Obelis SA
European Authorized Representative Center

EUROPEAN AUTHORIZED REPRESENTATIVE CENTER Obelis SINCE 1988

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: AF 4366-2015

Order No.: AF 3972-2015

BELGIUM

Date:19/10/2015

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: BODITECH MED INC.

ADDRESS: 43, GEODUDANJI I-GIL, DONGNAE-MYEON, CHUNCHEON-SI, GANG-WON-DO 200-883, REPUBLIC OF KOREA

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 14/10/2015 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 (10 PAGES, 49 DEVICES)

As of the 15/10/2015, 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;

- Places 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.
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SEEN by the Brussels Chamber of Commerce Nastaoja OTTE

Mr. G. Elkaïm CEO
Obelis sa
date & stamp

Brussels Enterprise Commerce & Industry 21 OCT. 2015
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.

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Annex A* - List of Devices

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

No.	Catalogue reference number	Commercial name	Generic Device Term	Short description and intended use	GMDN/EDMS code**	Class***
1	i-CHROMA PSA-25	ichroma™ PSA	*in vitro* diagnostic device for PSA	ichroma™ PSA is a fluorescence Immunoassay(FIA) for the quantitative determination of Prostate Specific Antigen (PSA) in human whole blood / serum / plasma. ichroma™ PSA is useful as an aid in prescreening of prostate disease.	12.03.01.32	List B
2	FR203	ichroma™ Reader	Fluorometer for performing *in vitro* diagnostic tests based on immune-fluorescence technology	ichroma™ Reader is a portable fluorescence scanning instrument for measuring the concentration of designated analytes in the human blood, urine and other specimens; duly processed and tested in accordance with various ichroma™ Immunoassay Tests manufactured by Boditech Med Incorporated.	29.01.10.01	Others
3	CFPC-38	ichroma™ HbA1c	*in vitro* diagnostic device for HbA1c	ichroma™ HbA1c is a fluorescence immunoassay system for quantitative measurement of Hemoglobin A1c in Human blood. The test is used for routine monitoring of the long-term glycemic status in patients with diabetes mellitus.	11.70.01.07	Others
4	i-CHROMA MAU-25	ichroma™ Microalbumin	*in vitro* diagnostic device for Microalbumin	ichroma™ Microalbumin along with ichroma™ Reader is a fluorescence immunoassay that measures concentration of Microalbumin in human urine.	12.01.03.01	Others
5	i-CHROMA AFP-25	ichroma™ AFP	*in vitro* diagnostic device for AFP	ichroma™ AFP is a fluorescence immunoassay test that measures AFP in human whole blood, serum and plasma.	12.03.90.01	Others

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6	i-CHROMA CRP-25	ichroma™ CRP	*in vitro* diagnostic device for CRP	ichroma™ CRP is a fluorescence immunoassay that measures CRP in serum, plasma, and whole blood.	12.11.01.09	Others
7	CFPC-6	ichroma™ hsCRP	*in vitro* diagnostic device for hsCRP	ichroma™ hsCRP is a fluorescence immunoassay for the quantitative determination of High-Sensitivity C-Reactive Protein (hsCRP) in human whole blood/serum/plasma. Ichroma™ hsCRP is used as an aid in the screening and monitoring of infection and inflammation.	12.13.01.10	Others
8	13012	ichroma™ Testosterone	*in vitro* diagnostic device for Testosterone	ichroma™ Testosterone is a fluorescence immunoassay for the quantitative determination of testosterone in human serum or plasma. ichroma™ Testosterone is used as an aid in the screening and monitoring of androgen level.	12.05.01.10	Others
9	13011	ichroma™ Tn-I	*in vitro* diagnostic device for Tn-I	ichroma™ Tn-I along with the ichroma™ Reader is a fluorescence immunoassay that measures the cardiac troponin-I (Tn-I) concentration in human serum/plasma. Tn-I values are used to assist in the diagnosis of acute myocardial infarction (AMI).	12.13.01.07	Others
10	13010	ichroma™ LH	*in vitro* diagnostic device for LH	ichroma™ LH is a fluorescence immunoassay for the quantitative determination of Luteinizing hormone (LH) level in serum or plasma. ichroma™ LH is used as an aid in the screening or monitoring of determination of evaluating fertility issues, function of reproductive organs(ovaries or testicles), or detection of the ovulation.	12.05.01.02	Others

