

CODE	INT3104B	LOT	CE19J09L71
		Expiry Date	2021-09

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE19J30L11	Amotosalen
	2	N/A	1
	3	N/A	2
PCT sub-assembly	1	CE19J09L71	CAD material
			3
			190048
			N/A
			N/A
			90409C3 / 90415C3

DESCRIPTION : INTERCEPT Processing Set for Plasma

CONFORMITY OF TESTS RESULTS

PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)				
Product	Limits (≤)	Date Passed		Results
Final product	0.125 EU / mL	November 8, 2019		PASS
Amotosalen solution sub-assembly	<input type="checkbox"/> 3 mM → 2.0 EU / mL OR <input checked="" type="checkbox"/> 6 mM → 0.8 EU / mL	1	November 6, 2019	PASS
		2	N/A	N/A
		3	N/A	N/A
PCT sub-assembly	0.25 EU / mL	1	October 16, 2019	PASS

Disposition : **PASS**

BACTERIOLOGY-BIOBURDEN (TEST-B-17 / TEST-B-09)	Disposition : PASS <input checked="" type="checkbox"/>
FINAL PHYSICAL TESTING (TEST-C)	Disposition : PASS <input checked="" type="checkbox"/>
pH ANALYSIS ON CONNECTED KIT (TEST-A)	Disposition : PASS <input checked="" type="checkbox"/>
AMOTOSALEN FINAL CHEMICAL ANALYSIS (TEST-A-01)	Disposition : PASS <input checked="" type="checkbox"/>

STERILITY		
Amotosalen solution	Steam sterilization cycle according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
PCT sub-assembly	Gamma irradiation according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
Connected product	E-Beam irradiation according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
Sterility Test (TEST-B-13)	No positives	CONFORM <input checked="" type="checkbox"/>

Disposition : **PASS**

Note : N/A means Not Applicable PCT means Photo Chemical Treatment

QUANTITY **2568 UNITS**

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature

C. BERTHOMIER



November 20, 2019

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature



Romain LELIEVRE
Nov 22nd 2019

This is to certify that this product was manufactured according to current Good Manufacturing Practice and fulfills the requirements of the Device Master Record.