

Declaration of Conformity

FIRAT PLASTIK KAUCUK SAN. ve TIC. A.Ş.

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ALBACETE – ESPANA
B-02309524

Product : Refer to page 2

Classification : 98/79/EC In Vitro Diagnostic Medical Devices Directive Annex III
Low Risk Group

We hereby declare that the above mentioned products meet the provisions of the 98/79/EC In Vitro Diagnostic Medical Devices Directive. All supporting documentation is retained under the premises of the manufacturer.

General Applicable Directives

98/79/EC Invitro Diagnostic Medical Devices Directive

Standards

EN ISO 13485:2016, EN ISO 14971:2012, EN 556-1, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11737-2:2009, EN 14820:2004, EN 62366:2008, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 11137-3:2017, EN ISO 11737-1:2018, ISO 6710 , EN ISO 14698-1:2003, EN ISO 14698-2:2003, EN ISO 14644-1:2015, EN ISO 14644-2:2015, ISO 2859-1

Date of Issue: 16.05.2005

1.Revision: 01.05.2006

2.Revision: 01.06.2006

3.Revision: 15.05.2013

4.Revision: 05.05.2017

5.Revision: 30.10.2017

6.Revision: 06.04.2018

7.Revision: 20.04.2018

8.Revision: 21-03-2019

9.Revision: 27-04-2020

10.Revision: 05-11-2020

11.Revision : 10.02.2021

12.Revision : 29.07.2021

13.Revision: 02.08.2021

14.Revision: 16.08.2021

Approved by : Ramazan ERDOĞMUŞ
Position : Factory Manager
Approval date : 16.08.2021

signature

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Declaration of Conformity

	Product List
1.	NON-STERILE URINE SAMPLE CONTAINER 100ML
2.	STERILE URINE SAMPLE CONTAINER 100ML
3.	NON-STERILE URINE SAMPLE CONTAINER 60 ML
4.	STERILE URINE SAMPLE CONTAINER 60 ML
5.	NON-STERILE URINE SAMPLE CONTAINER 250 ML
6.	STERILE URINE SAMPLE CONTAINER 250 ML
7.	PNEUMATIC NON-STERILE URINE SAMPLE CONTAINER
8.	PNEUMATIC STERILE URINE SAMPLE CONTAINER
9.	INTERGRATED NON-STERILE URINE SAMPLE CONTAINER 100ML
10.	INTERGRATED STERILE URINE SAMPLE CONTAINER 100ML
11.	INTERGRATED NON-STERILE URINE SAMPLE CONTAINER 60ML
12.	POLYPROPYLENE CENTRIFUGE TEST TUBE 12 X 75
13.	POLYSTYRENE CENTRIFUGE TEST TUBE 12 X 75
14.	WITH CONICAL BOTTOM POLYPROPYLENE CENTRIFUGE TEST TUBE 16 X 100
15.	WITH CONICAL BOTTOM POLYSTYRENE CENTRIFUGE TEST TUBE 16 X 100
16.	WITH ROUND BOTTOM POLYPROPYLENE CENTRIFUGE TEST TUBE 16 X 100
17.	WITH ROUND BOTTOM POLYSTYRENE CENTRIFUGE TEST TUBE 16 X 100
18.	POLYSTYRENE CENTRIFUGE TEST TUBE WITH CAP 12 X 75
19.	WITH CONICAL BOTTOM POLYSTYRENE CENTRIFUGE TEST TUBE WITH CAP 16 X 100
20.	WITH ROUND BOTTOM POLYSTYRENE CENTRIFUGE TEST TUBE WITH CAP 16 X 100
21.	STERILE PETRI DISH 90MM
22.	STERILE PETRI DISH WITH TWO DIVISIONS 90MM
23.	STERILE PETRI DISH 60MM
24.	STERILE RODAC PETRI DISH 60MM
25.	STERILE GAITA CONTAINER WITH SPOON
26.	NON-STERILE GAITA CONTAINER WITH SPOON
27.	SPUTUM CONTAINER 100ML – OPAQUE
28.	GAITA CONTAINER WITHOUT SPOON 50 G
29.	CONICAL BASE CENTRIFUGE TUBE 50 ML –NON -STERILE
30.	CONICAL BASE CENTRIFUGE TUBE STERILE 50 ML
31.	CONICAL BASE CENTRIFUGE TUBE 15 ML –NON -STERILE
32.	CONICAL BASE CENTRIFUGE TUBE STERILE 15 ML – ONE BY ONE PACKED
33.	LOOP 1 UL
34.	LOOP 10UL
35.	PIPETTE TIP - YELLOW
36.	PIPETTE TIP - BLUE
37.	COVERED CENTRIFUGAL TUBE 1,5 ML
38.	WINGED CAP 12 X 75
39.	WINGED CAP 16 X 100
40.	24 HOURS URINE COLLECTING POT
41.	24 HOURS INTERGRATED URINE COLLECTING POT 3000 ML
42.	SAMPLE JAR 2 ML
43.	SAMPLE CUP FOR HITACHI 3 ML
44.	SAMPLE BOTTLE FOR WATER WITH/WITHOUT THIOSULPHATE 250 ML – POLİPROPİLEN
45.	SAMPLE BOTTLE FOR WATER WITH/WITHOUT THIOSULPHATE 500 ML – POLİPROPİLEN
46.	SAMPLE BOTTLE FOR WATER WITH/WITHOUT THIOSULPHATE 250 ML – POLİETİLEN
47.	SAMPLE BOTTLE FOR WATER WITH/WITHOUT THIOSULPHATE 500 ML – POLİETİLEN
48.	URINE SAMPLE TUBE CONTAINING AND ADDITIVE
49.	URINE SAMPLE VACUMED TUBE
50.	PETRI DISH WITH MEDIUM
51.	SALIVA EJEKTOR
52.	POLİMER SAMPLE BOTTLE TRANSPARENT 250 ML
53.	POLİMER SAMPLE BOTTLE TRANSPARENT 500 ML
54.	POLİMER SAMPLE BOTTLE AMBER 250 ML
55.	POLİMER SAMPLE BOTTLE AMBER 500 ML
56.	MOLECULAR TRANSPORT MEDIUM-VTM
57.	DRY SWAB (DACRON)
58.	DRY SWAB (COTTON)
59.	DRY SWAB (NAZOFARİNGEAL)
60.	SAMPLE CONTAINER 0.5 ML (TECHNICON)
61.	SAMPLE CONTAINER 2 ML (TECHNICON)
62.	CENTRIFUGE TUBE 0.5 ML
63.	STERILE PETRI DISH 150 MM
64.	INTERGRATED STERILE URINE SAMPLE CONTAINER 100ML + VACUUM URINE TUBE
65.	POLYSTYRENE CENTRIFUGE TEST TUBE 11X55
66.	NASOPHARYNGEAL SWAB (FLOCKED SWAB)

Approved by : Ramazan ERDOĞMUŞ
Position : Factory Manager
Approval date : 16.08.2021

signature:

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