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11	13009	ichroma™ hCG	*in vitro* diagnostic device for hCG	ichroma™ hCG is along with ichroma™ Reader is a florescence immunoassay that quantifies the human chorionic gonadotrophin (hCG) concentration in the serum / plasma. The test is used as an aid in the early detection of pregnancy.	12.05.02.06	Others
12	13013	ichroma™ CEA	*In vitro* diagnostic device for CEA	ichroma™ CEA is a fluorescence immunoassay for the quantitative determination of Carcinoma Embryonic Antigen (CEA) in human serum or plasma. ichroma™ CEA further indicated for serial measurement of CEA to aid in the management of cancer patients.	12.03.01.31	Others
13	13303	ichroma™ D	Fluorometer for performing *in vitro* diagnostic tests based on immune-fluorescence technology	ichroma™ D is a fluorescence scanning instrument to be used in conjunction with various ichroma™ D Immunoassay test(s) for measuring the concentration of designated analyte(s) in human blood, urine and other specimens; duly tested in accordance with the test procedure recommended by Boditech Med Incorporated.	29.01.10.01	Others
14	CFPC-15	ichroma™ iFOB	*in vitro* diagnostic device for IFOB	ichroma™ iFOB is a fluorescence immunoassay for the quantitative determination of FOB in human Feces specimens. ichroma™ IFOB is used as an aid in the screening and monitoring of colorectal cancer.	12.03.90.04	Others
15	CFPC-22	ichroma™ TSH	*in vitro* diagnostic device for TSH	ichroma™ TSH is a fluorescence immunoassay that quantifies Thyroid Stimulating Hormone(TSH) concentration in human serum or plasma	12.04.01.11	Others

G. EL KAYAM
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16	CFPC-24	ichroma™ Cortisol	*in vitro* diagnostic device for Cortisol	ichroma™ Cortisol along with ichroma™ Reader is a fluorescence immunoassay that measures concentration of cortisol in human whole blood/serum/plasma.	12.06.02.04	Others
17	CFPC-27	ichroma™ PRL	*in vitro* diagnostic device for PRL	ichroma™ PRL is a fluorescence immunoassay that quantifies concentration of Prolactin (PRL) in human serum/plasma.	12.05.01.08	Others
18	CFPC-26	Ichroma™ T4	*in vitro* diagnostic device for T4	ichroma™ T4 along with Ichroma™ Reader is a fluorescence immunoassay that measures concentration of T4 in serum and plasma.	12.04.01.07	Others
19	CFPC-25	ichroma™ D-Dimer	*in vitro* diagnostic device for D-Dimer	ichroma™ D-Dimer is a fluorescence immunoassay that quantifies the concentration of D-Dimer in human whole blood and plasma.	13.02.05.03.	Others
20	CFPC-23	ichroma™ PCT	*in vitro* diagnostic device for PCT	ichroma™ PCT is a fluorescence immunoassay that quantifies the concentration of PCT in human serum and plasma.	12.06.90.16	Others
21	CFPC-33	ichroma™ CK-MB	*in vitro* diagnostic device for CK-MB	ichroma™ CK-MB is a fluorescence immunoassay for the quantitative determination of Creatine Kinase Isoenzyme-MB (CK-MB) in human whole blood/serum/plasma. Ichroma™ CK-MB is used as an aid in the screening and monitoring of acute myocardiac infarction (AMI) and acute coronary syndrome (ACS).	12.13.01.02	Others
22	CFPC-32	ichroma™ Ferritin	*in vitro* diagnostic device for Ferritin	Ichroma™ Ferritin is a fluorescence immunoassay that quantifies the concentration of Ferrtin in human serum and plasma.	12.07.01.02	Others

