

**CERTIFICATE OF CONFORMITY  
INTERCEPT PRODUCT**



<b>CODE</b>	<b>INT3104B</b>	<b>LOT</b>	<b>CE20K24L71</b>
		Expiry Date	2022-10

	Lot		Raw material batch
Amotosalen solution sub-assembly	1	CE20L14L11	Amotosalen
	2	N/A	1
	3	N/A	2
PCT sub-assembly	1	CE20K24L71	CAD material
			3

**DESCRIPTION : INTERCEPT Processing Set for Plasma**

**CONFORMITY OF TESTS RESULTS**

Product	PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)		
	Limits (≤)	Date Passed	Results
Final product	0.125 EU / mL	December 17, 2020	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	December 22, 2020
		2	N/A
		3	N/A
PCT sub-assembly	0.25 EU / mL	1	November 27, 2020

Disposition : **PASS**

<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"/>

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

**2376 UNITS**

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

January 6, 2021

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

**Romain LELIEVRE**  
Jan 07<sup>th</sup> 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.