Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: GF 7485-2019

Order No.: GF 7017-2018

BELGIUM

Date: 05/03/2019

THIS IS TO CERTIFY THAT, ACCORDING TO THE 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: BIOMEDICA DIAGNOSTICS INC.

ADDRESS: 94 WENTWORTH ROAD, WINDSOR
NOVA SCOTIA B0N 2T0
CANADA

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 17/01/2019 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 (5 PAGES, 23 DEVICES)

As of the 18/01/2019, 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).

Obelis s.a. - O.E.A.R.C.

Mr. G. Elkayam CEO
Obelis sa

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Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 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.

CE

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V2 – ID: 00454716

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Annex A - List of Devices

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

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
5	DLHK7	Dimertest® Latex	Cross-Linked Fibrin Degradation Product (XL-FDP) test kit	The DIMERTEST® Latex Assay is intended for the rapid qualitative or semi-quantitative evaluation of circulating derivatives of cross-linked fibrin degradation products (XL-FDP) in human plasma.	47346	General IVD
6	810	DVVtest® 10	Lupus Anticoagulant test reagent (2 mL)	DVVtest® is a dilute Russell's Viper Venom Time (dRVVT) test intended for the determination of Lupus Anticoagulants (LA) in patient plasma. DVVconfirm® is used to confirm the presence of LA in plasma which tested positive using DVVtest. DVVtest and DVVconfirm are single-step clotting tests that may be performed using manual, semi-automated and automated methods.	56202	General IVD
7	825	DVVtest® 25	Lupus Anticoagulant test reagent (5 mL)		56202	General IVD
8	815	DVVconfirm® 5	Lupus Anticoagulant confirm reagent (1 mL)		56202	General IVD
9	815L	DVVconfirm® 10	Lupus Anticoagulant confirm reagent (2 mL)		56202	General IVD
10	816N	LAtrol®	Lupus Anticoagulant Normal Control Plasma	The LAtrol™ Abnormal Control (REF 816A) and LAtrol™ Normal Control (REF 816N) plasmas have been developed for use as part of daily quality control procedures for Lupus Anticoagulant (LA) testing. These control plasmas are designed to be used with ACTICLOT® dPT™ (REF 824), DVVtest® (REF 810/825), and DVVconfirm® (REF 815/815L).	46029	General IVD
11	816A	LAtrol®	Lupus Anticoagulant Abnormal Control Plasma		46029	General IVD

12	812	ACTIFLUOR™ ADAMTS13 Activity	ADAMTS13 Activity fluorescence test kit	The ACTIFLUOR™ ADAMTS13 Activity assay is a fluorescence resonance energy transfer (FRET) assay for the measurement of ADAMTS13 in human plasma. The assay is for in vitro diagnostic use.	13.02.02.90	General IVD
13	813	IMUBIND® ADAMTS13 ELISA	ADAMTS13 ELISA test kit	The IMUBIND® ADAMTS13 ELISA is intended for the measurement of ADAMTS13 protein in human plasma. The assay is intended for in vitro diagnostic use.	13.02.02.90	General IVD
14	814	IMUBIND® ADAMTS13 Autoantibody ELISA	ADAMTS13 Autoantibody ELISA test kit	The IMUBIND® ADAMTS13 Autoantibody ELISA is intended for the measurement of ADAMTS13 IgG autoantibodies in human plasma. The assay is intended for in vitro diagnostic use.	13.03.04.90	General IVD
15	820	ACTICHROME® Heparin (Anti-FIIa)	Heparin (Anti-FIIa) – Chromogenic test kit	ACTICHROME® Heparin (Anti-FIIa) is an amidolytic chromogenic assay intended for the quantitative determination of therapeutic heparin in human plasma by measurement of factor IIa (thrombin) activity.	56005	General IVD
16	822	IMUBIND® Plasma PAI-1 ELISA	Plasminogen Activator Inhibitor Type-1 (PAI-1) antigen ELISA test kit	The IMUBIND® Plasma PAI-1 ELISA is an enzyme-linked immunosorbent assay for the quantitative measurement of human Plasminogen Activator Inhibitor Type-1 (PAI-1) antigen in plasma. This assay is for in vitro diagnostic use.	56129	General IVD

