CERTIFICATE OF IVD NOTIFICATION

Ref. No.: EZ 0734-2021

Order No.: OG 0582-2021

BELGIUM

Date: 10/02/2021

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: MICROBIX BIOSYSTEMS INC.

ADDRESS: 265 WATLINE AVENUE, MISSISSAUGA, ONTARIO L4Z 1P3, CANADA

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 05/02/2021 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 06/02/2021, 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 General Wahis 53
1030 Brussels
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.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B – 1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 – ID: 00454716 – 22/02/2019

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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.	RED-S-19-02	REDx™FLOQ® SARS-CoV-2 Ag Swab Positive Control	Unassayed SARS-CoV-2 Ag swab positive control	For IVD use as unassayed positive swab control intended to monitor the laboratory testing performance, procedures and workflow with immunodiagnostic assays that detect SARS-CoV-2 nucleoprotein antigen.	64922	All others
2.	RED-S-99-01	REDx™FLOQ® Respiratory Swab Negative Control	Unassayed SARS-CoV-2 Ag swab negative control	For IVD use as unassayed negative swab control intended to monitor the laboratory testing performance, procedures and workflow with immunodiagnostic assays.	64922	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 (IVD 98/79/EC).

Obelis s.a.

Signature: _____

Date: 10/02/2021

Stamp:

G.ELKAYAM C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
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Microbix Not Certificate

Final Audit Report 2021-02-11

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