CERTIFICATE OF IVD NOTIFICATION

Ref. No.: GZ 8821-2020

Order No.: GZ 8776-2020

BELGIUM

Date: 17/03/2020

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 FOSUN LONG MARCH MEDICAL SCIENCE CO., LTD

ADDRESS: 200444, 830 CHENGYIN ROAD, BAOSHAN DISTRICT, PEOPLE'S REPUBLIC OF 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 16/03/2020 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 (2 PAGES, 6 DEVICES)

As of the 17/03/2020, 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/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

G. ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
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Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

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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.	PCSYHF	Fosun 2019-nCoV qPCR	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	This product is intended for the rapid detection of 2019-nCoV by TaqMan multiplex real-time PCR in human throat swab or sputum samples.	15 04 40 90 (Other Virology - NA Reagents)	Others
2	PCSYHG	Fosun FluA/FluB/2019-nCoV qPCR	FluA/FluB/2019-nCoV RT-PCR Detection Kit	This product is intended for the rapid detection of Influenza A virus (FluA), Influenza B virus (FluB), 2019-nCoV by TaqMan multiplex real-time PCR in human nasopharyngeal swabs, throat swab, sputum samples or bronchoalveolar lavage fluid samples.	15 04 40 90 (Other Virology - NA Reagents)	Others
3	PCSYHE	Fosun 2019-nCoV rapid	Novel Coronavirus (2019-nCoV) Real-Time Isothermal Amplification Kit	This product is intended for the rapid detection of 2019-nCoV by real-time isothermal amplification in human nasopharyngeal swabs, throat swab, sputum samples.	15 04 40 90 (Other Virology - NA Reagents)	Others
4	PCSYHB	Fosun RSV rapid	Respiratory syncytial virus Real-time Isothermal Amplification Kit	This product is intended for the rapid detection of Respiratory syncytial virus by real-time isothermal amplification in human nasopharyngeal swabs, throat swab samples	15 04 40 05 (Respiratory Syncytial Virus (RSV) - NA Reagents)	Others
5	PCSYHA	Fosun CP/MP rapid	Chlamydia pneumoniae/ Mycoplasma pneumoniae Real-time Isothermal Amplification Kit	This product is intended for the rapid detection of Chlamydia pneumoniae and Mycoplasma pneumoniae by real-time isothermal amplification in human nasopharyngeal swabs, throat swab samples.	15 01 40 90 (Other Bacteriology - NA Reagents)	Others

6	PCSYHH	Fosun 2019-nCoV IgM/IgG rapid	Novel Coronavirus (2019-nCoV) IgM/IgG test Kit	The product is a solid phase immunochromatographic assay for the rapid, qualitative/ semi-quantitative and differential detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma.	15 04 80 90 (Other Viral Antigen/Antibody Detection)	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).

Obelis s.a.

Signature:

G. ELKAYAM C.E.O.

Stamp:

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