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Sample Identification: TIOR5001 - FACE MASK JEDNORAZOWA MASKA MEDYCZNA 3 WARSTWOWA, W KOLORZE BIAŁO-NIEBIESKIM Z GUMKAMI W KOLORZE BIAŁYM - NR.SERYJNY:TIO(001)MM2020TG08PL

Sampling: Customer

Sampling site: Customer Site

Transport : External Representate - Room Temperature

Storage : Room Temperature

Recording Date : 02/11/2020

Beginning Test Date : 02/11/2020

End Test Date : 03/11/2020

EVALUATION OF RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD/SPLASH TEST OF MEDICAL FACE MASK

Standard:

ISO 22609:2004

Document digitally signed in accordance with current legislation by Dott.ssa Sonia Giannone - Ordine Naz. Dei Biologi Albo Professionale N° 050063

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Splash Resistance Pressure

Principle and Normative References

Scope	Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
Normative References	UNI EN 14683:2019
Analytical Technique	ISO 22609:2004

Experimental conditions

N° of medical face masks tested	32
Blood delivered volume	2 mL
Distance canula - mask	30 cm
Side of the mask "impacted"	Outer side
Mask conditioning	21 ± 5 °C and 85 ± 5 % RH

Results

The number of 32 tested masks has been determined based on a single sampling plan providing an AQL of 4% (acceptable quality limit). If 29 masks or more over 32 obtain a "Passed" result the 4% AQL is reached. Consequently if more than 4 masks obtain a "Failed" result the 4% AQL is NOT reached.

Table 1 summarizes results obtained with the Splash resistance pressure test.

Table 1

Sample	Results (Pass/Fail)	Sample	Results (Pass/Fail)
Sample 1	Pass	Sample 17	Pass
Sample 2	Pass	Sample 18	Pass
Sample 3	Pass	Sample 19	Pass
Sample 4	Pass	Sample 20	Pass
Sample 5	Pass	Sample 21	Pass
Sample 6	Pass	Sample 22	Pass
Sample 7	Pass	Sample 23	Pass
Sample 8	Pass	Sample 24	Pass
Sample 9	Pass	Sample 25	Pass
Sample 10	Pass	Sample 26	Pass
Sample 11	Pass	Sample 27	Pass
Sample 12	Pass	Sample 28	Pass
Sample 13	Pass	Sample 29	Pass
Sample 14	Pass	Sample 30	Pass
Sample 15	Pass	Sample 31	Pass
Sample 16	Pass	Sample 32	Pass

Summary:

Blood pressure tested, P = 16,0 kPa.

Total Mask tested	Number of Passed masks	Number of Failed masks
32	32	0

Passed: no blood detected on the observed side; Failed: blood detected on the observed side.

Test Notes

MP: Laboratory-developed method
U.M.: Measurement Unit
Parameter Note: parameter information

N.R.: Not Detectable

The "Limits" column shows: the limits of quantification or detectability indicated with "LDQ or LDR", the legal limits and / or guide values agreed with the client (The value indicated, if expressed in round brackets (), is to be considered "Guide Value" - Otherwise it is to be considered "Law Limit").

The result of the quantitative evidence on surfaces is obtained by recalculation performed on the basis of the measure declared by the person who performed the sampling.

Quantitative microbiological tests:

Quantitative microbiological tests are performed in single replication in accordance with ISO 7218: 2007 / Amd1:

2013. Expression of the result by matrix Food / Surfaces in accordance with ISO7218: 2007 / Amd1: 2013:

Present <4 or Present <40 or Present <400: means "microorganisms present but less than 4 or 40 or 400 cfu / g or cfu / ml" which means that the number of colonies grown in the plate at the first useful dilution is between 1ufc and 3 ufc.

Estimates: the estimated expression means that the number of colonies grown in the plate at the first useful dilution is between 4 cfu and 9 cfu. Expression of the result by Water matrix in compliance with ISO 8199:2018:

Present <3 or Present <300: means "Microorganisms present in the volume taken into consideration but less than 3 or 300 cfu / Volume" which means that the number of colonies grown in the plate at the first useful dilution is between 1 or 2 cfu.

Estimates: the estimated expression means that the number of colonies grown in the plate at the first useful dilution is between 3 cfu and 9 cfu

Uncertainty of measurement (I.D.M.):

For microbiological parameters the extended uncertainty of measurement is expressed as confidence interval (lower limit-upper limit) with coverage factor K = 2 and with confidence level of 95%. Quantitative tests are performed in a single replica in accordance with ISO 7218: 2007 / Amd 1: 2013.

For chemical parameters the extended uncertainty values refer to a 95% confidence interval and a coverage factor K = 2

Documentation traceability:

The description of Laboratory-developed methods (MP), test procedures (PP) methods normed and Operating Procedures (P.O.) are at your disposal in the laboratory.

In laboratory are available all the documentation to trace the technicians who carried out the tests, as well as the sampling and transport.

The results included in this Test Report refer only to the sample tested. In case the sampling is not performed by our staff, the laboratory is not responsible for the sample information reported in this test report and the results refer only to the sample as received. This Test Report may not be partially reproduced, unless Tecnal's written approval.