

<b>CODE</b>	<b>INT3104B</b>	<b>LOT</b>	<b>CE19G18L71</b>
		Expiry Date	2021-06

	Lot		Raw material batch
<b>Amotosalen solution sub-assembly</b>	1	CE19H08L11	<b>Amotosalen</b> 1 180093
	2	N/A	2 N/A
	3	N/A	3 N/A
<b>PCT sub-assembly</b>	1	CE19G18L71	<b>CAD material</b> 81203A1 / 81203A3 / 81210A1

**DESCRIPTION : INTERCEPT Processing Set for Plasma**

**CONFORMITY OF TESTS RESULTS**

<b>PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)</b>			
Product	Limits (≤)	Date Passed	Results
<b>Final product</b>	0.125 EU / mL	August 20, 2019	PASS
<b>Amotosalen solution sub-assembly</b>	<input type="checkbox"/> 3 mM → 2.0 EU / mL OR <input checked="" type="checkbox"/> 6 mM → 0.8 EU / mL	1 August 20, 2019	PASS
		2 N/A	N/A
		3 N/A	N/A
<b>PCT sub-assembly</b>	0.25 EU / mL	1 July 24, 2019	PASS

Disposition : **PASS**

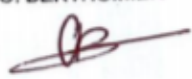
<b>BACTERIOLOGY-BIOBURDEN</b> (TEST-B-17 / TEST-B-09)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>FINAL PHYSICAL TESTING</b> (TEST-C)	Disposition : <b>PASS</b> <input checked="" type="checkbox"/>
<b>pH ANALYSIS ON CONNECTED KIT</b> (TEST-A)	Disposition : <b>PASS</b> <input checked=""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

<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 : **PASS**

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

QUANTITY **2400 UNITS**

**Reviewed by Fenwal**  
QA MANAGER or DELEGATE  
Date & Signature  
  
C. BERTHOMIER  
  
September 12, 2019

**Released by Cerus**  
QA MANAGER or DELEGATE  
Date & Signature  
  
  
**Romain LELIEVRE**  
Sept 13<sup>th</sup> 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.