biochem S.r.l.

ANALISI CHIMICO-FISICHE
MICROBIOLOGICHE
BIOCOMPATIBILITA'
CONSULENZA TECNICA
BIOTECNOLOGIE

Messrs
MASK AUTHORITY Sp. z o.o.
Targowa street, 4
52-326 Wroclaw Poland

Zola Predosa, 02/11/2020

Ref. Your Order /

Test Report N°20-1413-01

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description

Denomination: VS004 - Version 3
Code: -
Lot: 1
Sterilization: No
Receipt number: 18532
Receipt date: 27/10/2020
Sampling carried out by: MASK AUTHORITY Sp. z o.o.

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: internal side

Test date

The test was started on 29-10-2020 and was completed on 30-10-2020

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	2341.0					
Positive control run 2	2190.0					
Positive control average	2265.5					
Test 1	11.0	99.5	≥ 95	Compliant	≥ 98	Compliant
Test 2	2.0	99.9	≥ 95	Compliant	≥ 98	Compliant
Test 3	1.0	100.0	≥ 95	Compliant	≥ 98	Compliant
Test 4	0.0	100.0	≥ 95	Compliant	≥ 98	Compliant
Test 5	1.0	100.0	≥ 95	Compliant	≥ 98	Compliant
Sample average	**3.0**	**99.9**	≥ 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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Targowa street, 4
52-326 Wroclaw Poland

Zola Predosa, 29/10/2020

Ref. Your Order /

Test Report N°20-1413-02

DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Sample description

Denomination: VS004 - Version 3
Code: -
Lot: 1
Sterilization: No
Receipt number: 18533
Receipt date: 27/10/2020
Sampling carried out by: MASK AUTHORITY Sp. z o.o.

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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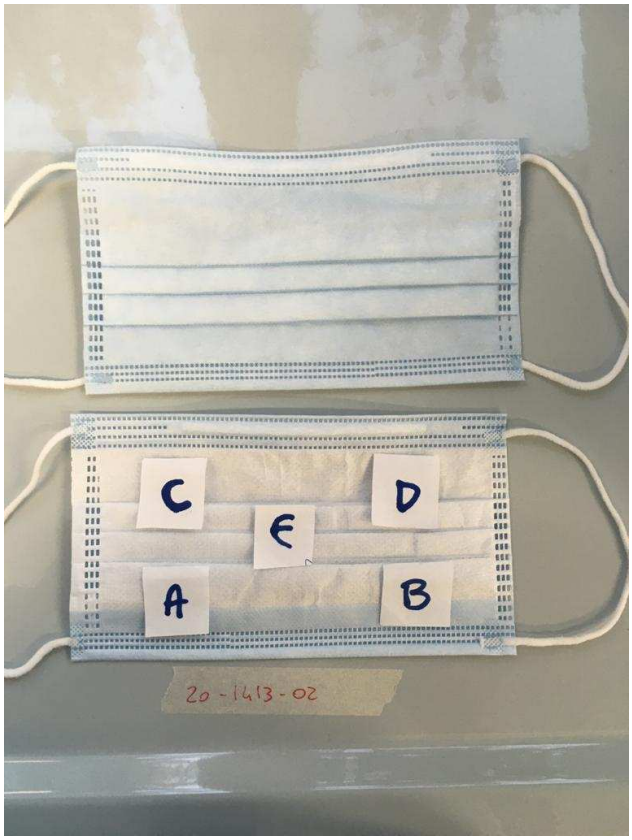
Picture of the sample:



Test date

29-10-2020

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	212	43.3	< 40	Not compliant	< 60	Compliant
Specimen 2 – Pos. B	227	46.3	< 40	Not compliant	< 60	Compliant
Specimen 3 – Pos. C	195	39.8	< 40	Compliant	< 60	Compliant
Specimen 4 – Pos. D	202	41.2	< 40	Not compliant	< 60	Compliant
Specimen 5 – Pos. E	220	44.9	< 40	Not compliant	< 60	Compliant
Total average of specimens		**43.1**	**< 40**	**Not compliant**	**< 60**	**Compliant**

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(#) Data provided by the Customer. The laboratory declines responsability 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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52-326 Wroclaw Poland

Zola Predosa, 02/11/2020

Ref. Your Order /

Test Report N°20-1413-04

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

Sample description

Denomination: VS004 - Version 3
Code: -
Lot: 1
Sterilization: No
N°of tested samples: 5
Receipt number: 18535
Receipt date: 27/10/2020
Sampling carried out by: MASK AUTHORITY Sp. z o.o.

The test was started on 28/10/2020 and was completed on 02/11/2020.

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 (1.22 – 1.37) obtained from the method validation (see test report N°20-1 413-03).

