AYSET
TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL
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QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

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REPORT NO	: R PY0252	DATE	: 26.08.2022
LOT NO	: PY0252	STERILIZATION	: 24.08.2022
PRODUCT NAME	: INSULIN PEN INJECTOR NEEDLE	EXPIRY	: 24.07.2027
PRODUCT TYPE	: 32G x 4mm (0,23x4mm)	LOT SIZE (N)	: 1.500 Box (100 pcs)
REFERENCE CODE	: 70092	# SAMPLES	: 1.250 Pcs.

PHYSICAL TESTS	STANDARDS	TEST METHOD	LIMITS	RESULTS
Needle Tubing Materials	TS EN ISO 11608-2 TS EN ISO 9626	TS EN ISO 9626 ISO 15510	Article 4	Stainless steel SUS 304
Needle Cannula Surface Quality and Visual Appearance	TS EN ISO 11608-2 TS EN ISO 9626	TS EN ISO 9626	Article 5.2	The outer surface of the tubing is smooth and free from defects;
Needle Cleanliness	TS EN ISO 11608-2 TS EN ISO 9626	TS EN ISO 9626	Article 5.3	the surface of the needle tube is free from particles and extraneous matter.
Needle Size Designation	TS EN ISO 11608-2 TS EN ISO 9626	TS EN ISO 9626	Article 5.5, 5.6	Outer Diameter: 0,231 mm (32G) RW Length: 15,50 mm Inner Diameter: 0,11 mm
Stiffness of Tubing Control	TS EN ISO 11608-2 TS EN ISO 9626	TS EN ISO 9626	Article 5.8 - Appendix B	Patency: 5,0±0.1 mm Bending Force:0,9±0.1 N
Resistance to Breakage	TS EN ISO 11608-2 TS EN ISO 9626	TS EN ISO 9626	Article 5.9 - Appendix C	Complied
Needle Points	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.2.4 - Appendix C 3.3	Sharp and free from feather edges, burrs and hooks
Freedom from defects	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.2.5 - Appendix C 3.4	Outer surface of the tubing is smooth and free from defects, particles and extraneous matter. Lubricant is not been visible as droplets of fluid.
Needle Point Bevel	TS EN ISO 7864	TS EN ISO 7864	Article 4.11	Complied
Lubricant	TS EN ISO 11608-2 TS EN ISO 7864	TS EN ISO 7864	Article 4.7	< 0,25 mg/ cm2
Needle Tip Stiffness	TS EN ISO 7864	TS 3592	TS 3592 Article 2.3.1	Complied
Bond Between Hub and Needle Tube	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.2.7 - Article 9.1. Appendix B - Appendix C 3.6	Complied
Flow Rate Through the Needle (Patency Lumen)	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.2.6 Appendix A - Appendix C 3.5	2,64 – 3,04 ml / min
Dislocation of measuring point at patient end	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.2.8 - 9.2	Complied
Ease of Assembly	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.2.9 - 9.3	Complied
Compatibility with Needle-Based Injection System	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.3 - 9.4.1	Complied
Dose delivery	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.3.2 - 9.4.2 – Appendix C.4.2	Complied
Needle Assembly Dimensions	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.2.3	L_1 : 3,45 -4,00 mm L_2 : 6,00 -6,35 mm
Needle Removal Torque	TS EN ISO 11608-2	TS EN ISO 11608-2	Article 5.3.3 - 9.4.3 – Appendix C.4.3	Complied

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CHEMICAL TESTS	STANDARDS	TEST METHOD	LIMITS	RESULTS
Neutrality	TS EN ISO 7864	TS EN ISO 7864	< 1 Unit pH	pH difference < 1 pH
Pb, Sn, Zn, and Fe Analysis	According to the report numbered 190422-16rev02 of Aya Validasyon Ambalaj Sterilasyon A.Ş., total is between < 5 Mg / lt limit.			
Cd Analysis	According to the report numbered 190422-16rev02 of Aya Validasyon Ambalaj Sterilasyon A.Ş., total is between < 0,1 mg/ lt limit.			
Corrosion	TS EN ISO 11608-2 TS EN ISO 9626	TS EN ISO 9626	Article 5.10 – Appendix D No corrosion effect	No corrosion effect
BIOLOGICAL TESTS	**STANDARDS**	**TEST METHOD**	**LIMITS**	**RESULTS**
Sterility	TS 556	TS 10409	Sterile	Sterile
Bacterial Endotoxin(Lal) Test	European Pharmacopeia 9 Section 2.6.14	European Pharmacopeia 9 Section 2.6.14	<0,125 IU/ml	<0,125 IU/ml
Toxicity	EN ISO 10993-11	EN ISO 10993-11	Non-Toxic	Non-Toxic
Hemolytic Effect	TS EN ISO 10993-4	TS EN ISO 10993-4	No hemolytic effect	No hemolytic effect
Sensitization	TS 5298 EN 30993-1 TS EN ISO 10993-10	TS 5298 EN 30993-1 TS EN ISO 10993-10	No cause to sensitization	No cause to sensitization
Irritation	TS 5298 EN 30993-1 TS EN ISO 10993-10	TS 5298 EN 30993-1 TS EN ISO 10993-10	No cause to irritation	No cause to irritation
Cytotoxicity Test	TS 5298 EN 30993-1 TS EN ISO 10993-5	TS 5298 EN 30993-1 TS EN ISO 10993-5	No Cytotoxicity	No Cytotoxicity

REMARKS : Validation check before test is acceptable and results are within limits.

RESULT : Products are appropriate for delivery.

PHYSICAL - CHEMICAL TEST PREPARED BY	BIOLOGICAL TEST PREPARED BY	QUALITY CONTROL MANAGER	RESPONSIBLE MANAGER
HACER TEKGÖZ	HACER TEKGÖZ	ÖMER DEĞİRMENCİOĞLU	ÖZGÜL UYAN