



CERTIFICATE OF COMPLIANCE

Customer Name	ISO-MED
Product Item Code	ISOEVA100
Lot Number	20211102
Lot Quantity	6900pcs
Report Date	2021/11/30
Manufacture Date	2021/11/10
Expiration Date	2024-11-01

Performance Testing Requirements		
Performance Test	Test Method	Results-Pass/Fail
Test for Leakage	100% leak testing with TME Solutions leak tester using pressure decay method	Pass
Test for Tensile/Bond Strength	15N/15S by ISO8536-7 Pull on Distal and Proximal PVC Tubing at EVA bag welded connector Connection point for 15 seconds	Pass
Non DEHP PVC Tubing Inspection Results	Visual Inspection 100%	Pass
Female Luer Connector Inspection Results	Visual Inspection 100%	Pass
Slide Clamp Inspection Results	Visual Inspection 100%	Pass
SAL (10 ⁻⁶)	Sterilized with Ethylene Oxide and found to conform to the Sterility Requirements EN550 & ISO 11135-2014	Pass
Sterilization Verification	Parameter Verification	Pass
	Biological Indicator	Pass
USP<788>Particulate testing	>10u=25/ml	1.9
	>25u=3/ml	0.1
CEM PARTICLE COUNTER	0.3UM	8

Inspected By: Shi Qiang (Manager EVA Container Products)

Date: 2021/11/30

Approved By: Alex Wang (Manager Quality Control, EVA Container Products)

Date:2021/11/30