EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer
Mask Authority Sp. z o.o., Targowa 4, 52-326 Wroclaw, Poland
hereby declaring the following medical disposable mask.

Product description: ***VIRSHIELDS VS004***

Type II R *Classification:* ***Class: I, Rule: 1***

is in conformity with the provisions of the following European Regulations and/or Directives:

Medical Devices Directive

and according to Annex IX rules of the Medical Device Directive is classified as a Class I device.

And is in conformity with the provisions of Annex VII and all other applicable provisions of Council Directive 93/42/EEC (Medical Device) including the National Standard transposing the harmonized European Standard Number:

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

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

Signed by: Robert Zachar CHAIRMAN OF THE BOARD

Date: 07.01.2021

Signature Certificate

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Document signed by:

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Signed via link

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07 Jan 2021 17:32:36 UTC

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

DREAM CONSULTING Piotr P. Pietrowski
Jurgensa 1, 95-010 Dobra-Nowiny

Test protocol

Customer	Mask Authority
Scope and test parameters	Breathability according to Annex C of EN 14683:2019 Volumetric air flow rate: 8 l/min Sample testing area: 4,9 cm^2 Each test specimen (sample) was conditioned at 23°C and 80% relative humidity for 4 hours.
Test object	Medical face mask VS004 - Version 2
Date of test	07.12.2020 r.

Number of pages: 1 (one)

Breathability test results

Test object: Medical face mask VS004 - Version 2

Sample number/marking	Test number corresponding to tested area	Measured value of the differential pressure, Pa	Average value of the breathability, ΔP, Pa/cm^2	The mask meets requirements of EN 14683:2019, ΔP, Pa/cm^2 in the range of:
1	1	193,0	38,28	Type I (<40), Type II (<40), Type IIR (<60)
	2	192,8		
	3	188,8		
	4	178,5		
	5	184,8		
2	1	194,1	39,59	Type I (<40), Type II (<40), Type IIR (<60)
	2	193,7		
	3	194,0		
	4	194,4		
	5	193,7		
3	1	188,7	38,87	Type I (<40), Type II (<40), Type IIR (<60)
	2	189,5		
	3	192,2		
	4	191,1		
	5	190,8		
4	1	200,2	39,94	Type I (<40), Type II (<40), Type IIR (<60)
	2	203,3		
	3	196,0		
	4	188,2		
	5	190,8		
5	1	195,6	39,77	Type I (<40), Type II (<40), Type IIR (<60)
	2	196,9		
	3	197,2		
	4	187,3		
	5	197,4		

Given results are related to tested samples/specimens only

END OF THE TEST PROTOCOL

Test protocol prepared by: Ph.D. (Eng.) Piotr Pietrowski

Nelson Labs
A Sotera Health company

Sponsor:
Ganna Pylpenko
Mask Authority Sp. z.o.o.
Targowa Street 4
Wroclaw, 52-326
POLAND

Flammability of Clothing Textiles Final Report

Test Article:	Virshields VS004 - Version 3
Study Number:	1372327-S01
Study Received Date:	15 Dec 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0073 Rev 07
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds, IBE, or DNI
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Adam Brigham electronically approved — 04 Jan 2021 14:46 (+00:00)
Study Director Adam Brigham — Study Completion Date and Time

Results: Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing. The test articles submitted by the sponsor achieved a Class 1 flammability rating.

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

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°20-1413-04

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°C 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°C 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)

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 responsability for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorised by:
Head of Laboratory Dr. Giovanni Bassini

END OF TEST REPORT

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
LAB N° 0283 L

Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

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CLIENT	**Mask Authority Sp. z o.o.** Panattoni City Logistics Wroclaw I, Hala 2, ul. Targowa 4 52-326 Wroclaw, Poland
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.

