Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1989

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: [redacted]

Belgium

Order No.: [redacted] Date: [redacted]

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. (O.E.A.R.C.) performed a ll notification duties and responsibilities as the European Authorized Representative (EC REP) of:

name: [redacted]

Address: [redacted]

as stipulated and demanded by the aforementioned directive.

The Manufacturer declares that the IVD device complIES with the Directive including all essential requireme nts. The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations accordi ng to the 98/79/EC Directive - article 10 requirements including the EC Declaration of Conformity confirmi ng that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable r equirements of the European Council Directive 98/79/EC The notification of the following In-Vitro Diagnos tic medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 26/10/2020 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 27/10/2020, 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 De cision 2010/227/EU).

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 Certificate will be automatically void if the notification is rejected by the EU Authorities or upon ter mination of the EAR agreement.

* This is not a CE mark and is only prov ided as a template for informational pur poses.

CE

Order No.:
Ref No.:

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.		Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	The test kit is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen in human throat swab, Nasal swab samples.		All 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.ELKAIAM C.E.O.

Stamp:

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