



LOT CERTIFICATE

Product Name:	IMUFLEX-WB-SP Blood bag (CPD/S.A.G.M.)		
Product Code/Cat No:	BB*LGQ456E6		
Lot number:	231226AF		
Lot size (amount):	2,942 sets		
Sterilization Date:	28/12/2023	Sterilization Method:	Moist heat
Expiration date:	31/05/2026		

Material validation	Quality of product is validated according to ISO3826-1, 3.
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QC specifications and inspection result	(1)Chemical test for PVC material based on internal standards	<input checked="" type="checkbox"/>	Passed
	(2)Chemical test for other plastic material based on internal standards	<input checked="" type="checkbox"/>	Passed
	(3)Function test for PVC container based on internal standards	<input checked="" type="checkbox"/>	Passed
	(4)Biological test (Bacterial Endotoxins) according to USP	<input checked="" type="checkbox"/>	Passed
	(5)Microbiological test (Sterility test) according to JP	<input checked="" type="checkbox"/>	Passed

Chemical testing for the anticoagulant CPD	(1)Volume of anticoagulant solution: +/-5 % of label	<input checked="" type="checkbox"/>	Passed
	(2)Identification and assay of the components	<input checked="" type="checkbox"/>	Passed
	(3)Impurities (Heavy metals, As, Cl)	<input checked="" type="checkbox"/>	Passed
	(4)pH: 5.4 - 5.8	<input checked="" type="checkbox"/>	5.7



Chemical testing for the preservation solution S.A.G.M.	(1)Volume of anticoagulant solution: +/-5 % of label	<input checked="" type="checkbox"/> Passed
	(2)Identification and assay of the components	<input checked="" type="checkbox"/> Passed
	(3)Impurities (Heavy metals, As)	<input checked="" type="checkbox"/> Passed
	(4)pH: 4.5 - 6.5	<input checked="" type="checkbox"/> 5.9

Comments results: Lot No. 231226AF meets all requirements of QC product
Product Code/Cat No: BB*LGQ456E6 specification

Release statement : Lot Released

Date of release determination : 25 / 01 / 2024
(Day) (Month) (Year)

Date of signature : 08 / 02 / 2024
(Day) (Month) (Year)