

CODE	INT3104B	LOT	CE19F21L72
		Expiry Date	2021-05

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE20G11L11	Amotosalen 1 190048
	2	N/A	2 N/A
	3	N/A	3 N/A
PCT sub-assembly	1	CE19F21L72	CAD material 81001A1 / 81008A1 / 81015A1

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	July 17, 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 July 17, 2019	PASS
		2 N/A	N/A
		3 N/A	N/A
PCT sub-assembly	0.25 EU / mL	1 June 25, 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"/>

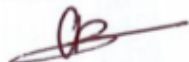
Disposition : **PASS**

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

QUANTITY **2208 UNITS**

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature

C. BERTHOMIER



April 14, 2020

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature



Romain LELIEVRE

April 15th 2020

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