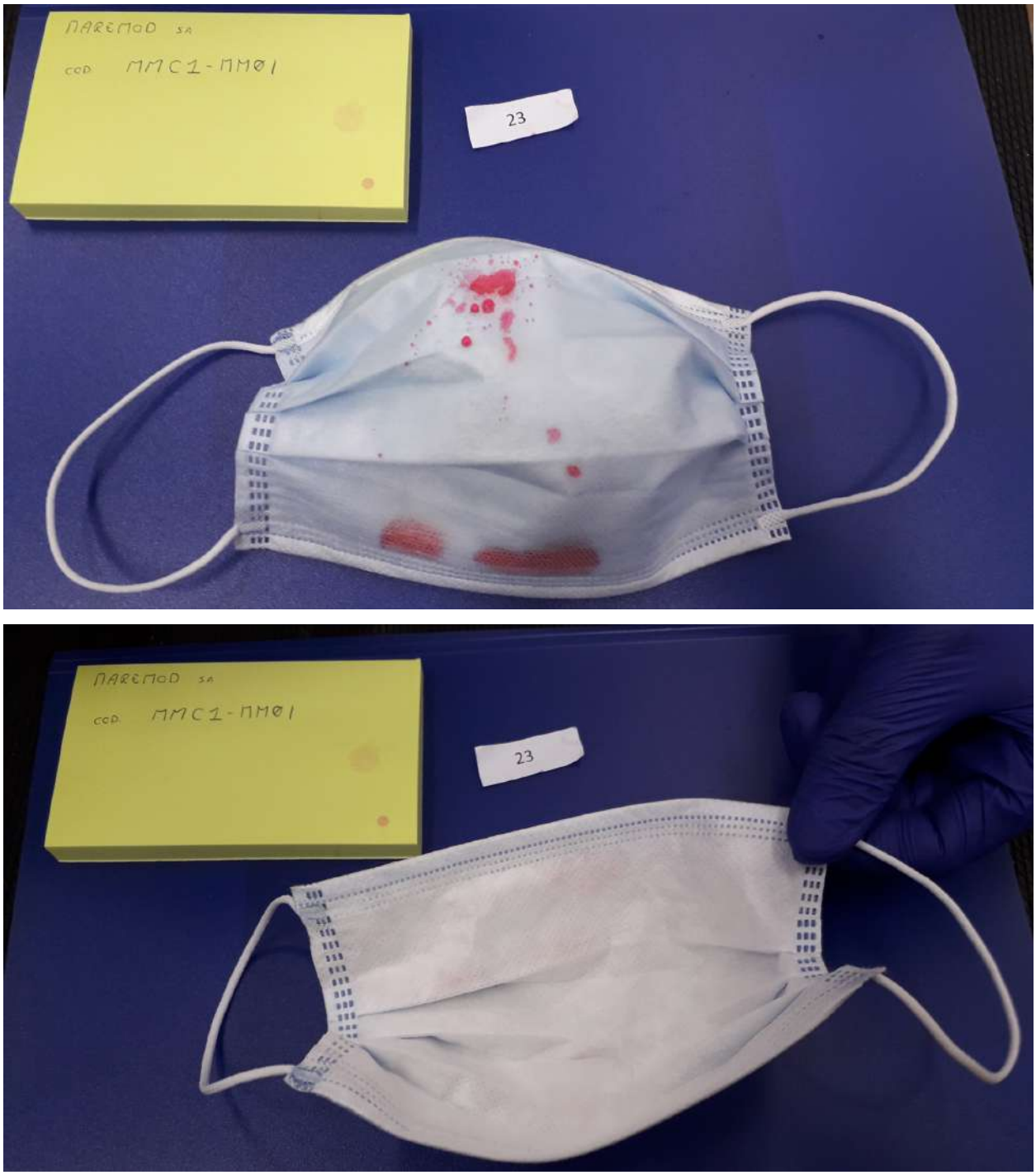

Figure 1: External side at the top and the internal side at the bottom, after splash resistance test

Of the 32 masks tested, none showed the permeation of synthetic blood in the internal part of the mask within 10 seconds, and also in greater times, from the application of the squirt of liquid at the pressure of 21kPa.

5. Conclusions

The tests carried out indicate that the materials used may be suitable for the construction of a mask classifiable as IIR.