EC DECLARATION OF CONFORMITY
According to Annex III of the IVD Directive 98/79/EC

This is to certify that following IVD products:

LC-2ndMTHFR-LP : LAMP Human MTHFR 2nd mutation KIT (rs1801131)

Manufactured by:

LaCAR MDx technologies S.A
Liège Science Park
10, Rue des Chasseurs Ardennais
4031 Liège (Belgium)

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.

2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
    a. availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
    b. the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
    c. the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

3. ***LaCAR MDx technologies S.A*** has a Quality System in place based on ISO 13485.

4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

This declaration is signed by the Manufacturer established in Belgium.

Arnaud Allaer, C.E.O

July, 25th 2022