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.
Conformity assessment procedure for the products listed in the appendix "Products" does not require the involvement of a notified body according to point (10) of Article 48 and point (1) of Article 51 of the Regulation (EU) 2017/746.

Signed for and on behalf of APIRO Diagnostics Kft.

Alexey Davidov
CQCO, PRRC

Budaörs, 2025-11-20
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	4011EU
Product name	Cups & Pins
Intended purpose	The Cups & Pins are single use specimen receptacles for professional use, intended for viscoelastometry analysis of citrated blood samples.
Basic UDI-DI	59998629924011EU_1UU
GMDN code	62225 - Assay container IVD, single-use
EMDN code	W0202029085 - Various hemostasis instruments - Consumables
Risk class (EU)	Class A / Classification rule 5c

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 18113-1	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-3	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) Part 3: In vitro diagnostic instruments for professional use
ISO 20417	Medical devices — Information to be supplied by the manufacturer
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

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