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Certificate of Analysis for Arteriovenous Fistula Needle Sets

OCI/CCZ-J001-R03_A02

Product Name	Arteriovenous Fistula Needle Sets			Report No.	CA25111702
Model	OCI-16G	LOT NO	251006	Total Quantity	13600
Sterilization LOT NO	2510028	Sampling date	2025.11.17	Report date	2025.11.25

Testing Basis	Inspection SOP for Arteriovenous Fistula Needle Sets

No	Test item	Standard clause	Standard requirement	Testing result
1	Particulate	3.1.1	The pollution index shall be no more than 90.	3.0
	Air-tightness	3.1.2	The Arteriovenous Fistula Needle Sets should be able to withstand a positive pressure of 100kPa and a negative pressure of 93.3kPa.	Pass
	Connection strength	3.1.3	The connection strength of each component of the Arteriovenous Fistula Needle Sets should be able to withstand a static axial tension of no less than 15N, and it should not break or fall off for 15s	Pass
	Flow rate	3.1.4	Specification/model: 14G — 10 kPa flow, ml/min: ≥45 — 30kPa flow, ml/min: ≥380 15G: ≥38: ≥320 16G: ≥30: ≥250 17G: ≥24: ≥200	10KPa: 262 30KPa: 455
	Clamp	3.1.5	The fixture on the catheter shall be closed by means of lock, and shall be unlocked and closed effectively. When it is closed, it shall be able to block the gas above the atmospheric pressure of 50kPa for 1min without any leakage.	Pass
	Needle tube	3.1.6.1	The tip of the Arteriovenous Fistula Needle Sets has a back hole, and the periphery of the back hole shall be smooth without burr or flange.	Pass
		3.1.6.2	The needle tube is ultrathin wall. The outer diameter of the needle tube, the length of the needle tube and the area of the back hole shall meet the requirements.	OD: 1.6552mm ID: 1.4115mm Length: 25.1155mm Dorsal hole area: 1.2476mm
			Model: 14G — OD: 2.10±0.01 — ID: ≥1.727 — Needle tube length, mm: 25±2/32±2 — Dorsal hole area, mm: ≥1.6 — Needle handle color: Purple	
			15G: 1.85±0.01: ≥1.560: ≥1.3: beige	
			16G: 1.65±0.01: ≥1.390: ≥1.0: Green	
			17G: 1.50±0.01: ≥1.244: ≥0.8: Orange	
	Needle tip	3.1.7	The needle tip shall be sharp without such defect as rough edge, burr or hook. The maximum puncture force of the needle tip shall be no more than 3.5N	0.96N
	Lubricant	3.1.8	There shall be no visible lubricant accumulation on the outer surface of the needle tube.	Pass
	Needle handle	3.1.9.1	The black dot on the needle handle (core) indicates the direction of the needle tip slope, and the red dot indicates the back of the needle tip	Pass
		3.1.9.2	(1) The needle handle (wing) can be rotated and the appearance shall be intact. (2) The color of the needle handle (wing) is used to indicate the outer diameter of the Arteriovenous Fistula Needle Sets, and the color specified shall be used; (3) There shall be a clear mark of the nominal outer diameter of the needle tube at the appropriate position of the needle handle (wing).	Pass
	Flexible tube	3.1.10.1	The catheter shall be evenly plastified, free from loop knot and collapse, transparent or sufficiently transparent. When some gas bulbs are passing through, a water-air interface can be found with normal eyesight or	Pass

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			corrected eyesight.	
		3.1.10.2	The inner diameter of the catheter shall be no less than 2.7 mm, the wall thickness shall be ≥ 0.65mm, and the length shall be 290^{0}_{-20}mm	3.12mm 1.21mm 273mm
	Inner conical connector	3.1.11	The end of the Arteriovenous Fistula Needle Sets has a locking inner conical connector that complies with GB/T1962.2-2001	Pass
	Connector protective sleeve	3.1.12	The connector protective sleeve shall be firmly connected to the inner conical connector and easy to dismantle	Pass
	Protective sleeve	3.1.13	The protective sleeve shall be smooth, free of flash and burr. The protective sleeve shall be firm, not easy to fall off naturally, and easy to dismantle.	Pass
2	Reducing substances	3.2.1	The volume difference of potassium permanganate solution [c ($KMn0_4$) = 0.002 mol/L] consumed by the 20 mL test solution and the blank control solution of the same batch shall not exceed 2.0mL.	0.25
	Heavy metal	3.2.2.1	When determined by the atomic absorption spectroscopy (AAS) or similar method, the total content of barium, chromium, copper, lead and stannum in the test solution shall not exceed 1μg/mL, and the content of cadmium shall not exceed 0.1μg/mL .	Pass
		3.2.2.2	When determined by the colorimetric method, the color of the test solution shall not be darker than that of the standard control solution at the mass concentration ρ (Pb^{2-}) = 1 μg/mL.	Pass
	pH value	3.2.3	Any standard solution required for the indicator to turn gray shall not exceed 1ml	0.08
	Residue on evaporation	3.2.4	The total residue on evaporation of 50 mL test solution shall not exceed 2 mg.	0.3mg 0.4mg
	Ultraviolet absorbance	3.2.5	The absorbance of the test solution shall not exceed 0.1 at 250-320nm.	0.020 0.017
	Ethylene oxide residue	3.2.6	When the Arteriovenous Fistula Needle Sets is sterilized with ethylene oxide gas, the residual amount of ethylene oxide shall not be greater than 10 μg/g	Pass
3	Sterility	3.3.1	The Arteriovenous Fistula Needle Sets shall be sterilized in a confirmed ethylene oxide sterilization process.	Pass
	Pyrogen	3.3.2	There shall be no pyrogen when using the pyrogen test method. When using the bacterial endotoxin test method, the extraction medium injected into each Arteriovenous Fistula Needle Set shall not exceed 10ml, and the endotoxin shall not be greater than 0.5Eu/ml.	Pass
Conclusion: Upon testing in accordance with the SOP for Arteriovenous Fistula Needle Sets, the results meet the requirements.				