E.A.R.-CERTIFICATE

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

REF. NO. : CMB 0479-2020
ORDER NO. : OG 0336-2020N

30/12/2020

MANUFACTURER:
SONA NANOTECH INC.
1 Research Drive, Dartmouth,
NS. Canada, B2Y 4M9

FACILITIES:
SONA NANOTECH INC.
1 Research Drive, Dartmouth,
NS. Canada, B2Y 4M9

PRODUCT CATEGORIES:
Please See Annex A - List of Devices (1 Device, 1 Page)

MODELS:
Please See Annex A - List of Devices (1 Device, 1 Page)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on 1st of December 2020.*

G.ELKAYAM C.E.O.

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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.

*This is not a CE mark and is only provided as a template for informational purposes

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

Order No.: OG 0336-2020N
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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.	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:

G.ELKAYAM
C.E.O.

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