JUF PRODUCTION

Medical Face Masks

JUF PRODUCTION

Product information

TECHNICAL DATA SHEET

Date: 12/06/2020

PRODUCT	MEDICAL FACE MASKS
CLASSIFICATION	TYPE II
MODEL	ZOGEAR
PRODUCT DESCRIPTION	Shingle pleats rectangular face masks with a shapeable nose-piece and two earloops present, one on each side, to hold mask in place.

The product covers the nose, mouth and chin of the mask wearer. Its purpose is to reduce the release of air droplets from the airways of an infected person into the environment to limit the further spread of the infection and to protect the carrier from other environmental hazards.

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MATERIAL

1st ply	Outer Material	25 g/m2 Non-Woven
2nd ply	Filter Layer	25 g/m2 Melt-Blown filter
3rd ply	Inner Material	25 g/m2 Fluid resistant Non-Woven
Nose-piece	Polypropylene (Non-Metal)	
Earloops	Polyester and Spandex	

Latex free

QUALITY

Norm EN 14683, Type I and Type II limit

EN 14683 - EFFICACY TESTS	STANDARD / METHOD
Bacterial filtration efficiency (BFE)	EN 14863:2019 Annex B 5.2.2
Breathability	EN 14863:2019 Annex C 5.2.3
Bioburden method validation	ISO 11737-1:2018 Annex B.2
Bioburden (microbiological contamination)	EN 14683:2019 Annex D 5.2.5

FIXTURE

3-layer mask body, with nose-piece on the upper edge of the mask and with ultrasonically welded ear loops inside the mask body.

SIZE

Mask Body	175 x 95 mm	± 5 mm
Nose-piece	105	± 5 mm
Earloops	165 mm	± 10 mm

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PACKAGING

PRIMARY PACKAGING	SECONDARY PACKAGING
50 pcs per box Size: 18.5 x 10 x 9cm Weight: 180 g	40x50 pcs per box Size: 52 x 39 x 39.5cm Weight: 7750 g

SHELF LIFE

3 years after production date

STORAGE CONDITION

Store under cool, clean, and dry conditions. Avoid excessive heat (over 40°C or 104°F)

QUALITY ASSURANCE AND CONFORMITY

Directive 93/42/EEC

Regulation (EU) 2017/745

(Partly. The entry into force of the Regulation postponed to 26 May 2021 - REGULATION (EU) 2020/561)

EN 14683:2019

COUNTRY OF ORIGIN

LATVIA

SIA "JUF" – Reg. No.: 43603077785 – Manufacture: Aviacijas street 18, Jelgava, Latvia, LV-3004 – Tel.: +371 27 27 0010 – e- mail: info@juf.lv

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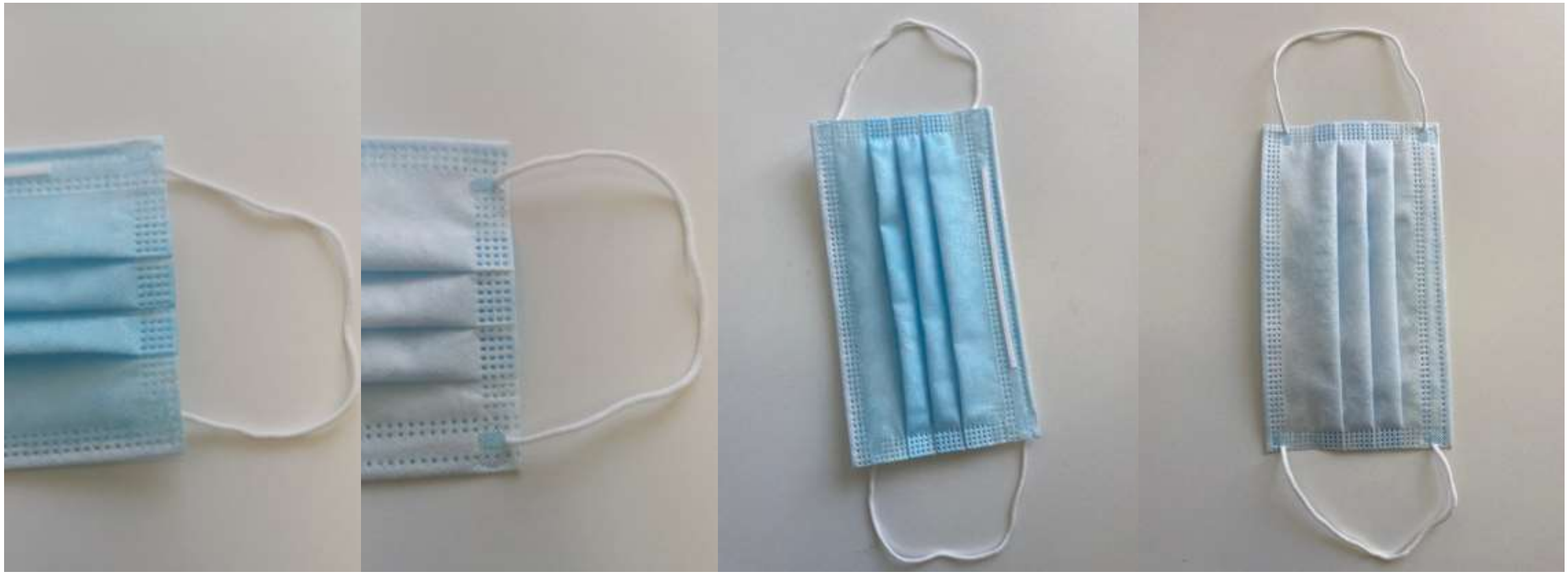

