

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: FA25B25137
DESCRIPTION: COMPOFLEX 1F - EMPTY - 400 - COUPLER	
DATE OF MANUFACTURE: 02/25/2025	EXPIRATION DATE: 2028-02
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 ☐ OR TURBIDIMETRIC ☒ METHOD): 02/26/2025	
LIMIT	: 0.250 EU/ML
SAMPLE RESULT	: <0.0100 EU/ML

STERILIZATION METHOD: N/A GAMMA E-BEAM EO DATE STERILIZATION PERFORMED: 03/04/2025

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MINIMUM IRRADIATION DOSE:	PER SPEC:	14.2 KGY	PER THIS LOT:	20.6 KGY
MAXIMUM IRRADIATION DOSE:	PER SPEC:	90.0 KGY	PER THIS LOT:	39.4 KGY

TEST OF PRODUCT

TEST	SPEC REFERENCE	RESULT
VISUAL INSPECTION	20-03-03-019	PASSED ☒ FAILED ☐
BACTERIAL ENDOTOXINS TEST	13-01-T	PASSED ☒ FAILED ☐
FUNCTIONAL INSPECTION, INCLUDING LEAK TEST	20-03-03-019	PASSED ☒ FAILED ☐
FINAL FUNCTIONAL	20-03-03-019	PASSED ☒ FAILED ☐
OTHER TEST: <u>N/A</u>	N/A	PASSED ☐ FAILED ☐

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

0.9% NACL 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: 03/10/2025 QTY: 13,344 UNITS

PREPARED BY/ DATE: 347012 M. Pala Rosa 03-11-2025 QUALITY APPROVER/ DATE: 34792 R. Rodriguez 03/12/2025

NOTE: FOR NOT APPLICABLE INFORMATION "N/A"