Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: RM 5283-2017

Order No.: MT 4617-2016

BELGIUM

Date: 14/02/2017

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 BIOTECH CO. LTD.,

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

SEEN by the Brussels Chamber of Commerce 15 FEV. 2017 Brussels, the

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 21/12/2016 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 22/12/2016, 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 15 -02- 2017 KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

P.O.

Mr. G. Elkayam CEO
Obelis sa

Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tel. +32 2 732 59 54 - Fax +32 2 732 60 03

S. FERRETTI
C.C.O.

date & stamp

Brussels Enterprise
Commerce & Industry

Caroline Dewet

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.

Corporate Offices Bd. Général Wahis 53 - 1030 Brussels I Registered Office Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net

*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	ER-0460-01	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 used for the detection of Zika virus in serum or plasma by using real time PCR systems. Kit Components: 1 ZIKV Super Mix 2 RT-PCR Enzyme Mix 3 Molecular Grade Water 4 Internal Control (IC) 5 ZIKV Positive Control The components of the kit are not being sold separately.	49102	others
	ER-0460-02			Zika Virus (ZIKV) Real Time RT-PCR Kit is used for the detection of Zika virus in serum or plasma by using real time PCR systems. Kit Components: 1 ZIKV Super Mix 2 RT-PCR Enzyme Mix 3 Molecular Grade Water 4 Internal Control (IC) 5 ZIKV Positive Control The components of the kit are not being sold separately.		

* 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).

Manufacturer's Name	***Obelis S.A.***	***BECI***
Shanghai ZJ Bio-Tech Co., Ltd.		
Signature: Jessica Zhu	***Signature:***	***Signature:***
Date: 15/09/2016	***Date:*** 14/02/2017	***Date:***
Stamp:	***Stamp:***	***Stamp:***

Shanghai ZJ Bio-Tech Co., Ltd. 上海之江生物科技股份有限公司

Obelis s.a.
Registered Address :
Bld. General Wahis 53
1030 Bruxelles
Tel. +32 2 732 59 54 - Fax +32 2 732 60 03

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
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C.C.O.

OBELIS s.a. Anti-Counterfeiting Label