EU Declaration of conformity

according to Annex IV of Regulation (EU) 2017/746

Manufacturer

Name	APIRO Diagnostics Kft.
Address	Liget utca 3/2, 2040 Budaörs, Hungary
Phone / email / web	+36 30 203 3334 / info@apiro.eu / www.apiro.eu
Single Registration Number	HU-MF-000043501

We, APIRO Diagnostics Kft., hereby declare under our sole responsibility that the products listed in the appendix "Products" are in conformity with the Regulation (EU) 2017/746, common specifications listed in the appendix "Common specifications" (if any) and all applied standards listed in the appendix "Applied standards". This declaration of conformity is issued according to Article 17 and Annex IV of the Regulation (EU) 2017/746.

Notified body

Name	3EC International a.s.
Address	Hraničná 18, 821 05 Bratislava, Slovakia
Identification Number	2265
Conformity Assessment procedure	Conformity assessment based on a quality management system and on assessment of technical documentation (pursuant to Annex IX of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices)
EU certificate number	2025-IVDR/QS-007/A
EU certificate expiry date	2030-10-07

Signed for and on behalf of APIRO Diagnostics Kft.

Alexey Davidov *(Aleksejs Davidovs)*
CQCO, PRRC

Budaörs, 2026-01-13
Place, Date

APIRO Diagnostics Kft.
Liget utca 3/2,
2040 Budaörs, Hungary

Reg: 13-09-232009
VAT: HU32476219
Tax: 32476219-2-13

Tel: +36 30 203 3334
E-mail: info@apiro.eu
Website: www.apiro.eu

Appendix PRODUCTS

REF	1051EU
Product name	AP
Intended purpose	The AP is a ready to use reagent for in-vitro diagnostic professional use, intended for examination of whole blood clot formation with fibrinolysis inhibition in citrated blood during viscoelastometry analysis.
Basic UDI-DI	59998629921051EU_1UP
GMDN code	30595 - Multiple coagulation factor IVD, reagent
EMDN code	W01030299 - Haemostasis reagents - other
Risk class (EU)	Class C / Classification rules 3j and 3k

Appendix COMMON SPECIFICATIONS

Common specifications as defined in the IVDR have not been developed to date for the products in scope.

Appendix APPLIED STANDARDS

ISO 2859-1	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 3864-1	Graphical symbols. Safety colours and safety signs - Design principles for safety signs and safety markings
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes
EN 13612	Performance evaluation of in vitro diagnostic medical devices
ISO 14971	Medical devices — Application of risk management to medical devices
ISO 15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO/IEC 17050-1	Conformity assessment - Supplier's declaration of conformity Part 1: General requirements
EN ISO 17511	In vitro diagnostic medical devices Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials
EN ISO 18113-1	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-2	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 2: In vitro diagnostic reagents for professional use
ISO 20417	Medical devices — Information to be supplied by the manufacturer
ISO 20916	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
EN ISO 22870	Point-of-care testing (POCT). Requirements for quality and competence
EN ISO 23640	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
IEC 62366-1	Medical devices — Part 1: Application of usability engineering to medical devices
IEC/IEEE 82079-1	Preparation of information for use (instructions for use) of products – Part 1: Principles and general requirements

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