Obelis GROUP

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CERTIFICATE OF IVD NOTIFICATION

Reference No.: VR 0408-2022

BELGIUM

Date: 06/05/2022

Order No.: EU AB 0174-2022

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

Name: Dia Sure Immunodiagnostic LLP
D-10/5, 201, 2nd Floor, Okhla Industrial Area, Phase-II, New Delhi, India (110020)

Address: Dia Sure Immunodiagnostic LLP
D-10/5, 201, 2nd Floor, Okhla Industrial Area, Phase-II, New Delhi, India (110020)

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The manufacturer declares that the IVD device(s) comply(ies) with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (EC REP) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical device(s), as stipulated here above, is/are fulfilling the applicable requirements of the European Council Directive 98/79/EC on the

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (EC REP) on in compliance with the European Council Directive 98/79/EC - article 10 requirements on the 28/04/2022

IN-VITRO DIAGNOSTIC MEDICAL DEVICE(S): Please See Annex A - List of Devices (1 Device; 1 Page)

As of the 28/04/2022 , and provided that the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on this(ese) device(s);

- Place this(ese) device(s) in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).*

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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.).
Obelis s.a. is ISO 9001 : 2015 and ISO 13485 : 2016 certified.

*This certificate will become void automatically upon termination of the EAR agreement

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Annex A - List of Devices

(Article 9, section 1 of the Directive 93/42/EEC on medical 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 / GIVD Code	Class and Rule under IVDD	Class and Rule under IVDR
1.	D-NCOV-19	DSI COVID-19 Ag RAPID TEST	Rapid Antigen Test for Novel Corona Virus (nCOVID-19)	DSI Covid-19 Ag Rapid Test is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in nasopharyngeal swab, using the rapid immunochromatographic method.	15.70.04.01	All Others	Class D Rule 1

Obelis s.a.

Date: 06/05/2022

Stamp

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