

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

This is to certify that following IVD products:

LC-HLAB27Direct-LP : LAMP Human HLA-B27 direct detection KIT

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