Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER – Obelis – SINCE 1988

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: MQ 8785-2020

Order No.: MQ 8760-2020

BELGIUM

Date: 10/03/2020

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: AUTOBIO DIAGNOSTICS CO., LTD.

ADDRESS: NO.87 JINGBEI YI ROAD,
NATIONAL ECO&TECH DEVELOPMENT AREA, 450016,
ZHENGZHOU, 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 09/03/2020 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, 5 DEVICES)

As of the 10/03/2020, 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.
Registered Address
Bld Général Wahis 53
1030 Bruxelles
Tel: +32.2.732.59.54 - Fax: +32.2.732.60.03

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.

Autobio Diagnostics Co.,Ltd
No.87 Jingbei Yi Road, National Eco&Tech Development Area Zhengzhou, China, 450016
Tel:+86-371-67985313 E-mail:info@autobio-diagnostics.com
www.autobio-diagnostics.com

Ref. No.: MQ 8785-2020
Order No.: MQ 8760-2020

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.	CMU0101/CMU0102/CMU0103/CMU0104/CMU0105	SARS-CoV-2 IgG CLIA Microparticles	Coronavirus	This assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the qualitative detection of SARS-CoV-2 IgG (IgG antibodies to Severe Acute Respiratory Syndrome Coronavirus 2) in human serum and plasma.	15.04.80.19	Other
2.	CMU0201/CMU0202/CMU0203/CMU0204/CMU0205	SARS-CoV-2 IgM CLIA Microparticles	Coronavirus	This assay is based on a chemiluminescent microparticle immunoassay (CLIA Microparticles) for the qualitative detection of SARS-CoV-2 IgM (IgM antibodies to Severe Acute Respiratory Syndrome Coronavirus 2) in human serum and plasma.	15.04.80.19	Other
3.	PCRA0101	SARS-CoV-2 rRT-PCR	Coronavirus-NA reagent	This assay is an in vitro real-time Reverse Transcriptase (RT) PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in oropharyngeal swabs specimens from individuals.	15.04.40.19	Other
4.	ZKPCR0101/ZKPCR0201/ZKPCR0301	SARS-CoV-2 Control	Coronavirus-NA reagent	This product is intended for use as a quality control to monitor the precision of laboratory nucleic acid testing procedures for the detection of SARS-CoV-2.	15.04.40.19	Other
5.	RTA0101/RTA0102/RTA0103/RTA0104/RTA0201/RTA0202/RTA0203/RTA0204	Anti-SARS-CoV-2 Rapid Test	Coronavirus	This assay is based on a colloidal gold method for the rapid, qualitative determination of Anti-SARS-CoV-2 (IgG /IgM antibodies of Severe Acute Respiratory Syndrome Coronavirus 2) in human serum, plasma or whole blood.	15.04.80.19	Other

* Annex A is part of the Agreement

Autobio Diagnostics Co.,Ltd
No.87 Jingbei Yi Road, National Eco&Tech Development Area Zhengzhou, China, 450016
Tel:+86-371-67985313 E-mail:info@autobio-diagnostics.com
www.autobio-diagnostics.com

** 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.

G.ELKAYAM C.E.O.

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