

 <p><b>Fenwal™</b> A Fresenius Kabi Company La Châtre, Etailé, 36400 Lacs, France</p>	<b>CERTIFICATE OF CONFORMITY INTERCEPT PRODUCT</b>  	<b>Formulaire N° : C22-TEST-F</b> <b>Révision N° : A</b> <b>SOP N° : TEST-F</b> Page 1 of 1

<b>CODE</b>	<b>INT2504B</b>	<b>LOT</b>	<b>CE19C20L71</b>
		Expiry Date	2020-09

	Lot		Raw material batch
<b>Amotosalen solution sub-assembly</b>	1	CE19D08L11	<b>Amotosalen</b> 1 170131
	2	N/A	2 N/A
	3	N/A	3 N/A
<b>PCT sub-assembly</b>	1	CE19C20L71	<b>CAD material</b> 90102CC / 90103B / 90104B / 90107B / 90107C / 90108B

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

**CONFORMITY OF TESTS**

<b>PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)</b>			
Product	Limit (s)	Date Passed	Results
<b>Final product</b>	0.125 EU / mL	April 10, 2019	PASS
<b>Amotosalen solution sub-assembly</b>	<input checked="" type="checkbox"/> 3 mM → 2.0 EU / mL OR <input type="checkbox"/> 6 mM → 0.8 EU / mL	1 April 15, 2019	PASS
		2 N/A	N/A
		3 N/A	N/A
<b>PCT sub-assembly</b>	0.25 EU / mL	1 March 21, 2019	PASS
			Disposition : <b>PASS</b> <input checked="" type="checkbox"/>

<b>BACTERIOLOGY-BIOBURDEN</b> (TEST-B-17 / TEST-B-09)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>FINAL PHYSICAL TESTING</b> (TEST-C)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>pH ANALYSIS ON CONNECTED KIT</b> (TEST-A)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>AMOTOSALEN FINAL CHEMICAL ANALYSIS</b> (TEST-A-01)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>

<b>STERILITY</b>		
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 : <b>PASS</b> <input checked="" type="checkbox"/>

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


QUANTITY 4464 UNITS

**Reviewed by Fenwal**  
QA MANAGER or DELEGATE  
Date & Signature



M. Rovina , May 2, 2019

**Released by Cerus**  
QA MANAGER or DELEGATE  
Date & Signature



03 May 2019

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