

## **CERTIFICATE OF ANALYSIS**

Material	BP Protease GMP Grade (For <i>ex vivo</i> Use Only)				
Description	Aseptically dispensed purified neutral protease from <i>B. polymyxa</i>				
Lot Number	212221103		Pack Size		2.3 M NP Units
Catalog Number	003-2000		Storage		-20±5°C
Date of Manufacture	3 Nov 2022		Expiry Date		Nov 2026
TEST		ACCEPTANCE CRITERIA		RESULT	
Appearance		White lyophilized cake		Conforms	
Endotoxin EU/mg protein¹ USP <85>		< 50.0 EU/mg		2.6 EU/mg	
Total Neutral Protease Activity <sup>2</sup>		> 1,800,000 Units/bottle		2,704,515 Units/bottle	
Total Protein <sup>3</sup>		Report Only		17.9 mg/bottle	

## Signature:

Andrew Breite, Director of Quality Assurance

28 Nov 2022

<sup>&</sup>lt;sup>1</sup> Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system

Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54

 $<sup>^3</sup>$  Based on absorbance at 280 nm using an extinction coefficient of  $\epsilon^{0.1\%}$  =1.0