



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

Production Quality Assurance Certificate

Directive 93/42/EEC on Medical devices, Annex V

Notified Body	: Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Turkey (NB 1783)
Company Name	: SILA TEKNOLOJİ VE SAĞLIK ANONİM ŞİRKETİ
Company Address	: KAVACIK SUBAYEVLERİ MAH. ŞEHİT ÖMER HALİSDEMİR BLV. NO:73/1 KEÇİÖREN/ ANKARA /TURKEY
Manufacturing Site	: OĞULBEY MAH. 3059. CAD. NO:5 GÖLBAŞI/ ANKARA /TURKEY
Scope	: STERILE SYRINGE WITH OR WITHOUT NEEDLE, AND HYPODERMIC NEEDLE
GMDN Code	: 35904, 59230
Classification Rule	: Rule 6, Class IIa
Inspection Report Number	: 2197-MDD-167/2021-01
First Issue Date	: 11.03.2020
Validity Date	: 26.05.2024

The manufacturer's quality system is inspected in accordance with Annex V of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex V. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex V Section 4.

Certificate No: 1783- MDD-155

Firat HACIOĞLU
Deputy Director of Directives
ANKARA Rev02, 25/05/2021

Please check the validity of certificate from TSE's web page "<https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open>"



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Production Quality Assurance Certificate Certification History

Directive 93/42/EEC on Medical devices, Annex V

Certificate No: 1783-MDD-155, Rev 02

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
11.03.2020	Rev 00	-
24.02.2021	Rev 01	Scope change
25.05.2021	Rev 02	Scope change, title change





TÜRK STANDARDLARI ENSTİTÜSÜ

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Production Quality Assurance Certificate Scope Attachment

Directive 93/42/EEC on Medical devices, Annex V

Certificate No: 1783-MDD-155, Rev 02

Brand: TTT WORLD®

A. STERILE SYRINGES

	18G x 1 1/2" 1.2x38 mm	19G x 1 1/2" 1.1x38 mm	20G x 1 1/2" 0.9x38 mm	21G x 5/8" 0.8x16 mm	21G x 1 1/2" 0.8x38 mm	22G x 1 1/4" 0.7x32 mm	22G x 1 1/2" 0.7x38 mm	23G x 5/8" 0.6x16 mm	23G x 1" 0.6x25 mm	23G x 1 1/4" 0.6x32 mm	23G x 1 1/2" 0.6x40 mm
2ml 2P	01011	01012	01013	01014	01015	01016	01017	01214	01018	01019	01224
5 ml 2P	01024	01025	01026	01027	01028	01029	01030	01215	01031	01032	01225
10 ml 2P	01037	01038	01039	01040	01041	01042	01043	01216	01044	01045	01226
20 ml 2P	01050	01051	01052	01053	01054	01055	01056	01217	01057	01058	01227
50 ml 2P	01063	01064	01065	01066	01067	01068	01069	01218	01070	01071	01228
2 ml 3P	01076	01077	01078	01079	01003	01006	01080	01219	01081	01082	01229
5 ml 3P	01087	01088	01089	01090	01002	01005	01091	01220	01092	01093	01230
10 ml 3P	01098	01099	01100	01101	01001	01004	01102	01221	01103	01104	01231
20 ml 3P	01109	01110	01111	01112	01007	01009	01113	01222	01114	01115	01232
50 ml 3P	01120	01121	01122	01123	01008	01010	01124	01223	01125	01126	01233
Vaccination Syringe (2ml 3P)									01207	01208	
1ml 2P	01300	01301	01302	01303	01304	01305	01306	01307	01308	01309	01310
1ml 3P	01322	01323	01324	01325	01326	01327	01328	01329	01330	01331	01332
GMDN code: 35904											

	24G x 1" 0.55x25 mm	25Gx 5/8" 0.5x16 mm	25G x 1" 0.5x25 mm	25Gx1 1/2" 0.5x40 mm	26G x 1/2" 0.45x13 mm	27G x 1/2" 0.4x13 mm	27G x 1 1/2" 0.4x40 mm	27G x 2" 0.4x50 mm	30G x 5/16" 0.3x8 mm	30G x 1/2" 0.3x13 mm	Without needle
2ml 2P	01234	01244	01020	01254	01021	01264	01022	01023	01274	01284	01131
5 ml 2P	01235	01245	01033	01255	01034	01265	01035	01036	01275	01285	01132
10 ml 2P	01236	01246	01046	01256	01047	01266	01048	01049	01276	01286	01133
20 ml 2P	01237	01247	01059	01257	01060	01267	01061	01062	01277	01287	01134
50 ml 2P	01238	01248	01072	01258	01073	01268	01074	01075	01278	01288	01135
2 ml 3P	01239	01249	01083	01259	01084	01269	01085	01086	01279	01289	01136
5 ml 3P	01240	01250	01094	01260	01095	01270	01096	01097	01280	01290	01137
10 ml 3P	01241	01251	01105	01261	01106	01271	01107	01108	01281	01291	01138
20 ml 3P	01242	01252	01116	01262	01117	01272	01118	01119	01282	01292	01139
50 ml 3P	01243	01253	01127	01263	01128	01273	01129	01130	01283	01293	01140
Vaccination Syringe (2ml 3P)			01209								01213
1ml 2P	01311	01312	01313	01314	01315	01316	01317	01318	01319	01320	01321
1ml 3P	01333	01334	01335	01336	01337	01338	01339	01340	01341	01342	01343

GMDN code: 35904

Page 1/2



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TURKISH STANDARDS INSTITUTION

B. HYPODERMIC NEEDLES

Ref. No	Description	Needle Size (mm)	GMDN Code
01141	18G x 1 1/2"	1.2x38 mm	59230
01142	19G x 1 1/2"	1.1x38 mm	59230
01143	20G x 1 1/2"	0.9x38 mm	59230
01144	21G x 5/8"	0.8x16 mm	59230
01145	21G x 1 1/2"	0.8x38 mm	59230
01146	22G x 1 1/4"	0.7x32 mm	59230
01147	22G x 1 1/2"	0.7x38 mm	59230
01154	23G x 5/8"	0.6x16 mm	59230
01148	23G x 1"	0.6x25 mm	59230
01149	23G x 1 1/4"	0.6x32 mm	59230
01155	23G x 1 1/2"	0.6x40 mm	59230
01156	24G x 1"	0.55x25 mm	59230
01157	25Gx 5/8"	0.5x16 mm	59230
01150	25G x 1"	0.5x25 mm	59230
01158	25Gx1 1/2"	0.5x40 mm	59230
01151	26G x 1/2"	0.45x13 mm	59230
01159	27G x 1/2"	0.4x13 mm	59230
01152	27G x 1 1/2"	0.4x40 mm	59230
01153	27G x 2"	0.4x50 mm	59230
01160	30G x 5/16"	0.3x8 mm	59230
01161	30G x 1/2"	0.3x13 mm	59230

Page 2/2



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