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: FA25L12059
DESCRIPTION: COMPOFLEX 1F - EMPTY - 400 - COUPLER	
DATE OF MANUFACTURE: 12/12/2025	EXPIRATION DATE: 2028-12

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): 12/17/2025

LIMIT : 0.250 EU/ML

SAMPLE RESULT : <0.0100 EU/ML

STERILIZATION METHOD: N/A ☐ GAMMA ☐ E-BEAM ☒ EO ☐ DATE STERILIZATION PERFORMED: 12/15/2025

MINIMUM IRRADIATION DOSE:	PER SPEC:	14.2	KGY	PER THIS LOT:	19.8	KGY
MAXIMUM IRRADIATION DOSE:	PER SPEC:	90.0	KGY	PER THIS LOT:	36.6	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: N/A	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: 01/07/2026 QTY: 13,392 UNITS

PREPARED BY/ DATE: 347012 M. De la Rosa 01-09-2026 QUALITY APPROVER/ DATE: 347592 Rodolfo Rodolfo 01/09/2026

NOTE: FOR NOT APPLICABLE INFOMATION "N/A"