

Zhejiang Kindly Medical Devices Co., Ltd

Inspection Record of Hypodermic Needle

Version Number: 11/10 KDL/Record Quality -M006

Mfg Date: 25-10-2013 Report No.:2013071137

Department to be inspected	Assembly Machine C5	Inspection No.	2013071137	Specification	21Gx1 1/2 "
Production Batch No.	131020	Quantity	200,000	Sampling date	25-10-2013
Inspection basis	ISO7864-1993	Inspection quantity (set)	130	Inspection date	25-10-2013 to 01-11-2013
Sampling scheme	Inspection item	Clause and standard requirements		Actual inspection result	Determined
All qualified	pH value	5. Compare inspected liquid and comparison liquid of the same batch, and the difference should be no more than 1.0		0.16	Qualified
	Limit value of extractable metal	6. Metal content should be no more than 5mg/l		<5mg/l	Qualified
	Sterile	4.7.1 Hypodermic needle should be sterile		Sterile	/
	Pyrogen	4.7.2 Hypodermic needle should be apyrogenicity		Apyrogenicity	Qualified
S-1 2.5 n=5 Ac=0 Re=1	Rigidity/hardness	11.1.1 Deflection ≥ 0.41 mm		0.353-0.356	Qualified
	Needle tubing strength	11.1.2 It should not break after 20-circle times		Conform to requirements	Qualified
	Needle tubing corrosion resistance	11.1.3 Good		Conform to requirements	Qualified
S-2 2.5 n=20 Ac=1 Re=2	Needle tip requirements	12.1 It should be sharp, without deckle edges, burrs and hooks defect		Conform to requirements	Qualified
		12.2 $\alpha=11^{\circ}\pm 2^{\circ}$		10.61°-11.19°	Qualified
	Needle file cone connector	9.1 It should conform to provisions of ISO594-1 or ISO594-2		Conform to requirements	Qualified
	Connection firmness	13.1 Exert pulling force of 54N, there is no loosening or separation of needle file and needle tubing		Conform to requirements	Qualified
S-4 6.5 n=80 Ac=10 Re=11	External diameter size	7 D=0.82mm ± 0.01 mm		0.810-0.815	Qualified
	Needle tubing length	11.2 L=38.0 mm +1.5 mm -2.5 mm		36.5-37.5	Qualified
	Needle cleaning	4 No particles and foreign materials		Conform to requirements	Qualified
	Smooth	13.2 Under water pressure of ≥ 100 KPa, flow rate should be no less than 80% of minimum internal diameter or probe with corresponding size could pass smoothly		Conform to requirements	Qualified
	Needle file color	9.2 It should conform to ISO6009 provisions		Dark green	Qualified
	Needle tubing defect	11.3 It should be straight, with uniform cross section and wall thickness		Conform to requirements	Qualified
	Lubricant	11.4 Lubricant drop on needle tubing internal surface or external surface should be invisible		Conform to requirements	Qualified
	Jacket	10 It should protect needle tip		Conform to requirements	Qualified

Determination: conform to ISO7864-1993 <Sterile Hypodermic Needles for Single Use> standard provisions

Tested by: Guo Miaomiao Zheng Langxing Cheng Saihe

Reviewed by: Xiang Dongzhu

