

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: RM 5283-2017

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

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).

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 59 55

date & stamp

S. FERRETTI
C.C.O.

Brussels Enterprise
Commerce & Industry

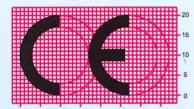
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Caroline Dewet



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.



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

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: P.O.

Signature: _____

Date: 15/09/2016

Date: 14/02/2017

Date: _____

Stamp:



Stamp:

Obelis s.a.
Registered Address:
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1030 Bruxelles

Stamp:

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**S. FERRETTI
C.C.O.**