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Results

Sample	1	2	3	4	5
Weight (g)	2.84	2.84	2.84	2.84	2.84
Mesophilic aerobic (CFU/sample)	4.9	9.8	4.9	2.4	2.4
Moulds (CFU/sample)	13.7	2.7	11.0	13.7	2.7
Yeasts (CFU/sample)	<2.7	<2.7	2.7	<2.7	<2.7
Sum of microorganism (CFU/sample)	<21.3	<15.2	18.6	<18.8	<7.8
CFU/g	<7.5	<5.4	6.5	<6.6	<2.7
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)

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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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DECLARATION OF CONFORMITY

CE

Manufacturer	**Mask Authority Sp. z o.o.** ul. Targowa 4 52-326 Wrocław
Name of product:	**VIRSHIELDS VS004**
Type/ version	Type II R, VERSION 3
Classification	Class: I, Rule: 1

Mask Authority Sp. z o.o. is solely responsible to issue this declaration that this product meets all applicable requirements of the European Directive (MDD) 93/42, Annex VII.

Applicable harmonized standards have been used to demonstrate safety and efficacy of the medical device.
The following standards were applied:

ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

EN 1041:2013
Information supplied by the manufacturer of medical devices

ISO 15223-1:2017
Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

ISO 14971:2012
Medical devices – Application of risk management to medical devices

ISO 62366:2015
Medical devices – Application of usability engineering to medical devices

EN 14683:2019
Medical face masks - Requirements and test methods

EN ISO 11737-1:2018
Sterilization of health care products - Microbiological methods - Part 1: Determination of microbial populations on products

Revision: 1

Approved by:

Robert Zachar *CHAIRMAN OF THE BOARD*

Prezes Zarządu
Mask Authority Sp. z o. o.
Robert Zachar

Ganna Pylepenko *quality representative*

Effective from: 13.11.2020

Pełnomocnik ds. Jakości
Mask Authority Sp. z o.o.
Ganna Pylypenko

Mask Authority

CONFORMITY ASSESSMENT – VS004 ver. 3

The conformity assessment of Virshields VS004 ver. 3 medical masks is based on the requirements of the standard "EN 14683 + AC: 2019-09. Medical masks. Requirements and test methods." This standard is harmonized with the Council Directive 93/42 / EEC on medical devices. In terms of functional properties, Virshields VS004 medical masks ver. 3 meet the requirements for type **IIR** medical masks in accordance with EN 14683 + AC: 2019-09. The requirements and test methods for the splash resistance and blood penetration of the VS004 ver. 3 masks demonstrate compliance with the ISO 22609: 2004 standard, in terms of microbiological cleanliness, the VS004 ver. 3 medical masks comply with "EN ISO 11737-1: 2018: 03 (Sterilization of heal care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products). Below are the results of the tests that were carried out in the accredited laboratory of Biochem Zola Predosa Italy.

Table 1 Functional requirements for medical masks

Test	Critical values for type IIR	Avg. Result
Bacterial filtration efficiency (BFE) (%)*	≥ 98	99,9
Differential pressure (Pa/cm^2)*	< 60	43,1
Splash resistance pressure (kPa)**	≥ 16	21
Microbial cleanliness (cfu/g)***	≤ 30	5,7

* based on the EN 14683 + AC: 2019-09 standard. Medical masks. Requirements and test methods;

** based on the ISO 22609: 2004 standard.Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

*** based on the EN 14683 + AC: 2019-09 standard (Medical masks. Requirements and test methods) and PN-EN ISO 11737-1: 2018: 03 (Sterilization of heal care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products)

Medical masks Virshields VS004 ver. 3 also meet the standards for biocompatibility assessment in accordance with EN ISO 10993-1: 2009 + AC: 2010 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

Biological compliance - carried out on the final product - was confirmed by tests verifying cytotoxicity.

The biocompatibility assessment contain:

- Biological assessment (based on a literature review of bibliographic data) - ISO 10993: 1
- In vitro cytotoxicity studies - ISO 10993-5

Approved by:

Robert Zachar Chairman of the Board

Prezes Zarządu
Mask Authority Sp. z o. o.
Robert Zachar

Anna Pylepenko Quality Representative

Pełnomocnik ds. Jakości
Mask Authority Sp. z o.o.
Pylypenko
Ganna Pylypenko

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LABORATORY	❒ **MaB – Applied microscopy and cell biology -** X **ToP – Toxicology and proteomics -** X **Ms² – Measurements, Sensors and Systems -**

Analysis conducted by: Mattia Piccini mattia.piccini@tpm.bio	**Signature**	**Date** 09/11/2020
Head of the laboratory: Alberto Ferrari Alberto.Ferrari@tpm.bio	**Signature**	**Date** 09/11/2020
Approved by Luigi Rovati, luigi.rovati@unimore.it Scientific Director of materials, sensors and systems laboratory	**Signature**	**Date** 09/11/2020

Ed.	Report n°	Date	Description
01	**MS2_2020_R103**	**09/11/2020**	**First edition**

Index

1. Order Reference

TPM_2020_1260_BIO18s

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) and in agreement with internal protocol MS2_01.