17	824	ACTICLOT® dPT™	Dilute Prothrombin Time test for the Determination of Lupus Anticoagulants (LA) – kit	The ACTICLOT® dPT™ is intended for the qualitative determination of Lupus Anticoagulants (LA) in human plasma. The test may be performed using semi-automated and automated coagulation analyzers. The test is for in vitro diagnostic use and is not intended for internal use in humans or animals.	56202	General IVD
18	832	ACTICHROME® Heparin (Anti-FXa)	Unfractionated (UF) and Low Molecular Weight (LMW) Heparin Chromogenic test kit	ACTICHROME® Heparin (Anti-FXa) is a chromogenic assay intended for the quantitative determination of unfractionated and low molecular weight heparins in human plasma by measurement of factor Xa inhibition.	56195	General IVD
19	840	ACTICLOT® Protein C resistance	Resistance of Activated Protein C test kit	ACTICLOT® Protein C Resistance is a plasma based functional assay for the determination of resistance to activated protein C caused by the factor V Leiden mutation (FV:Q506). For in-vitro diagnostic use.	56221	General IVD
20	840C	ACTICLOT® Protein C resistance control plasma	Resistance of Activated Protein C control plasma	Control plasmas for confirmation of factor V Leiden mutation (FV:Q506) in assays for determination of the functional phenotype for activated protein C resistance caused by the factor V Leiden mutation. For in-vitro diagnostic use.	41694	General IVD
21	843L	ACTICLOT® Protein S	Protein S Activity test kit	ACTICLOT® Protein S is a functional clotting assay intended for the quantitative determination of Protein S activity in human plasma. The assay is for in vitro diagnostic use.	56208	General IVD

22	885	IMUBIND® vWF Activity ELISA	Von Willebrand Factor (VWF) Activity ELISA test kit	The IMUBIND® vWF Activity ELISA is a quantitative direct enzyme-linked immunosorbent assay (ELISA) for the detection of von Willebrand Factor (vWF) activity in citrated human plasma. It is intended for the assessment of vWF activity in patients where this is deemed useful in the diagnostic process, particularly as an aid in the differential classification of von Willebrand's disease. vWF activity represents one parameter in a multicriterion diagnostic process.	62152	General IVD
23	899	FEMTELLE® uPA/PAI-1	Human Urokinase-type Plasminogen Activator (uPA) and Human Plasminogen Activator Inhibitor Type-1 (PAI-1) test kit	FEMTELLE® is intended for the quantitative measurement of human Urokinase-type Plasminogen Activator (uPA) and human Plasminogen Activator Inhibitor Type-1 (PAI-1) in detergent extracts of breast tumor tissue. The test results are useful for the following indications: 1) Prognosis for breast cancer patients who are either at low or high risk for disease recurrence following surgery.7,8,13,15,16,20,23 A low level of both uPA and PAI-1, below the established cutoff value of 3 ng uPA/mg of total protein and 14 ng of PAI-1/ mg total protein, places the patient in the low risk category for disease recurrence. A high level of uPA and/or PAI-1, above the respective cut-off values, places the patient in the high risk category for disease recurrence. 2) Prediction: It has been proposed that uPA and PAI-1 levels can be used to predict patient response to adjuvant chemotherapy.8,13,20 Clinical trials suggest that breast cancer patients with low uPA and PAI-1 are unlikely to benefit from adjuvant chemotherapy, whereas those patients with high uPA and PAI-1 levels are more likely to benefit from adjuvant chemotherapy.8,10,13,20 The relevant cut-off points are the same as for prognosis, above. uPA and PAI-1 values should be used in conjunction with information available from clinical and other diagnostic procedures in the management of breast cancer disease.20,23	54556	General IVD

24	101201	SPECTROLYSE® PAI-1	Plasminogen Activator Inhibitor Type-1 (PAI-1) test kit	SPECTROLYSE® PAI-1 is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. The test is for in vitro diagnostic use.	56129	General IVD
25	800DB	ActiScreenTM XL-FDP Latex Agglutination, 60 tests		Intended for the rapid qualitative or semi-quantitative evaluation of circulating derivatives of cross-linked fibrin degradation products (XL-FDP) in human plasma.	13.02.01.90	General IVD
26	838	ACTICHROM® AT III, activity assay, 60 tests		ACTICHROME® AT III is intended for the quantitative determination of antithrombin III in human plasma by chromogenic assay. The assay is intended for in vitro diagnostic use.	13.02.06.02	General IVD
27	ACC-45	ACtilot® C Protein C activiity assay, 45 tests		ACTICLOT® C is intended for the measurement of Protein C activity in human plasma via an end-point clotting assay. The assay is for in vitro diagnostic use.	13.02.06.08	General IVD

* 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).

Obelis s.a.

Signature: G.ELKAYAM CEO

Date: 05/03/2019

Obelis s.a. - O.E.A.R.C.

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