

CODE	INT3104B	LOT	CE20L09L71
		Expiry Date	2022-11

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE20L22L11	Amotosalen 1 200053
	2	N/A	2 N/A
	3	N/A	3 N/A
PCT sub-assembly	1	CE20L09L71	CAD material 01116C3 / 01116C2

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	January 5, 2021	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	January 5, 2021
		2	N/A
		3	N/A
PCT sub-assembly	0.25 EU / mL	1	December 11, 2020

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**

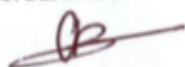
Note : N/A means Not Applicable PCT means Photo Chemical Treatment

QUANTITY

3240 UNITS

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature

C. BERTHOMIER



January 20, 2021

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature



Romain LÉLIEVRE
Jan 20th, 2021

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