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Cerba Research
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Declaration of Conformity (DoC) to the regulation (EU) 2017/746 Anti-AAV9 human IgG ELISA

23-Jan-2026

Cerba Research Europe B.V, an independent legal entity, represented by its Managing Director, Mrs Maria Fotiu, states that the requirements specified in regulation (EU) 2017/746 (IVDR), Article 5(5) have been fulfilled for the in vitro diagnostic device entitled: **Anti-AAV9 human IgG ELISA**.

This DoC is issued under the sole responsibility of Cerba Research Europe B.V. The **Anti-AAV9 human IgG ELISA** is an in-house diagnostic assay for which IVDR is applicable, and exempted from CE marking. The **Anti-AAV9 human IgG ELISA** is classified as Risk Class C (IVDR Annex VIII). Common Specifications (CS) are not applicable. The conformity assessment route follows the requirements stated in Article 5(5) of the IVDR. These requirements do not state the involvement of a notified body, making the device self-declared. A trade name is not assigned.

Name of the IVD: **Anti-AAV9 human IgG ELISA**
Unique Identification: **13052403** (catalogue number)
Address : Marconistraat 16, 3029 AK Rotterdam, The Netherlands

Cerba Research Europe B.V. has in place an ISO15189:2022 quality management system registered in the Netherlands, accredited by the Board of Accreditation, under registration number M010., Testing for anti-AAV9 human IgG antibodies is in scope of the accreditation under code MM.VID.16. This QMS is supplemented with a Risk Management System according to ISO14971:2019 and a Post Marketing Surveillance as specified in Annex III of the IVDR. Conformity to IVDR Annex I is documented in the Technical Dossier "Summary Technical Documentation IVDR-ELISA AAV9" and is considered appropriate for conforming to the IVDR for the manufacture and use of **the Anti-AAV9 human IgG ELISA**.

The Unique Device Identification (UDI) system as defined in the IVDR is not applicable for in-house tests. The identification of the **Anti-AAV9 human IgG ELISA** is made unique through the catalogue number mentioned above. To allow further specification, the intended use of the **Anti-AAV9 human IgG ELISA** is as follows: The adeno-associated virus serotype 9 (AAV9) immunoglobulin G (IgG) enzyme-linked immunosorbent assay (ELISA), is designed to estimate circulating anti-AAV9 antibody titers in human serum by detecting the specific binding of serum IgG antibodies to AAV9 capsid proteins immobilized on a microplate and quantified through an enzymatic colorimetric reaction. This assay is used to determine the AAV9 IgG titer in human sera for the screening of patients receiving AAV9 based gene therapy.

First Declaration of Conformity for the **Anti-AAV9 human IgG ELISA** is signed at 21 May 2024.

Maria Fotiu
Managing Director | Cerba Research Europe B.V.

Signed by:
Maria G. Fotiu
Signer Name: Maria G. Fotiu
Signing Reason: I approve this document
Signing Time: 26 January 2026 | 13:53:29 CET
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