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EC Declaration of Conformity

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SIA "JUF"
Reg. No.: 43603077785
Address: Parka street 26-1,
Eleja parish, Jelgava county,
Latvia, LV-3023

EC DECLARATION OF CONFORMITY

No. 20-512-02

SIA "JUF" declares that this product complies with the following regulations:

MANUFACTURER	SIA "JUF" Aviacijas street 18, Jelgava, Latvia, LV-3004
PRODUCT	**MEDICAL FACE MASK**
CLASSIFICATION	**TYPE II**
MODEL	**ZOGEAR**
PRODUCT DESCRIPTION	The product covers the nose, mouth and chin of the mask wearer. Its purpose is to reduce the release of air droplets from the airways of an infected person into the environment to limit the further spread of the infection and to protect the carrier from other environmental hazards.
QUALITY ASSURANCE AND CONFORMITY	Directive 93/42/EEC Regulation (EU) 2017/745 *(Partly. The entry into force of the Regulation postponed to 26 May 2021 – REGULATION (EU) 2020/561)* EN 14683:2019

EN 14863:2019	Annex B 5.2.2	Bacterial filtration efficiency (BFE) *Test report 20-0647-01*
EN 14863:2019	Annex C 5.2.3	Breathability *Test report 20-0647-02*
ISO 11737-1:2018	Annex B.2	Bioburden method validation *Test report 20-0647-03*
EN 14683:2019	Annex D 5.2.5	Bioburden (microbiological contamination) *Test report 20-0647-04*

This declaration of conformity is issued under the sole responsibility of the manufacturer. The object of the declaration identified above is in conformity with the relevant Union harmonisation legislation: Directive 93/42/EEC with its requirements and with the harmonised standards:

CE

We hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced standards and meets all essential requirements of the specified directives.

Signed Baiba Podane
Position Member of the Board
Location Jelgava, Latvia

Signature: _____

Date of issue: 2020/06/12

SIA "JUF" - Reg. No.: 43603077785
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Messrs
SIA "JUF"
Parka street 26-1, Eleja parish.
LV-3023 JELGAVA COUNTY LATVIA

Zola Predosa, 10/06/2020

Ref. Your Order del 2020

Test Report N°20-0647-01

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description

Denomination: Face mask
Code: /
Lot: /
Sterilization: No
Receipt number: 16211
Receipt date: 26/05/2020
Sampling carried out by: SIA "JUF"

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 08-06-2020 and was completed on 09-06-2020

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 $1,7 \times 10^3$ to $3,2 \times 10^3$ 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°C 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					
Positive control run 1	2858					
Positive control run 2	2872					
Positive control average	2865					
Test 1	6	99.8	≥ 95	In compliance	≥ 98	In compliance
Test 2	7	99.8	≥ 95	In compliance	≥ 98	In compliance
Test 3	9	99.7	≥ 95	In compliance	≥ 98	In compliance
Test 4	11	99.6	≥ 95	In compliance	≥ 98	In compliance
Test 5	8	99.7	≥ 95	In compliance	≥ 98	In compliance
Sample average	**8.2**	**99.7**	≥ 95	In compliance	≥ 98	In compliance

