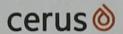


## CERTIFICATE OF CONFORMITY INTERCEPT PRODUCT



Formulaire N°: C22-TEST-F

Révision N° : B

SOP N° : TEST-F

Page 1 of 1

CODE	INT2504B	LOT	CE22H16L71	
		Expiry Date	2024-07	

		Lot	Raw material batch		
Amotosalen solution sub-	1	CE22I06L12	Amotosalen	1	210094
assembly	2	CE22I07L11		2	210094
	3	N/A		3	N/A
PCT sub-assembly	1	CE22H16L71	CAD material		11222A / 11226B / 11226BB / 11217B / 11228A

**DESCRIPTION: INTERCEPT Platelet Processing Set with Dual Storage Containers** 

## **CONFORMITY OF TESTS RESULTS**

	PYROGENICITY TEST: Turbidimetric Kinetic (TEST-B-03)			
Product	Limits (≤)		Date Passed	Results PASS
Final product	0.125 EU / mL	September 21, 2022		
Amotosalen solution sub-assembly	☑ 3 mM → 2.0 EU / mL	1	September 15, 2022	PASS
	OR	2	September 15, 2022	PASS
	$\square$ 6 mM $\rightarrow$ 0.8 EU / mL	3	N/A	N/A
PCT sub-assembly	0.25 EU / mL	1	September 27, 2022	PASS

Disposition : PASS

BACTERIOLOGY-BIOBURDEN (TEST-B-17 / TEST-B-09)	Disposition : PASS ☑
FINAL PHYSICAL TESTING (TEST-C)	Disposition : PASS ☑
pH ANALYSIS ON CONNECTED KIT (TEST-A)	Disposition : PASS ☑
AMOTOSALEN FINAL CHEMICAL ANALYSIS (TEST-A-01)	Disposition : PASS ☑

STERILITY		
Amotosalen solution	Steam sterilization cycle according to validated method reviewed & conform	CONFORM ☑
PCT sub-assembly	Gamma irradiation according to validated method reviewed & conform	CONFORM ☑
Connected product	E-Beam irradiation according to validated method reviewed & conform	CONFORM ☑
Sterilility Test (TEST-B-13)	No positives	CONFORM ☑
	Dis	sposition : PASS

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

QUANTITY

**9000 UNITS** 

Reviewed by Fenwal

QA MANAGER or DELEGATE

Date & Signature

P.MANDRELIER

October 6, 2022

Released by Cerus
QA MANASER or DELEGATE
Date & Signature

Oct 0619, 622

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