ΦΑΙΝΟΤΥΠΟΣ

ΑΙΜΑΤΟΛΟΓΙΚΟ ΔΙΑΓΝΩΣΤΙΚΟ ΚΕΝΤΡΟ

PUBLIC DECLARATION

regarding the manufacture and use of in-house devices by health institutions

(in accordance with Article 5(5) of Regulation (EU) 2017/746 — IVDR — and the format proposed in Annex A of MDCG 2023-1)

Name of health institution: ΦΑΙΝΟΤΥΠΟΣ ΙΑΤΡΙΚΗ ΙΚΕ (Phenotypos Iatriki IKE)

Address: Κατεχάκη 40Α, 11525 Αθήνα, Ελλάδα — Operating License No. 56862015

ΦΑΙΝΟΤΥΠΟΣ ΙΑΤΡΙΚΗ ΙΚΕ declares that the devices described in the accompanying table are only manufactured and used in ΦΑΙΝΟΤΥΠΟΣ ΙΑΤΡΙΚΗ ΙΚΕ and do meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Quality management. The manufacture and use of the in-house device(s) listed below take place under a quality management system accredited to EN ISO 15189:2022. Aspects of the manufacturing process and risk management not covered by EN ISO 15189 are addressed by incorporating relevant elements of EN ISO 13485 (manufacturing) and EN ISO 14971 (risk management), as recommended in section 3.5 of MDCG 2023-1.

Date and location: Athens, 28/04/2026_____

Name, function and signature of responsible person:

IOANNIS G. ANAGNOSTOPOULOS, MD, PhD

Biopathologist — Flow Cytometry Expert

Scientific Coordinator & Laboratory Director

Hellenic Medical Association Reg. No.: 062126

Signature: _____

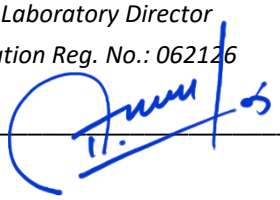

Table of in-house devices

Device identification (e.g. name, description, reference number)	Device type (IVD/MD)	Risk class of the device	Intended purpose	Applicable GSPR fully met? (Y/N)	Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR)
Phenotypos In-House B-ALL MRD Assay Reference: ΕΠ-06.03 (rev. 03, 17.12.2024) Description: 10-colour multiparameter flow cytometry protocol for the detection and quantification of Measurable Residual Disease (MRD), primarily in B-cell Acute Lymphoblastic Leukaemia (B-ALL); additionally validated for application in Chronic Lymphocytic Leukaemia (CLL), Acute Myeloid Leukaemia (AML), Multiple Myeloma (MM), and Myelodysplastic Neoplasms (MDS), as per disease-specific panels. Antibody panel: CD45, CD34, CD3, CD19, CD38, CD10, CD24, CD20, CD22, CD304. Platform: Beckman Coulter Navios (3 lasers / 10 colours, CE-IVD); analysis with Kaluza Flow Analysis Software.	IVD (in-house)	Class C (Annex VIII IVDR, Rule 3)	Detection and quantification of Measurable Residual Disease (MRD) by multiparameter flow cytometry in bone marrow and/or peripheral blood specimens from patients with diagnosed haematological malignancy — primarily B-ALL, additionally CLL, AML, MM, and MDS. Used for monitoring of response to therapy and informing of clinical management decisions, in line with international consensus guidelines (EuroFlow, ERIC, iwCLL, ELN, IMWG as applicable). Documented analytical performance: LoD ≥0.003% (3×10^{-5}), LoQ ≥0.005% (5×10^{-5}), acquisition target 1×10^{6} nucleated events.	**Y**	Not applicable — all applicable GSPR of Annex I IVDR are fully met.

Supplementary information

Justification for in-house manufacture (Article 5(5)(d) IVDR). At the time of putting into service, no equivalent CE-marked IVD device meeting the specific needs of the target patient group at the appropriate level of performance (LoD $\leq 10^{-4}$ for B-ALL MRD by flow cytometry, with the panel composition required by current consensus guidelines) was available on the Hellenic market. This justification is reviewed periodically, including consultation of EUDAMED.

External quality assessment. The laboratory participates in the UK NEQAS Leucocyte Immunophenotyping External Quality Assessment scheme.

Review and update. This declaration is reviewed regularly and updated as necessary, in accordance with section 3.8 of MDCG 2023-1.