CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES

Obelis SA

European Authorized Representative Center

EUROPEAN AUTHORIZED REPRESENTATIVE CENTER Obelis SINCE 1988

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: IU 4356-2015

Order No.: IU 4173-2015 U

BELGIUM

Date: 21/10/2015

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: SHANGHAI ZJ BIO-TECH CO., LTD.

ADDRESS: NO.20 BUILDING, 528 RUIQING ROAD ZHANGJIANG HIGH-TECH INDUSTRIAL EAST DISTRICT, 201203 SHANGHAI, 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 12/10/2015 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 (3 PAGES, 18 DEVICES)

As of the 13/10/2015, 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;

- 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
27-10-2015
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

OBELIS s.a. - O.E.A.R.C.
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T: +32 2 732 59 54 - Fax: +32 2 732 60 03

G. ELKAYAM CEO

Mr. G. Elkayam CEO
Obelis sa

Brussels Enterprise
Commerce & Industry

SEEN by the Brussels Chamber of Commerce date & stamp

SEEN by the Brussels Chamber of Commerce date & stamp

Brussels, the 27 OCT. 2015

Brussels, the 27 OCT. 2015

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.

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