



This declaration is provided in case of demand in Turkish or English with this format.

EC DECLARATION OF COMFORMITY

We, SILA TEKNOLOJİ VE SAĞLIK ANONİM ŞİRKETİ with Kavacık Subayevleri Mah. Şehit Ömer Halisdemir Bulvarı No: 73/1 Keçiören/Ankara/Türkiye central address and Oğulbey Mahallesi 3059. Cadde No:5/1 Gölbaşı/Ankara/Türkiye warehouse/ production/ fulfillment/ labelling/ packing address, state here that the products specified with model, class according to the 93/42/EEC MDD Annex IX rules and information of GMDN code are in compliance with;

All the requirements of 93/42/EEC Medical Device Directive,

EN ISO 13485:2016 TS EN ISO 14971:2020, EN ISO 7886-1:2018, TS EN ISO 8537:2016, EN ISO 11135:2014, EN ISO 17141:2020, EN ISO 11737-1:2015, TS EN ISO 11137-1/A2:2020; TS EN 556-1:2024, TS EN ISO 15223-1:2021, TS EN ISO 20417:2021, EN ISO 7864:2016, EN 6009:2016, TS EN ISO 9626:2016; EN ISO 20417:2021, EN ISO 11607-1:2020, TS EN ISO 11607-1/A11:2022; EN ISO 11607-2:2020, TS EN ISO 11607-2/A11:2022; MEDDEV 2.7.1. Rev.4 2016, MEDDEV 2.4/1. Rev.9: 2020, MEDDEV 2.12-1. Rev.8: 2013, MEDDEV 2.12-2. Rev.2: 2020, TS EN ISO 10993-1:2021, EN ISO 10993-4:2020, EN 10993-7:2010, EN ISO 10993-5:2010, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-18:2020, EN ISO 11737-2:2020, EN ISO 14644-2:2016, EN ISO 14644-3:2019, TS EN ISO /IEC 17050-1:2010, TS EN ISO /IEC 17050-2:2004, 93/42/EEC, ASTM F-1980-16, MDCG 2021-24:2021, Helsinki Prosedürü:2021, MDCG 2021-5 Rev. 1:2024, MDCG 2019-13:2019, MDCG 2021-19:2021, MDCG 2019-9 Rev.1:2022, MDCG 2020-13:2020, MDCG 2021-13 Rev.1:2021, MDCG 2020-15:2020; MDCG 2021-1 Rev. 1:2021, MDCG 2018-1 Rev.4:2018, MDCG 2018-2:2018, MDCG 2020-8:2020, MDCG 2020-7:2020, MDCG 2020-6:2020, MDCG 2019-4:2019, MDCG 2021-25:2024, MDCG 2019-07 Rev.1:2023, MDCG 2021-12:2021, MDCG 2020-5:2020, CE Marking Directive:2012, EP10, NBOG:2010-1 standards and guidelines.

All the supportive documents showing the compliance are stored within our company.
The conformity method is chosen as Annex V Production Quality Assurance System.

Product Name	Model	Class	Rule	GMDN Code
SYRINGE	Vaccine Syringe, Insuline Syringe, 1,2,5,10,20,50 ml Sterile Single Use Syringe	IIa	6	35904
NEEDLE	18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,30G Hypodermic Single Use Needle	IIa	6	59230

The compliance of our products with the above-mentioned directives and documents are approved via the below mentioned EC Product Compliance Certificate by the notified body TSE, located in Bakanlıklar, Necatibey cad No:112, 06570 Çankaya/Ankara address with 1783 ID number.

Certificate No : 1783-MDD-155

CE Label Publish Date : 11.03.2020

Certificate Extension Letter Date : 24.09.2024

Certificate Valid Till : 31.12.2028

Certificate Revision No : 02

Certificate Revision Date : 25.05.2021

Approved by : İhsan Şahin

Title : Chairman

Approval Date : 20.05.2025

Place of Approval

Declaration Revision No

Date of Revision of the Declaration : 20.05.2025

Signature

SILA TEKNOLOJİ VE SAĞLIK ANONİM
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Diskapı V.D. :769 058 42-13
Mersis No:0769058421300039



APPENDIX

APPENDIX		19G x 1 1/2" 1.3x3 8 mm	20G x 1 1/2" 0.9x3 8 mm	21G x 1 5/8" 0.8x1 5 mm	21G x 1 1/2" 0.8x3 5 mm	22G x 1 1/4" 0.7x3 2 mm	22G x 1 1/2" 0.7x3 8 mm	23G x 1 5/8" 0.6x1 6 mm	23G x 1 1" 0.6x2 5 mm	23G x 1 1/4" 0.6x3 2 mm	23G x 1 1/2" 0.6x4 0 mm	24G x 1 1/2" 0.5x4 0 mm	25Gx 5/8" 0.5x1 5 mm	25G x 1" 0.5x2 5 mm	25Gx 1 1/2" 0.5x4 0 mm	27G x 1 1/2" 0.4x1 3 mm	27G x 1 1/2" 0.4x4 0 mm	27G x 2" 0.4x5 0 mm	30G x 5/16" 0.3x8 mm	30G x 1/2" 0.3x1 3 mm	Without needle	
2ml 2P	01011	01012	01013	01014	01015	01016	01017	01214	01018	01019	01224	01234	01244	01020	01254	01021	01264	01022	01023	01274	01284	01131
5 ml 2P	01024	01025	01026	01027	01028	01029	01030	01215	01031	01032	01225	01235	01245	01033	01255	01034	01265	01035	01036	01275	01285	01132
10 ml 2P	01037	01038	01039	01040	01041	01042	01043	01216	01044	01045	01226	01236	01246	01046	01256	01047	01266	01048	01049	01276	01286	01133
20 ml 2P	01050	01051	01052	01053	01054	01055	01056	01217	01057	01058	01227	01237	01247	01059	01257	01060	01267	01061	01062	01277	01287	01134
50 ml 2P	01063	01064	01065	01066	01067	01068	01069	01218	01070	01071	01228	01238	01248	01072	01258	01073	01268	01074	01075	01278	01288	01135
2 ml 3P	01076	01077	01078	01079	01003	01006	01080	01219	01081	01082	01229	01239	01249	01083	01259	01084	01269	01085	01086	01279	01289	01136
5 ml 3P	01087	01088	01089	01090	01002	01005	01091	01220	01092	01093	01230	01240	01250	01094	01260	01095	01270	01096	01097	01280	01290	01137
10 ml 3P	01098	01099	01100	01101	01001	01004	01102	01221	01103	01104	01231	01241	01251	01105	01261	01106	01271	01107	01108	01281	01291	01138
20 ml 3P	01109	01110	01111	01112	01007	01009	01113	01222	01114	01115	01232	01242	01252	01116	01262	01117	01272	01118	01119	01282	01292	01139
50 ml 3P	01120	01121	01122	01123	01008	01010	01124	01223	01125	01126	01233	01243	01253	01127	01263	01128	01273	01129	01130	01283	01293	01140
Aşl Enjektörü (2ml 3P)									01207	01208				01209								01213
1ml 2P	01300	01301	01302	01303	01304	01305	01306	01307	01308	01309	01310	01311	01312	01313	01314	01315	01316	01317	01318	01319	01320	01321
1ml 3P	01322	01323	01324	01325	01326	01327	01328	01329	01330	01331	01332	01333	01334	01335	01336	01337	01338	01339	01340	01341	01342	01343
GMDN Code: 35904																						

GMDN Code: 35904

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Diskapı V.D.: 1769 058 42 13
Maksat No:0769058421300039



HYPODERMIC NEEDLES LIST

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

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