Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: IO 2045-2013

Order No.: IO 1490-2013

Date: 26/09/2013

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:

SEEN by the Brussels Chamber of Commerce
Evelien Jonckheere
Brussels, the 02 OCT. 2013

NAME: DNA-TECHNOLOGY, RESEARCH & PRODUCTION, LLC,

ADDRESS: 142281, MOSCOW REGION, PROTVINO, ZHELEZNODOROZHNAYA STR., 20, RUSSIA

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 10/09/2013 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
02 -10- 2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 4 DEVICES)

As of the 11/09/2013, 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
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Mr. G. Elkayam CEO
Obelis sa
date & stamp

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.

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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	Detecting thermocycler/PCR-Diagnostics	DTprime	neither A nor B according to annex II IVD 98/79/EC	O-DTPRIME4M1-EU O-DTPRIME4X1-EU O-DTPRIME4M3-EU O-DTPRIME4M6-EU O-DTPRIME5M1-EU O-DTPRIME5X1-EU O-DTPRIME5M3-EU O-DTPRIME5M6-EU	Detecting thermocyclers DTprimeXXX is intended use for in-vitro diagnostics of using PCR method.	48031
2	Detecting thermocycler/PCR-Diagnostics	DTlite	neither A nor B according to annex II IVD 98/79/EC	O-DTLITE4S1-EU O-DTLITE4S2-EU O-DTLITE4L1-EU O-DTLITE5S1-EU O-DTLITE5S2-EU O-DTLITE5L1-EU	Detecting thermocyclers DTliteXXX is intended use for in-vitro diagnostics of using PCR method.	48031
3	Fluorescent detector /PCR-Diagnostics	Gene-4	neither A nor B according to annex II IVD 98/79/EC	O-GENE4-EU	Fluorescent detector of a polymerase chain reaction is a special instrument to evaluate fluorescent radiation of light of a reactionary mixture in test tubes directly after finishing a polymerase chain reaction (PCR).	26.03.10.01
4	Real-time PCR Kit/PCR-Diagnostics	FEMOFLOR	neither A nor B according to annex II IVD 98/79/EC	R1-P801-S3/6EU R1-P802-S3/5EU R1-P803-S3/4EU	The FEMOFLOR® Real-time PCR Kit aimed to improve the efficiency of current diagnostic tools used for identification of female genital infections.	48208

* Annex A is part of the Agreement.

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

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

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
02 -10- 2013
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Manufacturer's Name «DNA-Technology, Research&Production», LLC — **Signature:** _____ **Date:** 27.05.2013 — **Stamp:**

Obelis S.A. — **Signature:** G.ELKAYAM, C.E.O. — **Date:** 30/9/2013 — **Stamp:**

Signature: _____ **Date:** _____ **Stamp:**

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