

Fenwal International, Inc

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

INTERNATIONAL PRODUCT CERTIFICATION

CODE: R6R2041	BATCH: FA24G10139
DESCRIPTION: COMPOFLEX 1F - EMPTY - 2000 - COUPLER - SEG.TUBES	
DATE OF MANUFACTURE: 07/10/2024	EXPIRATION DATE: 2027-07
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): 07/15/2024	
LIMIT	: 0.250 EU/ML
SAMPLE RESULT	: <0.0100 EU/ML

STERILIZATION METHOD: N/A GAMMA E-BEAM EO DATE STERILIZATION PERFORMED: 07/12/2024

MINIMUM IRRADIATION DOSE:	PER SPEC:	14.2 KGY	PER THIS LOT:	19.3 KGY
MAXIMUM IRRADIATION DOSE:	PER SPEC:	90.0 KGY	PER THIS LOT:	46.7 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: N/A	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: 07/22/2024 QTY: 7,440 UNITS

PREPARED BY/ DATE: 990947 Suarez 07/24/2024 QUALITY APPROVER/ DATE: 347592 Maldonado 07/25/2024

NOTE: FOR NOT APPLICABLE INFORMATION "N/A"