

 Fenwal™ A Fresenius Kabi Company La Châtre, Etaille, 36400 Lacs, France	CERTIFICATE OF CONFORMITY INTERCEPT PRODUCT 	Formulaire N° : C22-TEST-F Révision N° : B SOP N° : TEST-F Page 1 of 1
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CODE	INT2504B	LOT	CE21C26L72
		Expiry Date	2023-02

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE21D28L11	Amotosalen 1 200101
	2	N/A	2 N/A
	3	N/A	3 N/A
PCT sub-assembly	1	CE21C26L72	CAD material 00129B / 00203B / 00203C / 00205A / 00207B / 00207C

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
Final product	0.125 EU / mL	May 7, 2021	PASS
Amotosalen solution sub-assembly	<input checked="" type="checkbox"/> 3 mM → 2.0 EU / mL OR <input type="checkbox"/> 6 mM → 0.8 EU / mL	1 May 12, 2021	PASS
		2 N/A	N/A
		3 N/A	N/A
PCT sub-assembly	0.25 EU / mL	1 April 7, 2021	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"/>

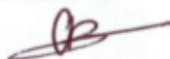
STERILITY		
Amotosalen solution	Steam sterilization cycle according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
PCT sub-assembly	Gamma irradiation according to validated method reviewed & conform	CONFORM <input checked="" type="checkbox"/>
Connected product	E-Beam 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 **5256 UNITS**

Reviewed by Fenwal
 QA MANAGER or DELEGATE
 Date & Signature
 C. BERTHOMIER



June 1, 2021

Released by Cerus
 QA MANAGER or DELEGATE
 Date & Signature



Romain LÉLIEVRE
 June 1st, 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.