Fenwal™ A Fresenius Kabi Company La Châtre, Etaillé, 36400 Lacs, France	CERTIFICATE OF CONFORMITY INTERCEPT PRODUCT CERUS	Formulaire N° : C22-TEST-F Révision N° : A SOP N° : TEST-F Page 1 of 1

CODE	INT2504B	LOT	CE18L12L72
		Expiry Date	2020-06

		Lot			Raw material batch
Amotosalen solution sub-assembly	1	CE19A10L12	Amotosalen	1	170131
	2	CE19A14L11		2	170131
	3	N/A		3	N/A
PCT sub-assembly	1	CE18L12L72	CAD material		80816C / 80817C / 80728B / 80924C / 80925B

DESCRIPTION : INTERCEPT Processing Set with Dual Storage Containers

CONFORMITY OF TESTS

	PYROGENICITY TEST : Turbidimetric Kinetic (TEST-B-03)			
Product	Limit (≤)	Date Passed		Results
Final product	0.125 EU / mL	January 16, 2019		PASS
Amotosalen solution sub-assembly	☑ 3 mM → 2.0 EU / mL OR ☐ 6 mM → 0.8 EU / mL	1	January 16, 2019	PASS
		2	January 23, 2019	PASS
		3	N/A	N/A
PCT sub-assembly	0.25 EU / mL	1	December 13, 2018	PASS
				Disposition : **PASS** ☑

BACTERIOLOGY-BIOBURDEN (TEST-B-17 / TEST-B-09)	Disposition : **PASS** ☑
FINAL PHYSICAL TESTING (TEST-C)	Disposition : **PASS** ☑
pH ANALYSIS ON CONNECTED KIT (TEST-A)	Disposition : **PASS** ☑
AMOTOSALEN FINAL CHEMICAL ANALYSIS (TEST-A-01)	Disposition : **PASS** ☑

STERILITY		
Amotosalen solution	Steam sterilization cycle according to validated method reviewed & conform	CONFORM ☑
PCT sub-assembly	Gamma irradiation according to validated method reviewed & conform	CONFORM ☑
Connected product	E-Beam irradiation according to validated method reviewed & conform	CONFORM ☑
Sterility Test (TEST-B-13)	No positives	CONFORM ☑
		Disposition : **PASS** ☑

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

QUANTITY **4680 UNITS**

Reviewed by Fenwal
QA MANAGER or DELEGATE
Date & Signature

Released by Cerus
QA MANAGER or DELEGATE
Date & Signature
LELIEVRE
14 MARS 2019

M. Rovina , March 13, 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.