EDTA K3 (Tube with lavender cap)

- This tube contains Dipotassium Ethylenediamine tetra acetic acid As anticoagulant.
- It mainly used for hematological Tests.

Ex. Blood group (ABO) & RH typing, Hemoglobin glycosylated (A1C)

2 ml | 3 ml | 4 ml | 5 ml | 6 ml

Gel-Clot Activator (Tube with yellow cap)

- This tube contains BCA as coagulation Catalyst and gel as serum separator.
- It mainly used for collection of serum for Various laboratory tests.

Ex. Heavy metals tests (Ca, Na , Mng, Pb ...) Serology tests.

2 ml | 3 ml | 4 ml | 5 ml

Coagulation (Tube with light blue cap)

- This tube contains Sodium citrate with Concentration 3.2% as anticoagulant.
- It mainly used for coagulation studies

Ex. Prothrombin time & concentration Test (PT) , Partial thromboplastin time Test (PTT) and coagulation factors

2 ml | 3 ml | 4 ml | 5 ml | 6 ml

Digitally signed by Iurcu Nicolae
Date: 2024.02.17 14:54:34 EET
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity

the CЄ IVD Medical Device Directive 98/79/EC

Manufacturer		
Name	:	International Company For Medical Necessities.
Address	:	**First Location:** 3rd Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt. **Second Location:** Public Free Zone – Ismailia- Egypt.
Phone	:	+2 088 49 50 200
Fax	:	+2 088 49 50 300
Email	:	info@medical-ico.com
Website	:	www.medical-ico.com
Notified Body		
Name	:	3EC International
Address	:	3EC International a.s Hranicna 18, 821 05 Bratislava, Slovak Republic
Phone	:	+421 (0)2 5831 8343
Fax	:	+421(02) 5831 8345.
Email	:	info@3ec.sk
Website	:	www.3ec.sk
Number	:	2265
Authorized Representative (AR)		
Name	:	Obelis s.a.
Address	:	Bd. Général Wahis 53, B-1030 Brussels, Belgium
Phone	:	32.2.732.59.54
Fax	:	32.2.732.60.03
Email	:	mail@obelis.net
Website	:	www.obelis.net
Declares that the Products		
Product Name	:	IVAC (International Vacuum Blood collection tube)
Description	:	Non-sterile product For Single Use
Class	:	Annex III, General IVD
Codes	:	Refer to attached table page no.4

We here declare that the above mentioned product meets the provisions of the CЄ IVD Medical Device Directive 98/79/EC and related Standards which applied to them, as stated in all.

General Manager

Dr. Ahmed Adel Khalil

1.1. Table of Variants

#	Product Name	Code	Class
1.	IVAC 3 ml No additives	Y01	General IVD
2.	IVAC 3ml with silicon	Y02	General IVD
3.	IVAC 2 ml K2EDTA	Y03	General IVD
4.	IVAC 2ml K3EDTA	Y04	General IVD
5.	IVAC 2ml Coagulation ESR 1:4	Y05	General IVD
6.	IVAC 2ml Coagulation 1:9	Y06	General IVD
7.	IVAC 2 ml glucose	Y07	General IVD
8.	IVAC 2ml Clot activator (BCA)+ gel	Y08	General IVD
9.	IVAC 2ml Lithium heparin	Y09	General IVD
10.	IVAC 3 ml K2EDTA	Y10	General IVD
11.	IVAC 3ml K3EDTA	Y11	General IVD
12.	IVAC 3ml Clot activator (BCA)	Y12	General IVD
13.	IVAC 3ml Coagulation ESR 1:4	Y13	General IVD
14.	IVAC 3ml Coagulation 1:9	Y14	General IVD
15.	IVAC 3 ml glucose	Y15	General IVD
16.	IVAC 3ml Clot activator (BCA)+ gel	Y16	General IVD
17.	IVAC 3ml Lithium heparin	Y17	General IVD
18.	IVAC 4 ml K2EDTA	Y18	General IVD
19.	IVAC 4ml K3EDTA	Y19	General IVD
20.	IVAC 4ml Clot activator (BCA)	Y20	General IVD
21.	IVAC 4ml Coagulation ESR 1:4	Y21	General IVD
22.	IVAC 4ml Coagulation 1:9	Y22	General IVD
23.	IVAC 4 glucose	Y23	General IVD
24.	IVAC 4ml Clot activator (BCA)+ gel	Y24	General IVD
25.	IVAC 4ml Lithium heparin	Y25	General IVD
26.	IVAC 6 ml No additives	Y26	General IVD
27.	IVAC 1ml Coagulation 3:2	Y27	General IVD
28.	IVAC 5 ml Gel + Clot activator (BCA)	Y28	General IVD
29.	IVAC 4 ml No additives	Y29	General IVD
30.	IVAC 4 ml Sodium heparin	Y30	General IVD
31.	IVAC 2ml Clot activator	Y31	General IVD
32.	IVAC 5ml Coagulation 3:2	Y32	General IVD
33.	IVAC 6ml Coagulation 3:2	Y33	General IVD
34.	IVAC 6ml Clot activator	Y34	General IVD

