

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

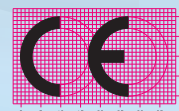
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO

Obelis sa



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Order No.: OG 0625-2021

Ref No.: BS 0713-2021

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 / GIVD Code	Class
1.	NA	Coronavirus (SARS-Cov-2) Antigen Rapid sampling and detection tube(Colloidal Gold)	SARS-Cov-2 Antigen IVD, kit	COVID-19 Detection	64787	All Others
2.	NA	COVID-19 Antigen Saliva Rapid Test Kit (Colloidal Gold)	SARS-Cov-2 Antigen IVD, kit	COVID-19 Detection	64787	All Others
3.	NA	SARS-CoV-2 Neutralizing Antibody Test Kit	SARS-Cov-2 Total Antibody Neutralization IVD, kit	COVID-19 Detection	65307	All Others

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