

22/08/2023
No.026688.23

To:
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CERTIFICATE OF ANALYSIS No.026688.23

Aminolab No.:	068118.23-M - 068120.23-M	Examination date:	17/08/2023
Sample reception:	16/08/2023	Completion date:	20/08/2023
Sampled by:	The Customer	Storage temp.:	Room Temp.
Sampling type:	--		
Order No:	AL230815		

References:

- 1.Aminolab SOP: 50.WI.104, Version 18 - Limulus Amebocyte Lysate (LAL) Test for Bacterial Endotoxin.
- 2.Current USP<85>Bacterial Endotoxins Test.
- 3.Current EP<2.6.14>,Bacterial Endotoxins.

Analyses Results:

Aminolab No.	Sample	Detected Endotoxin	Spike Recovery
		EU/Device	%
068118.23-M	UH8 Implant Pure&Porous D3.75 - Lot: LG1937	<0.20	102
068119.23-M	UH8 Implant Pure&Porous D3.3 - Lot: LH0683	<0.20	131
068120.23-M	UH8 Implant Pure&Porous D3.75 - Lot: LF3383	<0.20	108
Remarks:		1	2

Analyses Remarks:

(-) = No Comments

1. Acceptance Criteria: <20.0 EU/ Device, USP<161>.
2. Spike Recovery Inhibition/Enhancement (Test is valid if Recovery is between 50 and 200)

Quality Assurance:

Analysis	Method / Standard	Remarks
Bacterial Endotoxin Test - Kinetic Turbidir	SOP# 50.WI.104 - Turbidimetric method	a

Approved by: Natasha Ronkin M.Sc-Team Leader



Signature: _____

Aminolab No.: 068118.23-M - 068120.23-M

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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.

This document must be referred to entirely and copying of any part of it to other documents is forbidden.

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 Ltd's name or its reputation in respect to the above - specified results, without Aminolab written consent.

*** End of Certificate of analysis ***