



## CERTIFICATE OF COMPLIANCE

<b>Customer Name</b>	ISO-MED
<b>Product Item Code</b>	ISOEVA250
<b>Lot Number</b>	20220116/20220220
<b>Lot Quantity</b>	5350pcs/5700pcs
<b>Report Date</b>	2022/03/09
<b>Manufacture Date</b>	2022/01/15
<b>Expiration Date</b>	2025-01-15/2025-02-19

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 <sup>-6</sup> )	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	6.43/6.57
	>25u=3/ml	0/0.1
CEM PARTICLE COUNTER	0.3UM	10.52/11.5

**Inspected By: Shi Qiang (Manager EVA Container Products)**

**Date: 2022/03/09**

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

**Date: 2022/03/09**