

Messrs.
HELLENIC MEDICAL SUPPLIES GP
6 th km Xanthi - Lefkopetra
67100 XANTHI GREECE

Zola Predosa, 25/01/2021

Ref. Your Order /

Test Report N° 21-0013-04

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

Sample description

Denomination: SURGICAL FACE MASKS
Code: 005001
Lot: 30112020
Sterilization: No
N° of tested samples: 5
Receipt number: 19635
Receipt date: 15/01/2021
Sampling carried out by: HELLENIC MEDICAL SUPPLIES

The test was started on 19/01/2021 and was completed on 25/01/2021.

Test method

ISO 11737-1:2018

Summary of practice

Samples were aseptically treated. Micro-organisms were extracted from samples using sterile physiological saline containing 0.05 % of Tween 80 in mechanical agitation. The extract was collected and filtered through a 0.45 µm sterile membrane filter. One half of the filter was incubated on Tryptone Soya Agar (TSA) culture medium for 72 hours at $32 \pm 2^\circ\text{C}$ in order to evaluate non-selective aerobic bacteria. The other half was incubated on Potato Dextrose Agar (POT) culture medium for 5 days at $22 \pm 2^\circ\text{C}$ in order to evaluate yeasts and moulds. Results were multiplied by correction factor (1.58 – 1.25) obtained from the method validation (see test report N°21-0 013-01).

Results

| Sample | 1 | 2 | 3 | 4 | 5 |
|-----------------------------------|-------|-------|-------|-------|-------|
| Weight (g) | 3.18 | 3.18 | 3.18 | 3.18 | 3.18 |
| Mesophilic aerobic (CFU/sample) | 25.3 | 44.2 | 19.0 | 9.5 | 6.3 |
| Moulds (CFU/sample) | <2.5 | <2.5 | <2.5 | <2.5 | 2.5 |
| Yeasts (CFU/sample) | <2.5 | <2.5 | <2.5 | <2.5 | <2.5 |
| Sum of microorganism (CFU/sample) | <30.3 | <49.2 | <24.0 | <14.5 | <11.3 |
| CFU/g | <9.5 | <15.5 | <7.5 | <4.6 | <3.6 |
| Compliance (*) | Y | Y | Y | Y | Y |

Legenda

Y = Compliant

N = Not compliant

OPINIONS AND INTERPRETATIONS - Not included in ACCREDIA accreditation

(*) Compliance with EN 14683:2019 5.2.5 Microbial cleanliness (Bioburden)

The present test report exclusively refers to the referenced test sample.

If the sample has been sampled by the Customer, the results are referred to the sample as received.

The present test report may not be partially reproduced without Biochem authorization.

(#) Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorised by:

Head of Laboratory Dr. Giovanni Bassini

END OF TEST REPORT