Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: DP 3393-2014

Order No.: DP 2930-2014

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: SHANGHAI ZJ BIO-TECH CO. LTD.,

ADDRESS: 2ND FLOOR, BUILDING 15, 188 XINJUNHUAN ROAD, CAOHEJING PUJIANG HI-TECH PARK, SHANGHAI, 201114, CHINA

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 03/10/2014 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, 2 DEVICES)

As of the 04/10/2014, 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).

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
22 -10- 2014
KAMER VAN KOOPHANDEL EN NIJVERHEID VAN BRUSSEL

P.O. S. FERRETTI C.C.O.

Mr. G. Elkayam CEO
Obelis sa
date & stamp

Obelis s.a.
Registered Address :
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1030 Bruxelles
Tel. +32 2 732 59 54 Fax +32 2 732 60 03

SEEN
by the Brussels Chamber of Commerce
Evelien Jonckheere

Brussels Enterprise
Commerce & Industry
date & stamp

22 OCT. 2014

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	Kit for virus detection	High-risk Human Papillomavirus （HPV）Genotyping Real time PCR kit	Others	TD-0324-02 TD-0324-04	Detect HPV nucleic acid and differentiation 15 types of HPV 16, 18,31,33,35,39,45, 51,52,56,58,59,66,68,82 by real time PCR	49997
2	Instrument for nucleic acid extraction	Autrax Automated Nucleic Acid Extraction Workstation	Others	SB-Z-10020	Automatically extraction high-purified nucleic acid from various samples such as whole blood, serum, plasma, feces, milk and isolated cells; also automatically preparation PCR reagents.	60736

* 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***
Shanghai ZJ Bio-Tech Co., Ltd		
Signature: Patty Wang	***Signature:***	***Signature:***
Date: 04/MAY/2014	***Date:*** 21/10/2014	***Date:***
Stamp:	***Stamp:*** S. FERRETTI C.C.O.	***Stamp:*** 23-10-2014

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

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OBELIS s.a. Anti-Counterfeiting Label