



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

EC DECLARATION OF CONFIRMITY

We, SILA TEKNOLOJİ VE SAĞLIK ANONİM ŞİRKETİ-GÖLBAŞI ŞUBESİ with Kavacık Subayevleri Mah. Şehit Ömer Halisdemir Bulvarı No: 73/1 Keçiören/Ankara/Türkiye central address and Oğulbey Mahallesi 3059. Cadde No:5 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;

EN ISO 13485:2016, EN 14971:2019, TS EN ISO 11135+A1:2020, TS EN 556-1:2009, TS EN ISO 15223-:2016, EN ISO 7886-1:2018, EN 1041+A1: 2014, EN ISO 7864:2016, EN ISO 20594, EN 6009:2016, TS EN ISO 80369-7, TS EN ISO 9626:2016, MEDDEV 2.7.1. Rev.4 2016, EN 1422:2014, TS EN ISO 10993-1:2021, EN ISO 10993-4:2020, EN 10993-7:2010, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2013, EN ISO 11737-2:2020, TS EN ISO 14644-1:2015, NBOG:2010 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	Rules	GMDN Code
SYRINGE	Vaccination Syringe,1,2,5,10,20,50 ml Sterile Single Use Syringes	IIa	6	35904
NEEDLE	18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,30G Single Use Hypodermic Needles	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 Validity Date : 26.05.2024

Certificate Revision No : 02

Certificate Revision Date : 25.05.2021

Approved by : İhsan Şahin

Title : Chairman

Approval Date : 25.05.2021

Place of Approval : ANKARA

Declaration Revision No : 02

Declaration Revision Date : 25.05.2021

SILA TEKNOLOJİ VE SAĞLIK
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Disiplinli V.D. :769 058 42 13
Mersis No:0769058421300016

ANNEX

A. STERILE SYRINGES

	18G x 1 1/2" mm	19G x 1 1/2" mm	20G x 1 1/2" mm	21G x 5/8" mm	21G x 1 1/2" mm	22G x 1 1/4" mm	22G x 1 1/2" mm	23G x 5/8" mm	23G x 1" mm	23G x 1 1/4" mm	23G x 1 1/2" mm	24G x 1" mm	25G x 5/8" mm	25G x 1" mm	25Gx1 1/2" mm	26G x 1/2" mm	27G x 1/2" mm	27G x 1 1/2" mm	27G x 2" mm	30G x 5/16" mm	30G x 1/2" mm	Without Needle
0.2ml 2P	01011	01012	01013	01014	01015	01016	01017	01214	01018	01019	01224	01234	01244	01020	01254	01021	01264	01022	01023	01274	01284	01131
0.5ml 2P	01024	01025	01026	01027	01028	01029	01030	01215	01031	01032	01225	01235	01245	01033	01255	01034	01265	01035	01036	01275	01285	01132
0.0ml 2P	01037	01038	01039	01040	01041	01042	01043	01216	01044	01045	01226	01236	01246	01046	01256	01047	01266	01048	01049	01276	01286	01133
0.0ml 2P	01050	01051	01052	01053	01054	01055	01056	01217	01057	01058	01227	01237	01247	01059	01257	01060	01267	01061	01062	01277	01287	01134
0.0ml 2P	01063	01064	01065	01066	01067	01068	01069	01218	01070	01071	01228	01238	01248	01072	01258	01073	01268	01074	01075	01278	01288	01135
0.0ml 3P	01076	01077	01078	01079	01080	01081	01082	01219	01083	01084	01229	01239	01249	01085	01259	01086	01269	01086	01086	01279	01289	01136
0.0ml 3P	01087	01088	01089	01090	01091	01092	01093	01220	01094	01095	01230	01240	01250	01096	01260	01097	01270	01096	01097	01280	01290	01137
0.0ml 3P	01098	01099	01100	01101	01102	01103	01104	01221	01105	01106	01231	01241	01251	01107	01261	01108	01271	01107	01108	01281	01291	01138
0.0ml 3P	01109	01110	01111	01112	01113	01114	01115	01222	01116	01117	01232	01242	01252	01118	01262	01119	01272	01118	01119	01282	01292	01139
0.0ml 3P	01120	01121	01122	01123	01124	01125	01126	01223	01127	01128	01233	01243	01253	01129	01263	01128	01273	01129	01130	01283	01293	01140
0.0ml 3P /accination syringe(2ml IP)									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

3MDN Code: 35904

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B. HYPODERMIC NEEDLES

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

GMDN Code: 59230

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