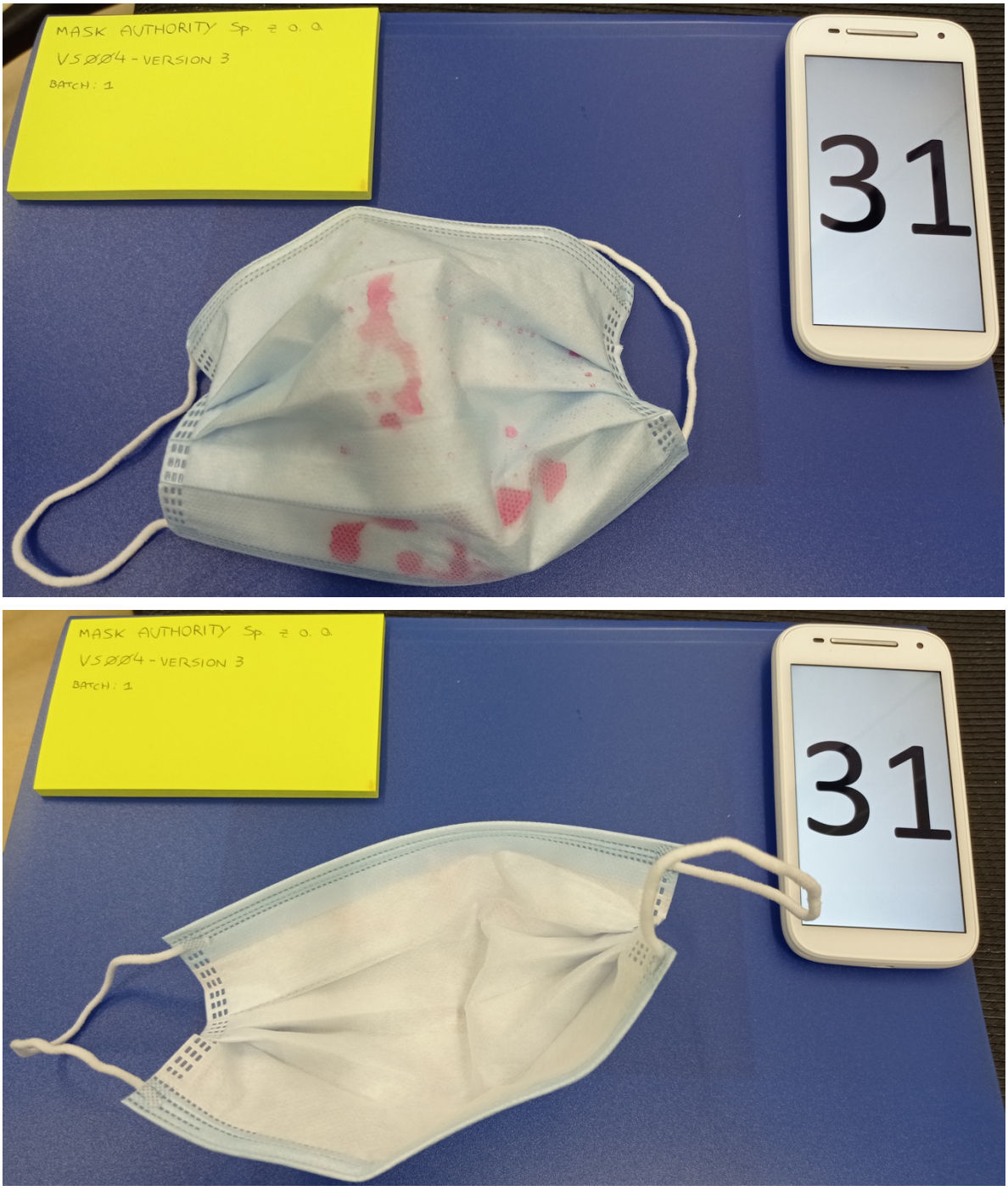

Figure 1: External side at the top and internal side at the bottom, after splash resistance test

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.

Sponsor:
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Viral Filtration Efficiency (VFE) Final Report

Test Article:	Virshields VS004 - Version 3
Study Number:	1361465-S01
Study Received Date:	10 Nov 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Test Area:	~40 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	1.2 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.9 µm

Results:

Test Article Number	Percent VFE (%)
1	99.6

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} x\ 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Mikell Goldsberry electronically approved — 14 Dec 2020 22:33 (+00:00)
Study Director Mikell Goldsberry — Study Completion Date and Time