Obelis GROUP

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CERTIFICATE OF IVDR LEGACY DEVICE

Reference No.:

Date: 12/02/2024

Order No.: EU JC 0442-2023

This is to certify that the following devices fall into the scope of Article 110.3 of the Regulation (EU) 2017/746. Obelis s.a. maintains a copy of product related technical documentation including key procedures of the manufacturer's quality management system. Obelis s.a. has verified that the following manufacturer complies with the IVDR articles related to registration of economic operators and devices, market surveillance, post-market surveillance including vigilance:

Name: Geneyx Genomex Ltd.

Address: 11/B Galgaley-Haplada St.
Herzliya, 4672211 Israel

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED REGULATION:

The above mentioned devices fall under the scope of Article 110 IVDR (as amended by REGULATION (EU) 2022/112) and have a Declaration Of Conformity in accordance with Directive 98/79/EC prior to 26 May 2022.

By way of derogation to Article 5 of the IVDR, those devices may be placed on the market or put into service until 26 May 2026 provided there are no significant changes in the design or intended purpose and provided that IVDR Articles 10.2, 10.7, 10.8, 10.9, 10.10, 10.11, 10.12, 10.13, 10.14, 10.15 as well as Articles 11 to 15, Art 26 and 28, Articles 82 to 87 and Articles 88 to 95 are complied with.

The application of Article 110.3 becomes void in case any significant change is made to the devices listed in the Annex A.

DEVICES NAME AND DESCRIPTION: PLEASE SE ANNEX A - LIST OF DEVICES

(1 Device, 1 page)

According to the IVDR, the manufacturer can continue to place its devices listed in Annex A on the European Union market until 26 May 2026 except in case of significant change to their device. The manufacturer may place these devices in the European Union territory with Obelis s.a. as European Authorised Representative.

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Mr. G. Elkayam CEO
Obelis sa

EAAR

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.

This certificate will become void automatically upon termination of the EAR agreement or removal of the products from EAR Mandate

Order No.: EU JC 0442-2023
Ref No.:

Annex A - List of Devices

Regulation (EU) 2017/746 on in vitro diagnostic medical devices

#	Catalogue reference number	Commercial Name	Short description and intended use	Device already on the EU market? (y/n)	Legacy Device (y/n)	GMDN	EMDN	BASIC UDI - DI	Risk class & Classification Rule IVDD	Risk class & Classification Rule IVDR
1	N/A	Geneyx Analysis	An in vitro diagnostic interpretive software program intended to be used for the analysis and visualization of human genome data from in vitro diagnostic results obtained through molecular genetic testing (e.g., whole genome, targeted genome, or exome analyses). It provides predictive and/or diagnostic information (e.g., gene-drug associations, congenital and/or acquired aneuploidy status, genotype-phenotype relationships) used by a professional in the assessment of patient adverse health condition risk, disease prevention, and/or health management, or for lifestyle guidance as pertains to a patient genomic profile.	Yes	Yes	65871	W02079092	N/A	All others	Class C, Rule 3i

OBELIS SA

Date

Stamp