

**Fenwal International, Inc**  
 Carretera Sanchez Km 18.5  
 Parque Industrial Itabo, Zona Franca Ind. de S.C.  
 Haina, Dominican Republic

INTERNATIONAL PRODUCT CERTIFICATION

CODE: R6R1401	BATCH: FA21A05234
DESCRIPTION: SAMPLING SITE COUPLER WITH NEEDLE INJECTION SITE	
DATE OF MANUFACTURE: 01/05/2021	EXPIRATION DATE: 2025-12
THIS IS TO CERTIFY THAT THE SUBJECT BATCH HAS BEEN MANUFACTURED TO COMPLY WITH U.S. F.D.A. 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 <input type="checkbox"/> OR TURBIDIMETRIC <input checked="" type="checkbox"/> METHOD): 01/07/2021 ,	
LIMIT	: 0.250 EU/ML
SAMPLE RESULT	: 0.0100 EU/ML

STERILIZATION METHOD: N/A    GAMMA     E-BEAM     EO     DATE STERILIZATION PERFORMED: 02/17/2021

MINIMUM IRRADIATION DOSE:	PER SPEC:	N/A KGY	PER THIS LOT:	N/A KGY
MAXIMUM IRRADIATION DOSE:	PER SPEC:	N/A KGY	PER THIS LOT:	N/A KGY

**TEST OF PRODUCT**

TEST	SPEC REFERENCE	RESULT
VISUAL INSPECTION	20-03-05-100	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
BACTERIAL ENDOTOXINS TEST	13-01-T	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
FUNCTIONAL INSPECTION, INCLUDING LEAK TEST	20-03-05-100	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
FINAL FUNCTIONAL	20-03-05-100	PASSED <input checked="" type="checkbox"/> FAILED <input type="checkbox"/>
OTHER TEST: <u>N/A</u>	N/A	PASSED <input type="checkbox"/> FAILED <input type="checkbox"/>

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

0.9% NA CL 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
N/A	N/A	N/A	N/A

BATCH RELEASE DATE: 03/26/2021    QTY: 8,000    UNITS

PREPARED BY/ DATE: 974212 Myrpaon    RELEASE SUPERVISOR/ DATE: 34771 Z. Delacruz  
03-31-2021    3/31/2021

NOTE: FOR NOT APPLICABLE INFORMATION "N/A"