

[Redacted]		Document No	YX-10-JL17
Document Name	Certification of EO Sterilization		Version
			A/0

Report No.:2024080401

Sterilizer number: YX-EO6-01

Customer:	[Redacted]						
Product Name	Product No.	Specification	Lot No.	Carton Size (cm)	Quantity		
Needles/Cartridges	—	M1	M2305	/	600PCS		
Needles/Cartridges	—	F7	M2207	/	100PCS		
Needles/Cartridges	—	F7	M2306	/	100PCS		
Needles/Cartridges	—	12 Needle	M2207	/	200PCS		
Needles/Cartridges	—	Round Nano	M2207	/	300PCS		
灭菌日期 Sterilization date:	2024-07-27	灭菌批号 Ster.Lot		20240727-01			
<b>Sterilization Parameters</b>		<b>Validated</b>		Control area	<b>Min</b>	<b>Max</b>	<b>Accept/Reject</b>
Heating Temperature		°C	50	±5	50		Pass
Holding Time After Heating		min	120	±2	120		Pass
Initial Evacuation Vacuum		kpa	-50	±2	-50.3		Pass
EO-weight		kg	4.8	±0.2	4.8		Pass
Exposure temperature		°C	50	±5	49.6	50.8	Pass
Exposure RH		%RH	N/A	30-80	52.1	73.4	Pass
EO exposure time		min	480	±10	479.8		Pass
Post-Evacuation Vacuum		kpa	-50	±2	-50.2		Pass
Numbers of times of repetition		time	5	5	5		Pass
Ventilation time		min	20	±1	20.1		Pass
BI Type	EZG/6		BI Strain	ATCC9372		Nominal population(cfu/unit)	2.2×10 <sup>6</sup>
BI Lot No	G-247	Bquantity 4pcs	Incubation Temperature	37°C		Culture time	4Day (96H)
Culture time(d)	1st (24h)	2nd (48h)	3rd (72h)	4th (96h)	5th (120h)	6th (144h)	7th (168h)
Observation Record	—	—	—	—			
Positiue control	+	+	+	+			
BI test of sterility				<input checked="" type="checkbox"/> conformity <input type="checkbox"/> non-conformity			
Note: (-): represent negative, (+): represent positive.							
conclusion							
The results showed that the above products were routinely sterilized with ethylene oxide, and the sterilization parameters were qualified. The products were allowed to be released.							

Approval by: 吴春花

Prepared by: [Signature]

Date: 2024-8-4