



E.A.R.-CERTIFICATE

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

C. C. AM

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 0117-2020 Ref No.: BS 0170-2020

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	GF102B1	SARS-CoV-2 Antigen Rapid Test Kit	SARS-CoV-2 (COVID-19) Antigen Rapid Test Kit (Colloidal Gold)	SARS-CoV-2 (Covid-19) Antigen Rapid Test Kit is used to qualitatively detect antigen of the novel coronavirus in nasal swab.	15.04.80.19	Others

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Registered Address:
Bid Général Wahis 53
1030 Bruxelles
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