CERTIFICATE OF IVD NOTIFICATION

Ref. No.: SN 0154-2020

Order No.: SN 9975-2020

BELGIUM

Date: 16/11/2020

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: SHANGHAI ZJ BIO-TECH CO., LTD.

ADDRESS: BUILDING #26, 588 XINJUNHUAN ROAD, PUJIANG HIGH-TECH PARK, 201114, SHANGHAI, 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 13/11/2020 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, 3 DEVICES)

As of the 14/11/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on 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 General Wahis 53
1030 Brussels
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.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B–1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 – ID: 00454716 – 22/02/2019

Order No.: SN 9975-2020
Ref No.: SN 0154-2020

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	GMD Ncode	Class
1	ME-0089-120 ME-0089-480	Viral RNA Isolation Kit (for Auto-Extraction)	Nucleic acid extraction/isolation kit IVD	Viral RNA Isolation Kit (for Auto-Extraction) utilizes magnetic particle technology for isolation and purification of pathogen's nucleic acids from biological specimens. This kit can be used in combination with automated nucleic acid extraction systems. The product is intended to be used by professional users, such as technicians who are trained in molecular biological techniques. Viral RNA Isolation Kit (for Auto-Extraction) is intended for in vitro diagnostic use.	52521	others
2	ME-0092-96 ME-0092-384	Viral RNA Extraction Kit (for Auto-Extraction)	Nucleic acid extraction/isolation kit IVD	Viral RNA Extraction Kit (for Auto-Extraction) utilizes magnetic particle technology for isolation and purification of pathogen's nucleic acids from biological specimens.The nucleic acid extracted by this kit is intended for in vitro diagnostic use. The product is intended to be used by professional users, such as technicians who are trained in molecular biological techniques.		
3	RR-0485-02	Novel Coronavirus (SARS-CoV-2) Real-Time Multiplex RT-PCR Kit	SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT)	The Novel Coronavirus (SARS-CoV-2) Real-Time Multiplex RT-PCR Kit is an in vitro diagnostic test is for manual qualitative detection of ORF 1ab, N and E genes of SARS-CoV-2 RNA in nasopharyngeal or oropharyngeal swabs and sputum specimens collected from individuals suspected of being infected with SARS-CoV-2. The kit is for aiding in the diagnosis of COVID-19 infection and it is for professional use in level 2 biosafety laboratory by laboratory personnel trained in RT-PCR. 1, SARS-CoV-2 Super Mix 1 vial, 513 µL 2, RT-PCR Enzyme Mix 1 vial, 27 µL 3, SARS-CoV-2 Internal Control 1 vial, 30 µL 4, SARS-CoV-2 Negative Control 1 vial, 400 µL 5, SARS-CoV-2 Positive Control 1 vial, 30 µL	64747	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:

Date: 16/11/2020

Stamp:

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