

17/08/2023
No.026264.23

To:
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CERTIFICATE OF ANALYSIS No.026264.23

Aminolab No.:	064814.23-M - 064823.23-M	Examination date:	07/08/2023
Sample reception:	07/08/2023	Completion date:	15/08/2023
Sampled by:	The Customer	Storage temp.:	Room Temp.
Sampling type:	--		
Order No:	AL230629		
Sample ID:	Implant- Lot: LH0736		

References:

- 1.Aminolab SOP No. 50.WI.106, version 7: Bioburden test - pre-sterilization estimation of population of microorganisms on/in medical devices
- 2.ISO 11737-1:2018 (E) & A1:2021: Sterilization of health care products- Microbiological methods Part 1: Determination of a population of microorganisms on products Amendment 1.
- 3.The test was performed using Membrane Filtration technique.
- 4.The test was conducted according to Sponsor's Report: 110349TTT/25.10.2018.

Analyses Results:

Aminolab No.	Sample	Bacteria	Molds	Total	Correction Factor	Estimated Bioburden
		CFU/sample	CFU/sample	CFU/sample	--	CFU/sample
064814.23-M	#1	1	0	1	1.1	2
064815.23-M	#2	2	0	2	1.1	3
064816.23-M	#3	2	0	2	1.1	3
064817.23-M	#4	0	0	0	1.1	<1
064818.23-M	#5	3	0	3	1.1	4
064819.23-M	#6	4	0	4	1.1	5
064820.23-M	#7	0	0	0	1.1	<1
064821.23-M	#8	1	0	1	1.1	2
064822.23-M	#9	1	0	1	1.1	2
064823.23-M	#10	2	0	2	1.1	3
Remarks:		-	-	-	-	-

Approved by: Natasha Ronkin M.Sc-Team Leader



Signature: 

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Analyses Remarks:

(-) = No Comments

Quality Assurance:

Analysis	Method / Standard	Remarks
Bioburden Estimation - MF Method	SOP# 50.WI.106 V7, ANSI/AAMI/ISO 11737-1:2018 (E)	a

Accreditations / Certifications:

The laboratory is accredited under ISO/IEC 17025 with standard operating procedures.

a. Aminolab is accredited to perform this analysis under ISO/IEC 17025 by ISRAC.

ISRAC is not responsible for the testing results conducted by Aminolab Laboratories.

Aminolab's accreditation is not considered as an approval of ISRAC to the testing results.

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ISRAC accreditation is not considered as an approval of either the Aminolab procedures or its personnel.

Approved by: Natasha Ronkin M.Sc-Team Leader



Signature: _____

This certificate is valid only when it is presented in its complete format, and it is not permitted to extract part for inclusion in any other document. The data presented accurately expresses the results for the sample received only. It is not permitted to use Aminolab Ltds' name or its reputation in respect to the above - specified results, without Aminolab written consent.