



E.A.R.-CERTIFICATE

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

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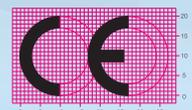
Mr. G. Elkayam CEO

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Order No.: OG 0336-2020N

Ref No.: CMB 0479-2020

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.	CV2-25	Sona Nanotech COVID-19 Lateral Flow Assay	SARS-CoV-1/SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	The Sona Nanotech COVID-19 Lateral Flow Assay is an immunochromatographic assay for the qualitative detection of the spike protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider. The assay is intended for professional and laboratory use.	64912	Other

* 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).

Obelis s.a.**Signature:****Stamp:****Obelis s.a. - O.E.A.R.C.**

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