IVDR Technical Documentation Checklist

A completeness check for your technical documentation file under the In Vitro Diagnostic Regulation (EU) 2017/746. Every line traces to Annex II or Annex III. Companion article with full explanations: evysaif.com/blog/ivdr-technical-documentation-guide/

1. Device description and specification

- [ ] Product name, general description, and intended purpose statement covering analyte, function, condition, specimen type, population, and user
- [ ] Basic UDI-DI assigned
- [ ] Assay principle and components (antibodies, antigens, primers, calibrators, controls)
- [ ] Variants, configurations, and accessories listed completely
- [ ] Specimen collection and transport materials or specifications
- [ ] Previous generations and similar devices referenced

2. Information supplied by the manufacturer

- [ ] Labels for the device and every packaging configuration
- [ ] IFU in required languages, current versions, with change history
- [ ] Self-test or near-patient additional content where applicable

3. Design and manufacturing

- [ ] Design process description
- [ ] Manufacturing process description with in-process and release controls
- [ ] All sites, critical suppliers, and subcontractors identified with roles and controls

4. General safety and performance requirements (GSPRs)

- [ ] Checklist covering every Annex I requirement
- [ ] Applicability justified for every N/A
- [ ] Standards cited with dates and application scope
- [ ] Pinpoint cross-references to evidence

5. Risk management

- [ ] Risk management plan, analysis, evaluation, controls, and verification (ISO 14971)
- [ ] Overall residual risk evaluation and benefit-risk conclusion
- [ ] Consistency verified against IFU and performance data

6. Verification and validation

- [ ] Scientific validity report
- [ ] Analytical performance studies covering all claimed characteristics and specimen types
- [ ] Clinical performance evidence (studies, literature, or routine-use data) with documented justification of the route chosen
- [ ] Performance evaluation plan and performance evaluation report, mutually consistent
- [ ] Shelf-life, in-use, and transport stability evidence with commitments for ongoing real-time work
- [ ] Software verification and validation, cybersecurity risk assessment
- [ ] Metrological traceability of calibrators and controls
- [ ] Sterility, measuring function, and compatibility evidence where applicable
- [ ] Class D: common specifications conformity, EURL testing, and batch verification arrangements

7. Post-market documentation (Annex III)

- [ ] PMS plan with device-specific data sources, methods, and action thresholds
- [ ] PMPF plan, or a defensible justification for its absence
- [ ] PMS report (Class A/B) or PSUR (Class C/D, at least annual) current

8. Administrative and 2026 obligations

- [ ] Declaration of conformity current
- [ ] Transition conditions documented for legacy devices (pre-2022 IVDD declaration, no significant change, QMS)
- [ ] Notified body application and written agreement status tracked: Class C written agreement by 26 September 2026; Class B and A sterile application by 26 May 2027, agreement by 26 September 2027
- [ ] EUDAMED actor and device registration complete or scheduled ahead of 28 November 2026 (legacy devices)

Reflects the position as of August 2026, including Regulation (EU) 2024/1860 transition milestones and Commission Decision (EU) 2025/2371 on EUDAMED. This checklist is general information; verify current requirements for your specific device. For gap analysis, authoring, or remediation support: info@evysaif.com or +91 94135 73253