

MICROBIAL CLEANLINESS (BIOBURDEN)

REPORT N. 06259-21 Rev. 00

Customer: **SC EURO IMPACT Srl**
Strada Pricipala, Ruscova, NO. 698 - Judetul Maramures

TEST METHOD UNI EN 14683: 2019 App. D

TIME SCHEDULE

Acceptance N.:	21-05556
Reception date:	09/09/2021
Start test date:	14/09/2021
End test date:	19/09/2021
Operator:	Dr. F. Napoleone

TEST SAMPLE IDENTIFICATION

Name:	DISPOSABLE MEDICAL MASK ELIMEDICAL
Sample Typology:	MEDICAL MASK
Composition:	Polypropylene nonwoven , Non-woven filter fabric Meltblown , 25g m2 ,elastic 3mm , nosewire 3mm
Quantity tested:	5
Code (REF):	not provided
LOT:	A1-98-01.09.2021
Manufacturing date:	01.09.2021
Expiry date:	36 MONTHS FROM THE DATE OF PRODUCTION
Sterilization Method:	Not sterile

The information concerning the test sample were provided by the Customer. All data related to the test sample are under the responsibility of the Customer and have not been verified by the test laboratory.

Issue Date	Rev.	Change Description	Prepared by Dr. F. Napoleone F. Napoleone (Laboratory Technician)	Verified and Approved by Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
20/09/2021	00	First Issue		

This test report is digitally signed by Dr. Renzo Giovanni Coronati.
The digital signature has legal value according to Italian D. Lgs. 82/2005 and subsequent amendments.

*The sampling is performed by the Customer. The test results are related only to the test samples as received.
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TEST LABORATORY: **Coronati Consulting srl** Via L. Gavioli, 3 I-41037 Mirandola (MO) Italy Tel. +39 0535611533 Fax +390535410441
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PROCEDURES

All procedures used during this study are recorded in the Laboratory Coronati Consulting s.r.l.

OPERATING METHODS

The test was performed in aseptic conditions under ISO Class 5 laminar flow hood. Each sample was immersed in washing solution for sonication according to the standard ISO 11737-1 and in particular conditions determined during validation of bioburden recovery efficiency.

The washing solution was divided in half and each part was filtered. One filter was incubated for 72h at $32,5 \pm 2,5$ °C on a Petri dish containing TSA (Tryptone Soya Agar) suitable for bacteria investigation, the other filter was incubated for 5 days at $22,5 \pm 2,5$ °C on a Petri dish containing SDA (Sabouraud Dextrose Agar) suitable for yeasts and moulds investigation.

At the end of incubation, C.F.U. (Colony-Forming Units) were countered, considering the Correction Factor, derived from validation of bioburden recovery efficiency (see Internal Report n. 45).

ACCEPTANCE CRITERIA (according to UNI EN 14683:2019 par.5.2.5)

The tests are conformed when the results are not higher then limit 30 C.F.U./g.

RESULTS

Id.	Weight of Mask (g)	Microbiological Contamination			Correction Factor	Bioburden (C.F.U./Mask)	Bioburden (C.F.U./g)	Acceptance Criteria (C.F.U./g)	Conformity Evaluation ⁽¹⁾
		Bacteria (C.F.U./Mask)	Yeasts and Moulds (C.F.U./Mask)	Total (C.F.U./Mask)					
1	3,2	8	12	20	1,7	34,0	10,6	≤ 30	PASS
2	3,2	2	2	4	1,7	6,8	2,1	≤ 30	PASS
3	3,2	10	4	14	1,7	23,8	7,4	≤ 30	PASS
4	3,2	4	2	6	1,7	10,2	3,2	≤ 30	PASS
5	3,2	8	8	16	1,7	27,2	8,5	≤ 30	PASS
⁽¹⁾ The evaluation of Conformity Evaluation is carried out without taking into account the uncertainty ⁽²⁾ "Limit of detection (LOD) applied"									

-----End of Report-----