



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

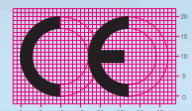
Mr. G. Elkayam CEO

Obelis sa



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Registered Address : Bd. Général Wahis 53-1030 Brussels | Registered Office Address : Bd Brand Whitlock 30, B-1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 | F: + 32 (0) 2 732 6003 | Email: mail@obelis.net | Website: www.obelis.net
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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.	SG0010A	SG Diagnostics COVID-19 Antigen Rapid Test kit (Colloidal Gold-based)	COVID-19 Antigen Test Kit immunoassay, lateral flow, IVD	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	64787	Others SA
2.	SG0020A	SG Diagnostics Covid-19 IgG/IgM Rapid Test Kit (Colloidal Gold-based)	SARS-CoV-2 immunoglobulin test kits, IVD, immunoassay lateral flow	This test kit is used for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in human whole blood, serum and plasma samples	64756	Others
3.	SG0030A	SG Diagnostics Covid-19 Triplex RT-qPCR Detection Kit	SARS-CoV-2 nucleic acid detection, IVD, nucleic acid	This test kit is used for the qualitative detection of SARS-CoV-2 in human throat swab, nasal swab samples	64747	Others

4.	SG0040A	SG Diagnostics Influenza A/B + Covid-19 Antigen Rapid Test Kit (Colloidal Gold- based)	COVID-19 Antigen Test Kit immunoassay, lateral flow, IVD	The test kit is applicable to detect the antigen of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Antigen together with Influenza A/B in human throat swab, nasal swab samples	64787	Others
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