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Client Account Number: A00497571PI2
Eurofins Quote Number: FU2HPH20021201

Eurofins Sample Number RS20AA3537-2

Original Received Date: 14-Sep-2020
Description: Mask
Lot Number: 2200708
Control Number: Xinlong Surgical face mask type IIR artnr. 1037117
Containers Submitted: 1 Bag(s)

Protocol Reference: IVA.M.MI.062

General Method Reference: Sterilization of health care products - Microbiological methods - Part 1:
 Determination of a population of microorganisms on products (ISO11737-1:2018); UNE-EN ISO 11737-1:2018
 December 2018

General Specification Reference: EN14683:2019+AC:2019 Medical face masks

Analysis	Specification	Result
# Total Aerobic Microbial Count	≤ 30 CFU/g	See attached table
Analysis Date: 28-Sep-2020 to 01-Oct-2020		
# Total Yeast Microbial Count	≤ 30 CFU/g	See attached table
Analysis Date: 28-Sep-2020 to 05-Oct-2020		
Sample Compliance Assessment		
RS20AA3537-2 meets the requirement(s) for all listed test(s) where specifications were applied.		

**Supplemental Information**

For RS20AA3537-2:

Method applied: Dilution of 1 SIP in 300 ml of extraction liquid (EL) and agitation in orbital shaker at 250 rpm during 5 minutes. Fractions of 100 ml of the solution were filtered and filter placed on culture media to determine the following parameters:

Total Aerobic Microbial Count (TAMC) - Incubation in TSA during 3 days at 30 °C.

Total Yeast and Mould Count (TYMC) - Incubation in SDA with chloramphenicol during 7 days at 20 - 25°C.

Correction factor applied for cfu estimation according to the standard: 1.0

El Laboratorio de ensayo está acreditado por ENAC únicamente para los ensayos marcados con #. A menos que se indique lo contrario en el informe de ensayo, el muestreo ha sido realizado por el promotor (Test performing laboratory is accredited by ENAC only for tests marked with #. Unless specifically indicated on the test report, sampling is always intended to be made by the Sponsor/Manufacturer).

Contracted Company: Eurofins Biopharma Product Testing Spain

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This Certificate of Analysis cannot be partially reproduced without the written authorization of the laboratory.

The enclosed results apply only to the test samples referenced in this certificate of analysis.

Questions about this report should be directed to your project manager or the general email listed above.

Este Certificado de Análisis no puede ser reproducido parcialmente sin la autorización por escrito del laboratorio contratado para el análisis.

Los resultados indicados aplican únicamente a las muestras referenciadas en este Certificado de Análisis.

Cualquier duda sobre este informe debe ser dirigida a su Project Manager o a la dirección de correo electrónico general.

Reviewed and electronically signed for Laboratory Manager Release by

5.1.2e

for Eurofins BioPharma Product Testing Spain SLU, on 05-Oct-2020 09:15:33 UTC+02:00

Test unit	BIOLOGICAL LOAD ESTIMATION		TOTAL	TOTAL
	TAMC	TYMC	TOTAL	TOTAL
	CFU/g	CFU/g	CFU/g	CFU/unit
1	<1,0	<1,0	<1,9	<6,0
2	1,9	1,9	3,9	12,0
3	<1,0	1,9	<2,9	<9,0
4	<1,0	1,0	<1,9	<6,0
5	<1,0	2,0	<3,0	<9,0
		AVERAGE	1,8	5,4