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23	FPRR005	hemochroma PLUS	*in vitro* diagnostic instrument intended to quantify the concentration of total hemoglobin	hemochroma PLUS is a portable *in-vitro* diagnostic instrument intended to quantify the concentration of total hemoglobin in human blood. It can be used in central laboratories, hospitals or point-of-care testing facilities.	23.02.10.01	Others
24	SFPC-1	ichroma™ CRP (For Self-Testing)	*in vitro* diagnostic device for CRP	ichroma™ CRP is a fluorescence immunoassay that measures CRP concentration in whole blood for self-testing	12.11.01.09	Self-testing device
25	SFPC-2	ichroma™ HbA1c (For Self-Testing)	*in vitro* diagnostic device for HbA1c	ichroma™ HbA1c is a fluorescence immunoassay that measures a ratio of hemoglobin A1c to total hemoglobin in whole blood for self-testing	11.02.01.14	Self-testing device
26	SFPC-3	ichroma™ hCG (For Self-Testing)	*in vitro* diagnostic device for hCG	ichroma™ hCG is a fluorescence immunoassay that measures hCG concentration in whole blood for self-testing	12.05.02.06	Self-testing device
27	SFPC-4	ichroma™ iFOB (For Self-Testing)	*in vitro* diagnostic device for iFOB	ichroma™ iFOB is a fluorescence immunoassay that measures FOB concentration in human feces for self-testing	12.03.90.04	Self-testing device
28	SFPC-5	ichroma™ Microalbumin (For Self-Testing)	*in vitro* diagnostic device for Microalbumin	ichroma™ Microalbumin is a fluorescence immunoassay that measures albumin concentration in urine for self-testing	12.01.03.01	Self-testing device
29	SFPC-6	ichroma™ PSA (For Self-Testing)	*in vitro* diagnostic device for PSA	ichroma™ PSA is a fluorescence immunoassay that measures PSA concentration in whole blood for self-testing	12.03.01.32	Self-testing device
30	SFPC-7	ichroma™ RF(IgM)/CRP (For Self-Testing)	*in vitro* diagnostic device for RF(IgM)/CRP	ichroma™ RF(IgM)/CRP is a fluorescence immunoassay that measures RF(IgM) and CRP concentration simultaneously in whole blood for self-testing	12.11.01.90	Self-testing device
31	SFPC-8	ichroma™ Reader (For Self-Testing)	Fluorometer for performing *in vitro* diagnostic tests based on immune-fluorescence technology	ichroma™ Reader is intended for self-test use for quantify concentration of various type of analytes in blood or urine/ fecal to be used in conjunction with a designated test cartridge based on the lateral flow immune-chromatography technology	29.01.10.01	Self-testing device

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32	CFPC-35	ichroma™ FSH	*in vitro* diagnostic device for FSH	ichroma™ FSH along with ichroma™ Reader is a fluorescence immunoassay that measures follicle stimulating hormone(FSH) concentration in human serum / plasma.	12.05.01.04	Others
33	CFPC-39	ichroma™ RF IgM	*in vitro* diagnostic device for RF IgM	ichroma™RF IgM is a fluorescence immunoassay for the quantitative determination of RF IgM in human whole blood/serum/plasma. ichroma™ RF IgM is used as an aid in the screening and monitoring of rheumatoid arthritis.	12.11.01.11	Others
34	CFPC-37	ichroma™ Myoglobin	*in vitro* diagnostic device for Myoglobin	ichroma™ Myoglobin is a fluorescence immunoassay for the quantitative determination of Myoglobin in human whole blood / serum / plasma. ichroma™ Myoglobin is used as an aid in the screening and monitoring of acute myocardial infarction (AMI).	12.13.01.05	Others
35	CFPC-42	ichroma™ TSH WB	*in vitro* diagnostic device for TSH WB	ichroma™ TSH WB is a fluorescence immunoassay that quantifies the concentration of TSH in human whole blood. The test is useful in the diagnosis of thyroid and/or pituitary disorders.	12.04.01.11	Others
36	SMFP-1	ichroma™ SMART hsCRP	*in vitro* diagnostic device for hsCRP	ichroma™ SMART hsCRP along with ichroma™ SMART is a fluorescence immunoassay that measures hsCRP in serum, plasma and whole blood. The test is used as an aid to see cardiovascular inflammation.	12.13.01.10	Others
37	SMFP-2	ichroma™ SMART CRP	*in vitro* diagnostic device for CRP	ichroma™ SMART CRP along with ichroma™ SMART is a fluorescence immunoassay that measures CRP in human serum, plasma and whole blood. The test is used as an aid to see infection and inflammation.	12.11.01.09	Others

