CERTIFICATE OF IVD NOTIFICATION

Ref. No.: FD 0536-2021

Order No.: MA 0377-2020

BELGIUM

Date: 11/01/2021

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: BIO-HELIX CO., LTD.

ADDRESS: ROOM 312, MAF BLDG, NO.2
BEINING RD.,
KEELUNG CITY TAIWAN 202

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) 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 devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 08/01/2021 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 2 DEVICES)

As of the 09/01/2021 and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

G. ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Bruxelles
Tel: +32.2.732.59.54 - Fax: +32.2.732.60.03

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 will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Order No.: MA 0377-2020
Ref No.: FD 0536-2021

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 / GIVD Code	Class
1.	PDC03	Virus Nucleic Acid Isolation Kit (Column based)	Extraction Kit	The Virus Nucleic Acid Isolation kit provides a fast simple and effective method for the isolation of viral DNA/ RNA from cell-free samples such as serum, plasma, body fluids and the supernatant of virus-infected cell cultures. Its unique buffer system will efficiently lyse cells and degrade protein, allowing for the nucleic acid to be easily bound by the glass fiber matrix of the column.	15.90.40.01	All others
2.	PDM04	Mbead Virus Genomic Nucleic Acid Kit (Mbeads Based)	Extraction Kit	MBead Virus Genomic Nucleic Acid Kit was designed specifically for genomic DNA/RNA isolation from Virus samples. Its special buffer system will efficiently lyse cell and degrade protein, allowing for DNA/RNA to be easily bound by the surface of the magnetic beads.	15.90.40.01	All Others

* 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 (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

** 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.

G. ELKAYAM C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03