



## TECHNICAL DATA SHEET

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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**

**PHYSICAL 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
			l plunger + gasket = 77,80
Air Leakage during aspiration	TS EN ISO 7886-1	kPa/sn	No leakage at 88 kPa vacuum at 60 second
Liquid leakage under compression	TS EN ISO 7886-1	kPa/sn	No leakage at 300 kPa pressure at 30 second
Conic fittings (centric)	TS 3521-1 EN 20594-1	%	6% (Luer)
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 <sup>2</sup>	0,25 polydimethyl siloxane
Weight	AldarMed	gr	7,60-7,70

**CHEMICAL PROPERTIES**

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

**BIOLOGICAL PROPERTIES**

Cytotoxicity	EN ISO 10993		Not cytotoxic
Toxicity	EN ISO 10993		Does not cause acute systemic toxicity
Pyrogenity	EN ISO 10993-11. European Pharmacopoeia 7 <sup>th</sup>		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

**PACKAGING PROPERTIES AND HANDLING**

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	-	inner and out surface testliner, fluting 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

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