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38	SMFP-3	ichroma™ SMART Total βhCG	*in vitro* diagnostic device for Total βhCG	ichroma™ SMART Total βhCG along with ichroma™ SMART is a fluorescence immunoassay that measures Total βhCG in human serum, plasma and whole blood. The test is used as an aid to see fertility.	12.05.02.06	Others
39	SMFP-4	ichroma™ SMART D-Dimer	*in vitro* diagnostic device for D-dimer	ichroma™ SMART D-Dimer along with ichroma™ SMART is a fluorescence immunoassay that measures D-Dimer in plasma. The test is used as an aid to see the post therapeutic evaluation of thromboembolic disease patients.	13.02.05.03.	Others
40	SMFP-10	ichroma™ SMART TSH	*in vitro* diagnostic device for TSH	ichroma™ SMART TSH along with ichroma™ SMART is a fluorescence immunoassay that measures the concentration of Thyroid Stimulating Hormone(TSH) in human serum, plasma and whole blood.	12.04.01.11	Others
41	SMFP-6	ichroma™ SMART LH	*in vitro* diagnostic device for LH	ichroma™ SMART LH along with ichroma™ SMART is a fluorescence immunoassay that measures the concentration of luteinizing hormone(LH) in human serum, plasma and whole blood.	12.05.01.02	Others
42	SMFP-7	ichroma™ SMART PCT	*in vitro* diagnostic device for PCT	ichroma™ SMART PCT along with ichroma™ SMART is a fluorescence immunoassay for quantitative determination of Procalcitonin(PCT) in human serum and plasma. The test is useful in the diagnosis of bacterial infection and sepsis.	12.06.90.16	Others
43	SMFP-8	ichroma™ SMART PRL	*in vitro* diagnostic device for PRL	ichroma™ SMART PRL along with ichroma™ SMART is a fluorescence immunoassay that measures the concentration of prolactin(PRL) in human serum, plasma and whole blood.	12.05.01.08	Others

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44	SMFP-5	ichroma™ SMART FSH	*in vitro* diagnostic device for FSH	ichroma™ SMART FSH along with ichroma™ SMART reader is a fluorescence immunoassay that measures follicle stimulating hormone(FSH) concentration in human serum, plasma and whole blood.	12.05.02.06	Others
45	SMFP-9	ichroma™ SMART PSA	*in vitro* diagnostic device for PSA	ichroma™ SMART PSA along with ichroma™ SMART fluorescence Immunoassay that measures the concentration of Prostate Specific Antigen (PSA) in human whole blood / serum / plasma. Measurement of PSA using ichroma™ SMART PSA can be used for in vitro diagnosis or monitoring of prostate disease.	12.03.01.32	List B
46	CFPC-36	ichroma™ β-HCG	*in vitro* diagnostic device for β-HCG	ichroma™ β-HCG is a fluorescence Immunoassay (FIA) for the quantitative determination of total beta human chorionic gonadotropin (total β-HCG) level in human whole blood or serum or plasma.	12.05.02.06	Others
47	CFPC-43	ichroma™ Cystatin C	*in vitro* diagnostic device for Cystatin C	ichroma™ Cystatin C along with the ichroma™ Reader is intended for use in a fluorescence immunoassay for quantitative determination of cystatin C in human serum/plasma. The measurement of cystatin C is used as an aid in the diagnosis and treatment of renal disease.	12.01.90.09	Others

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48	CFPC-21	ichroma™ Progesterone	*in vitro* diagnostic device for Progesterone	**ichroma™ Progesterone is a fluorescence immunoassay for the quantitative determination of progesterone in human serum or plasma. ichroma™ Progesterone** is used as an aid in the screening of determination of the cause of infertility, track ovulation, diagnose an ectopic or failing pregnancy, monitor the health of a pregnancy, monitor **progesterone replacement therapy and cause of abnormal uterine bleeding.**	12.05.01.06	Others

49	SMFP	ichroma™ SMART	Fluorometer for performing *in vitro* diagnostic tests based on immune-fluorescence technology	The ichroma™ SMART is a portable fluorescence scanning instrument for measuring the concentration of designated analytes in the human blood, urine and other specimens; duly processed and tested in accordance with various ichroma™ SMART immunoassay tests manufactured by Boditech Med Incorporated. The ichroma™ SMART is to be used only in conjunction with various ichroma™ SMART immunoassay tests and meant only for *in vitro* diagnostic purpose. The ichroma™ SMART can be used for screening, monitoring and/or routine physical examination in centralized laboratories of hospitals, physicians' clinics.	29.01.10.01	Others

* Annex A is part of the Agreement
** GMDN or EDMS codes are mandatory information to complete the Notification.
*** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Manufacturer's Name	***Obelis S.A.***	***BECI***
Boditech Med Inc.		
Signature:	***Signature:*** G. ELKAIM CEO	***Signature:***
Date: 21/10/2015	***Date:*** 20/10/2015	***Date:***
Stamp:	***Stamp:***	***Stamp:***

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