CERTIFICATE OF IVD NOTIFICATION

Ref. No.: CMB 0105-2020

Order No.: DK 0015-2020

BELGIUM

Date: 05/11/2020

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: SANSURE BIOTECH INC

ADDRESS: NO. 680, LUSONG ROAD, YUELU DISTRICT, 410205 CHANGSHA, HUNAN PROVINCE, PEOPLE'S REPUBLIC OF CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD device complies 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 device, as stipulated here above,is fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 02/11/2020 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 (1 PAGE, 1 DEVICE)

As of the 03/11/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on this device;

- Place this device 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.
Registered Address
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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.

Order No.: DK 0015-2020
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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.	S3109E	SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	Coronavirus	The SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method) is an in vitro diagnostic test for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human nasopharyngeal or nasal swab specimens, which will provide information for clinical doctors to prescribe correct handing. Components of the Diagnostic Kit: SARS-CoV-2-Antigen Test Cassette (individually in a foil pouch with desiccant） Lysis Buffer Nozzle Cap with Protective Cover	15.04.80.19	**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).

G.ELKAYAM
C.E.O.

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