

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

G. ELKAYAM
C.E.O.

Obelis s.a. - O.E.A.R.C.

Registered Address :
Bld Général Wahis 53
1030 Bruxelles

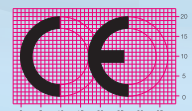
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

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.



Order No.: MN 8799-2020

Ref No.: MN 8847-2020

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	GMDN/EDMS Code	Class
1.	BIO2020-02	Real Time PCR Detection Kit For COVID-19 Coronavirus	Multiple respiratory virus nucleic acid IVD, kit, nucleic acid technique (NAT)	Real Time PCR Detection Kit For COVID-19 Coronavirus is used for the relative quantitative detection of new coronavirus (SARS-CoV-2) nucleic acid. It contains the following items: 1, Reaction solution 650µL 2, Primer probe 100µL 3, Positive control 250µL 4, Negative control 250µL	47922	Others
2.	BIO2020-03	Colorimetric And Isothermal Detection Kit For COVID-19 Coronavirus	Multiple respiratory virus nucleic acid IVD, kit, nucleic acid technique (NAT)	Colorimetric And Isothermal Detection Kit For COVID-19 Coronavirus is used for the relative quantitative detection of new coronavirus (SARS-CoV-2) nucleic acid. It contains the following items: 1, Reaction solution 500µL 2, Primer mix 100µL 3, Positive control 50µL	47922	SA 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:****Stamp:**

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