Fenwal International, Inc

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INTERNATIONAL PRODUCT CERTIFICATION

CODE: R6R2041 **BATCH:** FA23J19060

DESCRIPTION: COMPOFLEX 1F - EMPTY - 2000 - COUPLER - SEG.TUBES.

DATE OF MANUFACTURE: 10/19/2023 **EXPIRATION DATE:** 2026-10

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):** 10/24/2023

LIMIT : 0.250 **EU/ML**

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

STERILIZATION METHOD: N/A ☐ GAMMA ☐ E-BEAM ☒ EO ☐ **DATE STERILIZATION PERFORMED:** 10/21/2023

MINIMUM IRRADIATION DOSE:	**PER SPEC:**	14.2	**KGY**	**PER THIS LOT:**	17.7	**KGY**
MAXIMUM IRRADIATION DOSE:	**PER SPEC:**	90.0	**KGY**	**PER THIS LOT:**	41.3	**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: 11/09/2023 **QTY:** 2,736 **UNITS**

PREPARED BY/ DATE: 97422 11.09.2023 **QUALITY APPROVER/ DATE:** 347012 N. Dela Rosa 11-10-2023

NOTE: FOR NOT APPLICABLE INFOMATION "N/A"