



CERTIFICATE IVD NOTIFICATION



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.: OG 0416-2020N Ref No.: FG 0571-2021

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/ EDMS Code	Class
1.	105A	LooK SPOT	COVID-19 Antigen Rapid Test Reader	A smartphone based reader for COVID-19 Antigen Rapid Test	21.07.10.09	All others
2.	105B	LooK COVID-19 Antigen Rapid Test	COVID-19 Antigen Rapid Test Kit	A LFA assay intended for the qualitative detection of nucleocapsid protein from SARS-CoV-2 in nasal swabs from patients suspected of COVID-19 within the first eight (8) days of symptom onset.	15.04.09.01	All Others

S/NCE 1988

Obelis s.a.

Signature:

Stamp:

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