



CERTIFICATE OF IVD NOTIFICATION

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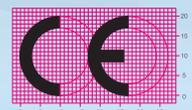
Mr. G. Elkayam CEO

Obelis sa



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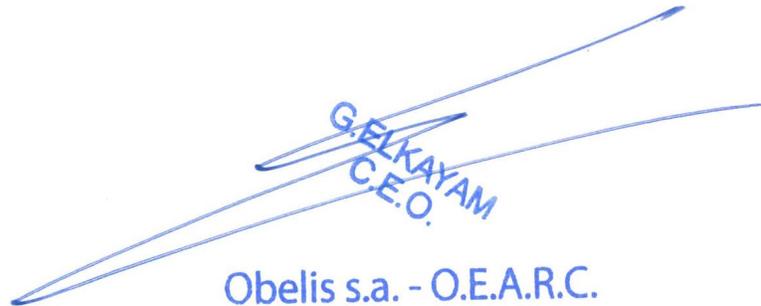
Order No.: DK 0015-2020

Ref No.: CMB 0105-2020

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.	S3109E	SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	Coronavirus	<p>The SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method) is an in vitro diagnostic test for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human nasopharyngeal or nasal swab specimens, which will provide information for clinical doctors to prescribe correct handling.</p> <p>Components of the Diagnostic Kit: SARS-CoV-2-Antigen Test Cassette (individually in a foil pouch with desiccant) Lysis Buffer Nozzle Cap with Protective Cover</p>	15.04.80.19 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).


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