EU DECLARATION OF CONFORMITY
According to Annex IV of the IVD Regulation 2017/746

Manufacturer: LaCAR MDx technologies S.A
SRN: BE-MF-000001212

Registered place and location:
Liège Science Park
10, Rue des Chasseurs Ardennais
4031 Liège (Belgium)

As manufacturer, we state that:

- This EU declaration of conformity is issued under our own responsibility.
- The device covered by the present declaration is in conformity with this Regulation.

Basic UDI-DI	Product Code	Product Name	EMDN Code	Risk Class
5430002471A02E010100BF	GeneFox	GeneFox	W02079092	Class A according to annex VIII Implementing rule 1.4 and the classification rule 5 b)

Intended purpose: GeneFox is an In Vitro Diagnostic Medical Device Software designed to allow a semi-automatic external interpretation suggestion of qualitative melting/anneal curve analysis following the use of LaCAR MDx Technologies kits on the validated instruments. GeneFox recreates the melting/anneal curve for each sample and gives the opportunity to set up interpretation criteria for each created kit. Those criteria are the following:

- Temperatures ranges (in which peaks are expected to be seen)
- Threshold (lower limit under which no peak should be detected)
- Suggested results linked to the observation of the peaks in the different set ranges

This In Vitro Diagnostic Medical Device Software is dedicated to professional use in diagnostic laboratory.

References of standards:
NBN EN ISO 13485:2016
NBN EN ISO 14971:2019
CEN ISO/TR 24971:2020
NBN ISO 16142-2:2021
IEC 62304:2006
ISO 18113-1:2022
NBN EN ISO 15223-1: 2021

LaCAR MDx technologies S.A has a Quality System in place based on ISO 13485.
This declaration is signed by the Manufacturer established in Belgium.

Place and Date
Liège, September, 08th 2023
Arnaud Allaer, C.E.O