Fenwal International, Inc

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INTERNATIONAL PRODUCT CERTIFICATION

CODE: R6R2004 **BATCH:** FA22K29019

DESCRIPTION: COMPOFLEX 4F - EMPTY - 150/150/150/150 - COUPLER - SEG. TUBE

DATE OF MANUFACTURE: 11/29/2022 **EXPIRATION DATE:** 2025-11

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):** 12/02/2022

LIMIT : 0.250 **EU/ML**

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

STERILIZATION METHOD: **N/A** ☐ **GAMMA** ☐ **E-BEAM** ☒ **EO** ☐ **DATE STERILIZATION PERFORMED:** 12/12/2022

MINIMUM IRRADIATION DOSE:	**PER SPEC:**	14.2 **KGY**	**PER THIS LOT:**	19.7 **KGY**
MAXIMUM IRRADIATION DOSE:	**PER SPEC:**	90.0 **KGY**	**PER THIS LOT:**	46.5 **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: 01/31/2023 **QTY:** 6,432 **UNITS**

PREPARED BY/ DATE: 974212 M Lopez 01-31-2023 **QUALITY APPROVER/ DATE:** 347012 M-Dela Rosa 02-01-2023

NOTE: FOR NOT APPLICABLE INFOMATION "N/A"