EC DECLARATION OF CONFORMITY

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

This is to certify that following IVD devices:

REF	Description
740001	CRP ELISA
740011	hsCRP ELISA

Classified in the IVD Directive 98/79/EC as Other Device, not part of Annex II list A or list B, and therefore eligible for CE marking by self-declaration.

Manufactured by: Advanced Practical Diagnostics BV, Raadsherenstraat 3, 2300 Turnhout, 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. The manufacturer declares to fulfil the obligations imposed by Annex III section 2 to 5:
   - 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.
   - 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).
   - 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. The manufacturer has a Quality System in place based on EN ISO13485:2016, issued by TÜV Süd.

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

Signature:

R. Berghmans
RA Responsible

Date: 02/02/2024