Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER – Obelis – SINCE 1988

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: AC 6721-2018

Order No.: AC 6402-2018

BELGIUM

Date: 11/06/2018

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: 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 30/05/2018 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, 1 DEVICE)

As of the 31/05/2018, 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).

G.ELKAYAM CEO

Mr. G. Elkayam CEO
Obelis sa
date & stamp

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

EAR

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 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

Order No.: AC 6402-2018
Ref No.: AC 6721-2018

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
1.	ER-0360-02	Zika Virus (ZIKV) Real Time RT-PCR Kit	Zika virus nucleic acid IVD, kit, nucleic acid technique (NAT)	Zika Virus (ZIKV) Real Time RT-PCR Kit is intended for the qualitative detection of Zika virus in serum, saliva and urine by using real time PCR systems.	49102	others

* 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).

Shanghai ZJ Bio-Tech Co., Ltd.

Signature: Lei Zhu

Date: 06/06/2018

Stamp:

Obelis s.a.

Signature: G. ELKAYAM C.E.O.

Date: 14/6/2018

Stamp:

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03