(#) 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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Parka street 26-1, Eleja parish
LV-3023 JELGAVA COUNTY LATVIA

Zola Predosa, 04/06/2020

Ref. Your Order of 2020

Test Report N°20-0647-02

DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Sample description
Denomination: Face mask
Code:
Lot:
Sterilization: No
Receipt number: 16212
Receipt date: 26/05/2020
Sampling carried out by: SIA "JUF"

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
01-06-2020

Test method
EN 14683:2019 Annex C

Summary of method
Each specimen is conditioned at 22 ± 2°C and 60 ± 10% 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 alignment 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	162	33.1	< 40	Compliant	< 60	Compliant
Specimen 2 – Pos. B	169	34.5	< 40	Compliant	< 60	Compliant
Specimen 3 – Pos. C	156	31.8	< 40	Compliant	< 60	Compliant
Specimen 4 – Pos. D	169	34.5	< 40	Compliant	< 60	Compliant
Specimen 5 – Pos. A	173	35.3	< 40	Compliant	< 60	Compliant
Total average of specimens		**33.8**	**< 40**	**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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Zola Predosa, 08/06/2020

Ref. Your Order del 2020

Test Report N°20-0647-03

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS – VALIDATION OF METHOD

Sample description

Denomination: Face mask
Code: /
Lot: /
Sterilization: No
N°of tested samples: 5
Receipt number: 16213
Receipt date: 26/05/2020
Sampling carried out by: SIA "JUF"

The test was started on 03/06/2020 and was completed on 08/06/2020.

Test method

ISO 11737-1:2018

Summary of practice

Sterile samples have been contaminated with a know concentration of *Staphylococcus aureus ATCC 6538* and *Candida albicans ATCC 10231*. Micro-organisms were extracted from samples using sterile physiological saline containing 0,05 % of Tween 80 in mechanical agitation. The extract obtained from each sample was filtrated through a 0,45 µm sterile membrane filter. One half of the filter was incubated on Tryptone Soya Agar (TSA) culture medium for 72 hours at 32°C ± 2°C to evaluate aerobic microrganisms. The other half was incubated on Potato Dextrose Agar (POT) culture medium for 5 days at 22 ± 2°C to evaluate recovered yeasts and moulds . Then was calculated the correction factor for each microrganism.

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Results

Staphylococcus aureus ATCC 6538

Sample	Contamination (cfu/sample)	Recovered micro-organism (cfu/sample)	Recovery (%)
1	56	32	57.1
2	56	44	78.6
3	56	22	39.3
4	56	46	82.1
5	56	50	89.3
Mean value		**38.8**	**69.3**
Correction factor		**1.44**	

Candida albicans ATCC 10231

Sample	Contamination (cfu/sample)	Recovered micro-organism (cfu/sample)	Recovery (%)
1	294	274	93.2
2	294	204	69.4
3	294	200	68.0
4	294	232	78.9
5	294	170	57.8
Mean value		**216**	**73.5**
Correction factor		**1.36**	

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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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Zola Predosa, 08/06/2020

Ref. Your Order del 2020

Test Report N°20-0647-04

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

Sample description

Denomination: Face mask
Code: /
Lot: /
Sterilization: No
N° of tested samples: 5
Receipt number: 16214
Receipt date: 26/05/2020
Sampling carried out by: SIA "JUF"

The test was started on 03/06/2020 and was completed on 08/06/2020.

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 (1.44 – 1.36) obtained from the method validation (see test report N°20-0 647-03).

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Results

Sample	Non-selective aerobic bacteria (cfu/sample)	Moulds (cfu/sample)	Yeast (cfu/sample)
1	10	4	<2
2	44	<2	<2
3	4	<2	<2
4	12	2	<2
5	14	<2	<2
Mean value	**16.8**	**<2.4**	**<2.0**
Correction factor	1.44	1.36	1.36
Corrected value	**24.2**	**<3.3**	**<2.7**
Value per gram	**9.5**	**<2**	**<2**

SUM OF MICROORGANISMS: <13.5 cfu\gram

OPINIONS AND INTERPRETATIONS – Not included in ACCREDIA accreditation

Compliance with EN 14683:2019 5.2.5 Microbial cleanliness (Bioburden): In compliance

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

Test verified by: Buriani Giampaolo, PhD.

Issue authorised by:
Head of Laboratory Dr. Giovanni Bassini

END OF TEST REPORT

Mod.BiobFiltrazRv20
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