



CERTIFICATE

This certifies that the Quality management system for medical devices of company

International Company For Medical Necessities (I.CO)

Site 1: 3rd Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt
Site 2: Public Free Zone - Ismalia, Egypt

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

MANUFACTURE AND STERILIZATION OF NON-ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES: SINGLE USE SYRINGES - SAFETY SINGLE USE SYRINGES - ORAL SYRINGE, SYRINGE CATHETER TIP - FEEDING, TRUE FIT SYRINGE, IN VITRO DIAGNOSTIC MEDICAL DEVICE: VACUUM BLOOD TUBES

Certificate No.: M-0283A/20

Date of issuance: August 19th, 2020


Original date of approval: May 17th, 2010

This certificate is valid from **August 19th, 2020** to **February 28th, 2022** on condition that organization will maintain effective quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

This certificate fully supersedes previous certificate No. M-0283/20 issued on February 6th, 2020.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic




Dr. Katarina Tomin Srdošová
Head of Certification Body 3EC International a.s.



Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.



Declaration of Conformity

the CE 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	: Self-Declared
Codes	: Refer to attached table page no.4

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

General Manager

Dr. Ahmed Adel Khalil



Declaration of Conformity

1.1. Table of Variants

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



Declaration of Conformity

35.	IVAC ESR 8x120 mm	Y35
36.	IVAC 5ml K3EDTA	Y36
37.	IVAC 5ml Clot activator	Y37
38.	IVAC 1ml K3EDTA	Y38
39.	IVAC 1ml Lithium heparin	Y39
40.	IVAC 5ml Lithium heparin	Y40

General Manager

Dr. Ahmed Adel Khalil

