IVDR Performance Evaluation Plan: Working Outline

A ten-section structure covering the Annex XIII content requirements in review order, with drafting reminders from MDCG 2022-2 and MDCG 2025-5. Companion article with full explanations: evysaif.com/blog/ivdr-performance-evaluation-pep/

Sections 1 to 4: set the frame

- [ ] 1. Device description, intended purpose, and claims (analyte, function, population, specimen, user)
- [ ] 2. Applicable GSPRs the evaluation supports
- [ ] 3. State of the art: condition, current diagnostic practice, comparator methods, expected performance levels
- [ ] 4. Standards, common specifications, and guidance applied, with versions

Sections 5 to 8: define the program

- [ ] 5. Scientific validity: existing evidence, search and appraisal methodology, gaps, and any studies planned
- [ ] 6. Analytical performance: characteristics to be demonstrated, study protocols and methods, acceptance criteria
- [ ] 7. Clinical performance: evidence route with written justification (Article 56(4) makes studies the default unless reliance on other sources is duly justified), studies or literature/routine-data methodology, acceptance criteria
- [ ] 8. Benefit-risk: parameters and pre-defined criteria for acceptability determination

Sections 9 and 10: keep it alive

- [ ] 9. PMPF: methods, data sources, analyses, and how findings update the evaluation
- [ ] 10. Governance: responsibilities, qualifications, review triggers, and update schedule, with the PER update cycle stated (at least annual for Class C and D)

Drafting reminders

- [ ] Write the PEP before the studies it plans; MDCG 2025-5 confirms it need not accompany a performance study application but must be available to the competent authority on request
- [ ] Set acceptance criteria in advance and defend them against the state of the art section
- [ ] Keep the PEP consistent with the risk management file; reviewers read them side by side
- [ ] Analytical performance is expected to be demonstrated through studies of your device in essentially all cases (MDCG 2025-5)

Reflects the position as of August 2026. There is no official EU template for the PEP; check any structure, including this one, line by line against Annex XIII. For PEP and PER writing or remediation support: info@evysaif.com or +91 94135 73253