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:** FA23H05013
DESCRIPTION: COMPOFLEX 1F - EMPTY - 400 - COUPLER	
DATE OF MANUFACTURE: 08/05/2023	**EXPIRATION DATE:** 2026-08

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):** 08/09/2023

LIMIT : 0.250 **EU/ML**

SAMPLE RESULT : <0.0100 **EU/ML**

STERILIZATION METHOD: N/A ☐ GAMMA ☐ E-BEAM ☒ EO ☐ **DATE STERILIZATION PERFORMED:** 08/06/2023

MINIMUM IRRADIATION DOSE:	**PER SPEC:**	14.2	**KGY**	**PER THIS LOT:**	18.3	**KGY**
MAXIMUM IRRADIATION DOSE:	**PER SPEC:**	90.0	**KGY**	**PER THIS LOT:**	34.6	**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: 08/26/2023 **QTY:** 12,000 **UNITS**

PREPARED BY/ DATE: 9883095. Rondon 08-27-2023 **QUALITY APPROVER/ DATE:** 347012 M. Dela Rosa 08-27-2023

NOTE: FOR NOT APPLICABLE INFOMATION "N/A"