Consultancy and Laboratory Services for Biomedical Quality

TOTAL MICROBIAL CONTAMINATION (Bioburden)

REPORT N. 8477-20 Rev. 00

Customer: IDEANTIS SRL
VIALE MONTE NERO 80 - 20135 - MILANO

TEST METHOD UNI EN 14683: 2019 App. D

TIME SCHEDULE

Acceptance N.:	20-7993
Reception date:	26/11/2020
Start test date:	02/12/2020
End test date:	07/12/2020
Operator:	Dr. F. Napoleone

TEST SAMPLE IDENTIFICATION

Name:	Maskèdra
Sample Typology:	Mascherina chirurgica
Composition:	poliuretano+poliammide12+Spunbond+Melt blown+natural rubber+poliestere
Quantity tested:	5
Code (REF):	N/A
LOT:	001
Manufacturing date:	ottobre 2020
Expiry date:	Non applicabile
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 (Laboratory Technician)	Verified and Approved by Dr. Renzo Giovanni Coronati (Managing Director Laboratory)
14/12/2020	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.

TEST LABORATORY: **Coronati Consulting srl** Via L. Gavioli, 3 I-41037 Mirandola (MO) Italy Tel.+39 0535611533 Fax +390535410441
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LAB N° 1496 L

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 submitted to the washing according to the standard ISO 11737-1:2018 Annex B.2 under particular conditions determined during validation phase for that kind of products or family of products. After the filtration of washing solution, the filters were incubated to one part on Petri dishes containing TSA (Tryptone Soya Agar) and incubated for 72h at 32,5 ± 2,5 °C suitable for bacteria investigation, and the other part on Petri dishes containing SDA (Sabouraud Dextrose Agar) and incubated for 5 days at 22,5 ± 2,5 °C suitable for yeasts and molds investigation. At the end of incubation, C.F.U. (Colony-Forming Units) were countered, considering Correction Factor determined during Recovery Validation Testing.
The Correction Factor below is derived from the report of Customer validation method n. 8476-20 dated 14/12/2020.

ACCEPTANCE CRITERIA
The tests are conformed when the results are not higher then limit 30 C.F.U./g (According to UNI EN 14683:2019 par.5.2.5).

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
		Bacteria (C.F.U./Mask)	Yeasts and Moulds (C.F.U./Mask)	Total (C.F.U./Mask)					
1	1,8	0	0	0	1,3	<2	**<2**	**≤ 30**	**PASS**
2	1,8	0	0	0	1,3	<2	**<2**	**≤ 30**	**PASS**
3	1,8	0	0	0	1,3	<2	**<2**	**≤ 30**	**PASS**
4	1,8	2	0	2	1,3	<2	**<2**	**≤ 30**	**PASS**
5	1,8	0	0	0	1,3	<2	**<2**	**≤ 30**	**PASS**
(1) according to UNI EN 14683:2019 par.5.2.5									

DEVIATION
No deviation has been remarked during the study.

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