 <p>Fenwal™ A Fresenius Kabi Company La Châtre, Etaillé, 36400 Lacs, France</p>	CERTIFICATE OF CONFORMITY INTERCEPT PRODUCT 	Formulaire N° : C22-TEST-F Révision N° : A SOP N° : TEST-F Page 1 of 1
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CODE	INT2504B	LOT	CE18H29L71
		Expiry Date	2020-02

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE18I18L11	Amotosalen
	2	N/A	1
	3	N/A	2
PCT sub-assembly	1	CE18H29L71	CAD material
			170131
			2
			3
			80517B / 80517C / 80521B / 80521C / 80524B

DESCRIPTION : INTERCEPT Platelet Processing Set with Dual Storage Containers

CONFORMITY OF TESTS

Product	PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)			Results
	Limit (≤)	Date Passed		
Final product	0.125 EU / mL	September 21, 2018		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	September 21, 2018	PASS
		2	N/A	N/A
		3	N/A	N/A
PCT sub-assembly	0.25 EU / mL	1	September 5, 2018	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 **4488 UNITS**

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature



M. Rovina , October 9, 2018

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature



09 OCT. 2018

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