2.1 Specimen

Mask Authority Sp. z o.o., supplied to the laboratory 32 complete face masks, from the production batch "**1**". Sample ID "**20-1413-08**", mask denomination **"VS004-Version 3"**.

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 (TOP_052). Calibration performed on 14/09/2020. Certificate of validity of performances valid until September 2021.
- "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 mask denomination **"VS004-Version 3"** 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.

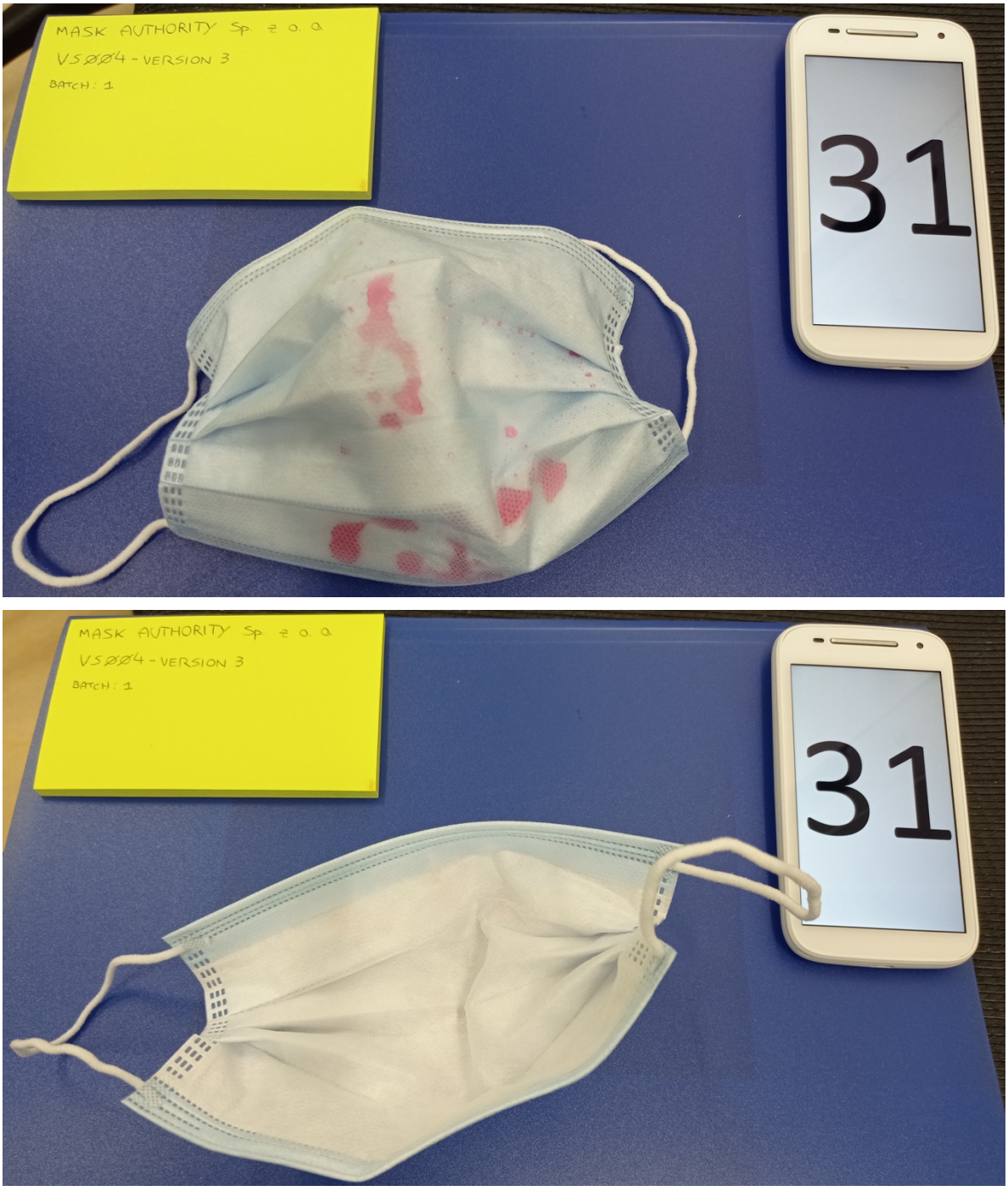

Figure 1: External side at the top and internal side at the bottom, after splash resistance test

Of the 32 masks tested, none showed the permeation of synthetic blood into the inner 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 are suitable for the construction of a mask classifiable as IIR.