G-CERTI Certificate

G-CERTI hereby certificate that

KUWAITI EGYPTIAN FOR MEDICAL INDUSTRIES CO

PLOT111A, ALMAHAGER BLOCK, INDUSTRIAL AREA(B&C), EL-OBOUR CITY, EGYPT

Has been audited by G-CERTI and has implemented

Medical Devices -- Quality Management Systems

ISO13485:2016

Scope of Registration

DESIGN, DEVELOPMENT AND MANUFACTURE OF IN VITRO DIAGNOSTIC DEVICES: BLOOD SPECIMEN COLLECTION SETS, TUBES AND ACCESSORIES

Code : A
Original Date : 22. Jun. 2017
Re-certification Date : 21. Jun. 2020
Approval Date : 22. Jun. 2017
Valid Period : 22. Jun. 2017 ~ 21. Jun. 2018
Certificate No : GIEG-0010-MD

Chief Executive

To verify the validity of this certificate please visit : www.gcerti.com 15f, 88, Eunpyeong-ro, Eunpyeong-gu, Seoul, Korea
This is to certify that the Management Systems of this company has been found to confirm to the above G-CERTI FI-12-03

ACCREDITED
Management Systems Certification Body
MSCB-113

G-CERTI SYSTEM SERVICE

Obelis s.a.
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: DP 3354-2014

Order No.: DP 2632-2014

Date: 17/10/2014

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: KUWAITI EGYPTIAN FOR MEDICAL INDUSTRIES CO. (KEMICO)

ADDRESS: PLOT 111A – AL MAHAGER BLOCK - INDUSTRIAL AREA (B&C)
EL-OBOUR CITY, EGYPT

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 22/09/2014 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 6 DEVICES)

As of the 23/09/2014, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL
22-10-2014

SEEN
by the Brussels Chamber of Commerce
Evelien Jonckheere
22 OCT. 2014

p.o. S. FERRETTI
C.C.O.
Mr. G. Elkayam CEO
Obelis sa
date & stamp

Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax. +32 2 732 60 03

Brussels Enterprise Commerce & Industry
date & stamp

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.) and ISO 9001-2008 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities.

Corporate Offices Bd. Général Wahis 53 - 1030 Brussels I Registered Office Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net

Ref. No.: DP 3354-2014
Order No.: DP 2632-2014

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Generic Device Term	Commercial name	Class**	Catalogue reference number	Short description and intended use	GMDN/EDMS code***
1	Evacuated blood sampling tube	KEMICO Vacutainer – Z Serum Clot Activator	All others	KV-XX-YY-Z Where KV refer to Kemico vacutainer XX is the volume of the samples YY is the additives used Z for additive status	A device designed as a tube which is used with a blood collection tube adapter and a blood collection needle to draw blood. This device is presealed tube which has been partially evacuated. The vacuum will make the tube fill with blood. The tube may be pre-treated with various preparations depending on the intended processing to be carried out eliminating the transfer of the blood to other tubes. See: Needle, blood collecting, and Adaptor, blood collecting tube.	58497
2	Evacuated blood sampling tube	KEMICO Vacutainer – 4NC Sodium Citrate	All others			58497
3	Evacuated blood sampling tube	KEMICO Vacutainer – 9NC Coagulation Sodium Citrate 3.2%	All others			58497
4	Evacuated blood sampling tube	KEMICO Vacutainer – NH Sodium Heparin	All others			58497
5	Evacuated blood sampling tube	KEMICO Vacutainer – K2 EDTA Blood Collection Tubes	All others			58497
6	Evacuated blood sampling tube	KEMICO Vacutainer – FX Fluoride Oxalate	All others			58497

* Annex A is part of the Agreement.
** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

*** GMDN or EDMS codes are mandatory information to complete the Notification.

Manufacturer's Name	***Obelis S.A.***	***BECI***
Kuwaiti Egyptian formedical industries co.	p.o.	
Signature:	***Signature:***	***Signature:***
Date: 28/9/2014	***Date:*** 21/10/2014	***Date:***
Stamp:	***Stamp:***	***Stamp:***

KUWAITI EGYPTIAN
For Medical Industries
CT 413 - 455 - 238
CT 5 - 0(0)443 - 252 - 00 - 00

S. FERRETTI
C.C.O.

22 -10- 2014

OBELIS s.a. Anti-Counterfeiting Label

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

E.A.R.-CERTIFICATE

(RECITAL 29 OF THE DIRECTIVE 98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES)

REF. NO. : DP 3399-2014
ORDER NO. : DP 3118-2014

DATE: 23/10/2014

MANUFACTURER: Kuwaiti Egyptian for Medical Industries Co. (KEMICO)
Plot 111a – Al Mahager Block
Industrial area (B & C)
El-Obour City, Egypt

FACILITIES: Kuwaiti Egyptian for Medical Industries Co. (KEMICO)
Plot 111a – Al Mahager Block
Industrial area (B & C)
El-Obour City, Egypt

PRODUCT CATEGORY(IES) Please See Annex A - List of Devices (6 Devices, 1 Page)

MODEL(S): Please See Annex A - List of Devices (6 Devices, 1 Page)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with IVD 98/79/EC on 01/01/2014.*

p.o. S. FERRETTI C.C.O.

Mr G. Elkayam CEO
Obelis sa
date & stamp

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
23 -10- 2014
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Brussels Enterprise Commerce & Industry
date & stamp

SEEN
by the Brussels Chamber of Commerce
Evelien Jonckheere
Brussels, the 23 OCT. 2014

Obelis s.a.
Registered Address:
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2008 and ISO 13485 : 2003 certified in accordance to the profession of a European Authorized Representative.

*According to the terms and conditions set out in the agreement signed between Obelis European Authorized Representative Center (O.E.A.R.C.) and Kuwaiti Egyptian for Medical Industries Co. (KEMICO)

CE 0459

Ref. No.: DP 3399-2014
Order No.: DP 3118-2014

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

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* Annex A is part of the Agreement.

** The Class above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

*** GMDN or EDMS codes are mandatory information to complete the Notification.

Manufacturer's Name	***Obelis S.A.***	***BECI***
Kuwaiti Egyptian formedical industries co.		
Signature:	***Signature:*** S. FERRETTI C.C.O.	***Signature:***
Date: 28/9/2014	***Date:*** 23/10/14	***Date:***
Stamp: KUWAITI EGYPTIAN For Medical Industries CF 413 - 455 - 238 CT 5 - 00443 - 252 - 00 - 00	***Stamp:*** Obelis s.a. Registered Address : Bld Général Wahis 53 1030 Bruxelles Tél. +32 2 732 59 54 - Fax +32 2 732 60 03	***Stamp:*** 23 -10- 2014

OBELIS s.a. Anti-Counterfeiting Label