

TEST REPORT NUMBER: PRTT00077164 Page 1 of 5
APPLICANT: TIME INTERNATIONAL TRADING SRL **DATE OF EMISSION:** 28/08/2020
7 IULIU MANIU BLVD, No. 7, BL COPR B ET 2
SECTOR 6 - BUCHAREST, ROMANIA
061072

SAMPLE DESCRIPTION:
Offer Number : RMN-20028 / New Price
Type Mask : Medical Face - Type I
Reference : FM/001
Colour : Blue/White
Type and Composition of Material : 100%Nonwoven Polypropylene
Mass per unit Weight: 0.2Kg
Batch Number : 001
End use : 2025
1 - Medical Face

DATE OF RECEPTION: 06/08/2020
TEST PERFORMED BETWEEN DATES: 06/08/2020 and 28/08/2020
WORK DAYS: 10
REQUEST: Tests performed in accordance with APPLICANT TEST REQUEST specification
NOTES:

Samples

Test	1
*‡ BFE (FILTRATION)	M
*‡ DIFFERENCIAL PRESSURE (BREATHABILITY)	M
*‡ MICROBIAL CLEANLINESS/BIOBURDEN	M
*‡ SPLASH RESISTANCE PRESSURE	NC

M = Meet buyer's requirement; NM = does not meet buyer's requirement; NR = Not requested; NA = Not applicable;
NC = No comment; SC = Still continues
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Test Method	Results	Requirements
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***‡ BFE (FILTRATION)**

EN 14683:2019+AC 2019

Sample: 1

Type I \geq 95%

RESULT

97.9%

Test Conditions:

Temperature: $21\pm 5^{\circ}\text{C}$ Humidity: $85\pm 5\%$

Dimensions of the test specimens: 49cm^2 (5 test specimens)

Side of the test specimen facing the challenge aerosol: intern

Air flow rate: 28.3 l/min.

MPS 3.0

Test specimen 1 (98.3%), Test specimen 2 (98.0%), Test specimen 3 (98.0%),

Test specimen 4 (97.5%), Test specimen 5 (97.5%).

The expanded uncertainty at a confidence level of 95%, $k=2$: 1.8%

***‡ DIFFERENCIAL PRESSURE (BREATHABILITY)**

EN 14683:2019+AC 2019

Sample: 1

Type I < 40 Pa/cm²

RESULT

30.2 Pa/cm²

Test Conditions:

Temperature: $21\pm 5^{\circ}\text{C}$ Humidity: $85\pm 5\%$

Number and general location of the areas of the mask the differential measurements were taken: Test performed with the direction of flow from the inside to the outside. Side and central location.

Air flow rate: 8L/min

Dimensions of the test specimens: 4.9cm^2 (5 test specimens)

Test specimen 1 (32.7 Pa/cm²), Test specimen 2 (30.6 Pa/cm²), Test specimen

3 (28.6 Pa/cm²), Test specimen 4 (31.6 Pa/cm²), Test specimen 5 (27.6

Pa/cm²)

The expanded uncertainty at a confidence level of 95%, $k=2$: 8.7%

***‡ MICROBIAL CLEANLINESS/BIOBURDEN**

EN ISO 11737-1:2018

Sample: 1

Type I \leq 30 cfu/g

RESULT

4 UFC/g

Test Conditions:

5 min shaker at 250rpm

Area of each test specimen: 5 test specimens

Mic30°C (3 days), Molds and yeasts 25°C (7 days)

The expanded uncertainty at a confidence level of 95%, k=2: 20%

***‡ SPLASH RESISTANCE PRESSURE**

ISO 22609:2004

Sample: 1

Type I + Type II Not required

RESULT

16 kPa

Test conditions: Samples pre-conditioned for at least 4 hours at Temperature and Relative humidity: $21 \pm 5^\circ\text{C}$ / $85 \pm 5\%$

Samples exposed to a jet of 2mL synthetic blood at pressure (low: 10.6 KPa; medium: 16.0 KPa; high: 21.3 KPa) aimed at the centre of the mask.

Test performed at laboratory temperature of 21°C and 45% relative humidity, within 60 seconds after the mask was removed from the conditioning chamber
Observation after 10+1 second of blood penetration on the opposite side of the mask.

Synthetic blood according to Annex B of ISO 22609: 2004 with surface tension of $42 + 2\text{mN} / \text{m}$, batch # 202006

Number and General location of the areas: 32 test specimen / center (pass at least Medium pressure test for 29 out of 32 samples as minimum, corresponding to AQL 4%, according EN 14683: 2019 mask Type IIR)

Results:

Medium pressure (16.0KPa) 32 specimen "pass", 0 specimen "fail"

Medium pressure test for 29 out of 32 samples as minimum, corresponding to

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Sample: 1

Type I + Type II Not required

RESULT

AQL 4%, according EN 14683: 2019 mask Type IIR)

