

Fenwal International, Inc

Carretera Sanchez Km 18.5
Parque Industrial Itabo, Zona Franca Ind. de S.C.
Haina, Dominican Republic

INTERNATIONAL PRODUCT CERTIFICATION

CODE: R6R2074	BATCH: FA23I01069
DESCRIPTION: COMPOFLEX 1F - EMPTY - 400 - COUPLER	
DATE OF MANUFACTURE: 09/01/2023	EXPIRATION DATE: 2026-09
THIS IS TO CERTIFY THAT THE SUBJECT BATCH HAS BEEN MANUFACTURED TO COMPLY WITH U.S. F.D.A., EDQM STANDARD FOR ENDOTOXIN TEST, G.M.P. AND CE REQUIREMENTS REGARDING THIS PRODUCT, AND HAS PASSED ALL FENWAL REQUIRED TESTING, AND HAS BEEN RELEASED FOR DISTRIBUTION.	
DATE BACTERIAL ENDOTOXINS TEST PASSED (CHROMOGENIC <input type="checkbox"/> OR TURBIDIMETRIC <input checked="" type="checkbox"/> METHOD): 09/05/2023	
LIMIT	: 0.250 EU/ML
SAMPLE RESULT	: <0.0100 EU/ML

STERILIZATION METHOD: N/A GAMMA E-BEAM EO DATE STERILIZATION PERFORMED: 09/07/2023

MINIMUM IRRADIATION DOSE:	PER SPEC:	14.2 KGY	PER THIS LOT:	15.4 KGY
MAXIMUM IRRADIATION DOSE:	PER SPEC:	90.0 KGY	PER THIS LOT:	30.4 KGY

TEST OF PRODUCT

TEST	SPEC REFERENCE	RESULT
VISUAL INSPECTION	20-03-03-019	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
BACTERIAL ENDOTOXINS TEST	13-01-T	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
FUNCTIONAL INSPECTION, INCLUDING LEAK TEST	20-03-03-019	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
FINAL FUNCTIONAL	20-03-03-019	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
OTHER TEST: <u>N/A</u>	N/A	PASSED <input type="checkbox"/> FAILED <input type="checkbox"/>

SUPPLIER SOLUTION BAG LOTS USED IN CLOSED KITS (ONLY APPLY AMICUS APHERESIS KIT)

0.9% NAACL BAG ASSY W/OVER POUCH	ACD-A BAG ASSY W/OVER POUCH	N/A	N/A
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

BATCH RELEASE DATE: 09/24/2023 QTY: 13,248 UNITS

PREPARED BY/ DATE: 9883095. Nondon 09-24-2023 QUALITY APPROVER/ DATE: 347012 M. Dela Rosa 09-26-2023

NOTE: FOR NOT APPLICABLE INFORMATION "N/A"