

DATA & ESSENTIALS SHEET

STERILE HYPODERMIC 10 ML SYRINGE FOR SINGLE USE



1. General Information		
1.1.	Description:	Manufactured by SILA TEKNOLOJİ VE SAĞLIK A.Ş. 10 ml sterile, hypodermic syringe for single use. Luer Slip. Can be packed with/without hypodermic needles according to need.
1.2.	Used for:	It is used intramuscularly, intradermally, intravenously for the injection of drug solutions or for the purpose of removing fluids from the body, according to the need of the authorized user.
1.3.	Advantages for user:	No air or liquid leakage with the perfect design. Resistant to pressure. User friendly ergonomic design. Smooth sliding of plunger through barrel. Uniform slipping of the syringe plunger. Stopper to prevent piston from coming out of the syringe. 2-stage plunger sealing gasket that prevents the solution from returning during administration.
1.4.	Warning:	The product may include sharp object. Only shall be used by trained healthcare professionals.
1.5.	Safety:	Phthalate Free. Non-toxic. Non-pyrogenic. For Single Use Only. Please check the usage information behind the blister pack and IFU provided.
1.6.	How to Use:	The plunger of the syringe should be pulled to take in the liquid, and pushed to expel the liquid according to the purpose of usage.

2 Design and Components



2.1.	Composed of:	3 parts: Barrel, Plunger, Gasket (latex free)
2.2.	Tip of the Barrel:	Luer slip, 6% conical Transparent
2.3.	Volume Lines:	Numeric indication in each 1 ml; lineation in each 0,5 ml printed with indelible ink. Easy to read.
2.4.	Package Details:	Blister Packing by medical grade paper and film suitable for EO sterilization. Individually packed. Labelled and put required packing icons in accordance with EEC Directives and EN Standards.
2.5.	Sterilization:	EO
2.6.	Shelf Life:	5 years
3	Complied Standards and Certificates	
3.1.	CE Marking	Yes
3.2.	Directive	93/42 / EEC Medical Device Directive
3.3.	Class	II,a
3.4.	Other Certificates	ISO 13485 ISO 9001
3.5.	GMDN	35904
4	Hypodermic Needle List for the syringes with needle	
4.1	Length and thickness in inches	
4.1.1	18G x 1 1/2"	
4.1.2	19G x 1 1/2"	
4.1.3	20G x 1 1/2"	
4.1.4	21G x 5/8"	
4.1.5	21G x 1 1/2"	
4.1.6	22G x 1 1/4"	
4.1.7	22G x 1 1/2"	
4.1.8	23G x 5/8"	
4.1.9	23G x 1"	
4.1.10	23G x 1 1/4"	
4.1.11	23G x 1 1/2"	
4.1.12	24G x 1"	
4.1.13	25Gx 5/8"	
4.1.14	25G x 1"	
4.1.15	25Gx1 1/2"	
4.1.16	26G x 1/2"	
4.1.17	27G x 1/2"	
4.1.18	27G x 1 1/2"	
4.1.19	27G x 2"	
4.1.20	30G x 5/16"	
4.1.21	30G x 1/2"	

