Obelis GROUP

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E.A.R. - CERTIFICATE

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

Reference No.: VR 0409-2022

Date: 06/05/2022

Order No.: EU AB 0174 - 2022

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

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

Product Category(ies): Please See Annex A - List of Devices (1 Device, 1 Page)

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

The European Authorized Representative Obelis s.a. declares that the aforementioned manufacturer has fulfilled the 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 20/01/2022 **

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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 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

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 Obelis s.a. - O.E.A.R.C.
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