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35.	IVAC ESR 8x120 mm	Y35	General IVD
36.	IVAC 5ml K3EDTA	Y36	General IVD
37.	IVAC 5ml Clot activator	Y37	General IVD
38.	IVAC 1ml K3EDTA	Y38	General IVD
39.	IVAC 1ml Lithium heparin	Y39	General IVD
40.	IVAC 5ml Lithium heparin	Y40	General IVD
41	IVAC 6ml K2EDTA	Y41	General IVD
42	IVAC 5ml K2EDTA	Y42	General IVD
43	IVAC 6ml K3EDTA	Y43	General IVD
44	IVAC ACD 3.2% &Gel	Y44	General IVD
45	IVAC ACD 3.2%	Y45	General IVD
46	IVAC Sodium Citrate3.8 % 9NC 2.7 ml	Y46	General IVD
47	IVAC Sodium Citrate3.8 % 9NC 3.6 ml	Y47	General IVD
48	IVAC Sodium Heparin 3ml	Y48	General IVD
49	IVAC Gel Heparin 3.5ml	Y49	General IVD

General Manager

Dr. Ahmed Adel Khalil

الشركة الدولية
I.CO
للمستلزمات الطبية

International Company for Medical

IVAC BLOOD COLLECTION TUBE

1	Product Description	: The evacuated tube system for blood collection in use for various laboratory tests consists of tubes of various sizes, with color coded tops indicating tube contents.
1-1	Tube	: Tube PET
1-2	Main Cap	: polypropylene
1-3	Cap Gasket	: (Rubber) Latex Free
1-4	Additives	: Different according to each type
1-5	Packing	: ABS rack
1-6	Lable	: Polyester
2	**Intended Purpose**	: IVAC tubes Intended to be used in hematology laboratory for withdrawing Whole blood or Plasma in order to examine various kinds of blood cells, tubes contain additives designed to stabilize and preserve the specimen to analytical testing
2-1	Yellow top tube **GeL+ Clot activator**	: This tube contains a BCA clot activator and serum gel separator – used for collction For variuos laboratort tests
2-2	Red-top tube Clot Activator	:This tube is a plastic Vacutainer containing a BCA clot activator Coagulation, Catalyst it mainly used for collection of serum for selected laboratory tests as indicated
2-3	Red-top tube No Additive	:This tube is a plain containing no anticoagulant. It mainly used for collection of Serum for selected chemistry test
2-4	Green-top tube (lithium heparin)	:This tube contains lithium & sodium heparin It mainly used for collection of heperinized plasma or whole blood for special tests
2-5	Grey-top tube (potassium oxalate/ sodium fluoride	:This tube contains potassium oxalate as an anticoagulant and sodium fluoride as a preservative – used to preserve glucose in whole blood and for some special chemistry tests
2-6	Lavender-top tube (EDTA) K2	:This tube contains Dipotassium Ethylenediaminetetra acetic acid as anticoagulant. It mainly used for hematological tests.
2-7	Lavender-top tube (EDTA) K3	:This tube contains Tripotassium Ethylenediaminetetra acetic acid As anticoagulant , It mainly used for hematological Tests

2-8	**Light blue-top tube** Coagulation	This tube contains Sodium citrate with Concentraion 3.2% as anticoagulation It used for Coagulation studies
2-9	**Black-top tube** ESR	:This tube contains Sodium citrate with Concentraion 3.8% as anticoagulant. It mainly used for coagulation studies
3	**Microbiological Test**	
3-1	Bio-burden	: Not more than 15 CFU ISO 11737-1&11737-3
4	Chemical Test	: the material (additives) Actually tested before production
5	**Physical Test**	
5-1	Draw volume test for non-evacuated containers	The container pass the draw volume test according to Annex A ISO 6710
5-2	Draw volume test for evacuated containers	:The container pass the draw volume test according to Annex B ISO 6710
5-3	Test for leakage of container	: The container has no Leakage according to Annex C ISO 6710
5-4	Test for robustness of the container	:The material s pass the test according to Annex D ISO 6710
5-5	Concentrations of additives and volume of liquid additives	:pass the test according to Annex E ISO 6710
5-6	colour codes for identifying additives and accessories	:pass the test according to Annex F ISO 6710
6	Packing	: Each 100 Tubes packed in one rake from ABS and sealed with shrinke Film, after that packed in carton
7	volume	2ml -4ml- 6ml -8ml
8-	Productio Capacity	40000000 tubes per year
	Business history	Tanzania – Oganda - Eritrea - Libya -Turkey