

TEST REPORT NUMBER: PRTT00081133 Revision 1 Page 1 of 6
APPLICANT: TIME INTERNATIONAL TRADING SRL **DATE OF EMISSION:** 08/01/2021
 7 IULIU MANIU BLVD, No. 7, BL COPR B ET 2
 SECTOR 6 - BUCHAREST, ROMANIA
 061072

SAMPLE DESCRIPTION:


Type Mask	:	Medical Face -Type IIR
Reference	:	FM/002
Colour	:	Blue/White
Type and Composition of Material	:	100% Nonwoven Polypropylene
Mass per unit Weight:	:	-
Batch Number	:	002/20112721
End use	:	2025
Supplier	:	Time International Trading

DATE OF RECEPTION: 09/12/2020
TEST PERFORMED BETWEEN DATES: 09/12/2020 and 08/01/2021
WORK DAYS: 20
REQUEST: Tests performed in accordance with APPLICANT TEST REQUEST specification
NOTES: The requirments were corrected by Supplier to Type IIR on 08-01-2021. This report replaces the report no. PRTT00081133 from 2020-12-22 and should be used instead.

Samples

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

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 IIR >= 98%

RESULT

99.1%

Test Conditions:

Temperature: 21±5°C Humidity: 85±5%

Dimensions of the test specimens: 49cm² (5 test specimens)

Side of the test specimen facing the challenge aerosol: intern

Air flow rate: 28.3 l/min.

MPS 2.9

Test specimen 1 (99.3%), Test specimen 2 (98.7%), Test specimen 3 (99.7%),

Test specimen 4 (99.7%), Test specimen 5 (99.0 %).

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

‡ DIFFERENCIAL PRESSURE (BREATHABILITY)

EN 14683:2019+AC 2019

Sample: 1

Type IIR <60 Pa/cm²

RESULT

32.7 Pa/cm²

Test conditions: Temperature and Relative humidity: 21±5°C / 85± 5 %

Dimensions of the test specimens: 4.9cm² (5 réplicas/ 5 test specimens)

Number of áreas per specimen: 5 áreas for test specimen (A,B,C,D,E)

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

Test specimen 1 (área A,B,C,D,E), Test specimen 2 (área A,B,C,D,E),Test

specimen 3 (área A,B,C,D,E), Test specimen 4 (área

A,B,C,D,E), Test specimen 5 (área A,B,C,D,E)

Test specimen 1 (33.7 Pa/cm²), Test specimen 2 (31.6 Pa/cm²), Test specimen

3 (32.7 Pa/cm²), Test specimen 4 (32.7 Pa/cm²), Test specimen 5 (32.7

Pa/cm²)

Sample: 1

Type IIR <60 Pa/cm2

RESULT

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

‡ MICROBIAL CLEANLINESS/BIOBURDEN

EN ISO 11737-1:2018

Sample: 1

Type IIR <= 30 cfu/g

RESULT

6 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)

Results: 4, 8, 6, 6, 6

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

‡ SPLASH RESISTANCE PRESSURE

ISO 22609:2004

Sample: 1

Type IIR >= 16.0 kPa

RESULT

16.0 kPa

Test conditions: Samples pre-conditioned for at least 4 hours at Temperature and Relative humidity: 21±5°C / 85± 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

Sample: 1

Type IIR >= 16.0 kPa

RESULT

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 + 2mN / m, batch # L202012

Number and General location of the áreas: 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:

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

Medium pressure test for 29 out of 32 samples as minimum, corresponding to AQL 4%, according EN 14683: 2019 mask Type IIR)

Sample	Medium Pressure 16.0 Kpa
Amost1	Pass
Amost2	Pass
Amost3	Pass
Amost4	Pass
Amost5	Pass
Amost6	Pass
Amost7	Pass
Amost8	Pass
Amost9	Pass
Amost10	Pass
Amost11	Pass
Amost12	Pass
Amost13	Pass
Amost14	Pass
Amost15	Pass
Amost16	Pass
Amost17	Pass
Amost18	Pass

Sample: 1

Type IIR >= 16.0 kPa

RESULT

Amost19	Pass
Amost20	Pass
Amost21	Pass
Amost22	Pass
Amost23	Pass
Amost24	Pass
Amost25	Pass
Amost26	Pass
Amost27	Pass
Amost28	Pass
Amost29	Pass
Amost30	Pass
Amost31	Pass
Amost32	Pass

