

	TECHNICAL DATA SHEET	Document No	DD.8.2.6.2.03
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ITEM : 3 PARTS 10 ML SYRINGE with 21G x 1 ½" NEEDLE			
DESCRIPTION : Sterile hypodermic syringe for single use that is made of plastic material, pyrogen free, non-toxic, sterilized with ethylene oxide and used for aspiration of liquids or used for injection of liquid after filled for			
PROPERTIES			
<u>PHYSICAL PROPERTIES</u>	<u>STANDARD (TEST METHOD)</u>	<u>UNITE</u>	<u>RESULT</u>
Material	TS EN ISO 7886-1	–	Medical
Capacity	TS EN ISO 7886-1	ml	10 (± % 5)
Death Space	TS EN ISO 7886-1	ml	Max.0,1
Total graduated capacity	TS EN ISO 7886-1	ml	10 ml
Dimensions	TS EN ISO 7886-1	mm	Ø inside = 15,90
			Ø outside = 16,70
			l barrel = 84,51
			l plunger = 75,55
Air Leakage during aspiration	TS EN ISO 7886-1	kPa/sn	l plunger + gasket = 77,80
			No leakage at 88 kPa vacuum at 60 second
			No leakage at 300 kPa pressure at 30 second
			6% (Luer)
Liquid leakage under compression	TS EN ISO 7886-1	kPa/sn	
Conic fittings (centric)	TS 3521-1 EN 20594-1	%	
Needle size	TS 4002 EN ISO 7864	mm	0.80 x 40
Needle penetration force	TS 4002 EN ISO 7864	N	0.58-0.68
Bond between needle and tube	TS 4002 EN ISO 7864	N	Does not broken by 44N
Cylinder-piston difference	TS EN ISO 7886-1 (Article 12)	mm	11 mm
Scale length	TS EN ISO 7886-1 (Article 10.3)	mm	50,50 mm
Scale interval	TS EN ISO 7886-1 (Article 10.2)	ml	0,5 ml
Increment between graduation lines to be numbered	TS EN ISO 7886-1 (Article 10.2)	ml	1 ml
Lubricant	TS EN ISO 7886-1	gr/cm ²	0,25 polydimethyl siloxane
Weight	AldarMed	gr	7,60-7,70
<u>CHEMICAL PROPERTIES</u>			
Neutrality	TS EN ISO 7886-1	pH	Difference less than 1
Pb, Zn, Sn, Fe	TS EN ISO 7886-1	mg/lt	Totally less than 5
Cd	TS EN ISO 7886-1	mg/lt	Less than 0,1
Ethylene oxide residue	TS 9897	mg/lt	Less than 5
<u>BIOLOGICAL PROPERTIES</u>			
Cytotoxicity	EN ISO 10993		Not cytotoxic
Toxicity	EN ISO 10993		Does not cause acute systemic toxicity
Pyrogenity	EN ISO 10993-11. European Pharmacopoeia 7 th		Apyrogen
Sterility	EN ISO 556, TS 10409/October 1992		Sterile
Hemolytic effect	EN ISO 10993-11, TS 6459/January		Not hemolytical
Sensitization	EN ISO 10993-10/March 1998		No sensitivity
Irritation	EN ISO 10993-10/March 1998		No irritation effect
<u>PACKAGING PROPERTIES AND HANDLING</u>			
Primary Packing	TS EN ISO 7886-1	–	Transparent film + Blister Packing from medical grade paper and statements expressed in the standards
Secondary Packing	TS EN ISO 7886-1	–	innerand out surface testliner, flutting wave, offset printed box and statements expressed in the standards
Transport-Storage-Packing	AldarMed	–	8 inner boxes are put in outer boxes or wrapped container
Storage Condition	AldarMed	–	Kept out of direct sun light and stored in clean and dry storage areas at max. 45 °C
PREPARED BY		APPROVED BY	
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