IVDR GSPR Evidence Map: the 20 Annex I Requirements

Regulation (EU) 2017/746, Annex I. Conformity method and evidence documents per requirement. Read with Annex II Section 4.

GSPR	Subject (Annex I)	Conformity method	Evidence documents
1	Performance as intended; safe and effective under normal conditions of use; acceptable benefit-risk	Performance evaluation; risk management	Performance evaluation report; risk management report; intended purpose statement
2	Risks reduced as far as possible without harming the benefit-risk ratio	Risk management	Risk management plan and report; residual risk acceptability record
3	Risk management system, documented and maintained through the lifecycle	Risk management	Risk management plan; hazard analysis; risk management report; post-market inputs
4	Risk control measures: eliminate, protect, inform	Design controls; verification of risk controls	Risk control table with verification references; design verification reports; IFU warnings
5	Risks from use error reduced; intended user considered	Usability engineering	Usability engineering file; formative and summative evaluations; user profile
6	Characteristics and performance kept during the lifetime	Stability and reliability testing	Shelf-life, in-use and transport stability reports; reliability and calibration data
7	Protection during transport and storage	Packaging validation; transport simulation	Packaging validation report; transport study; storage condition study
8	Known and foreseeable risks acceptable against the benefit	Benefit-risk determination	Benefit-risk analysis in the risk management report and performance evaluation report
9	9.1 analytical and clinical performance; 9.2 stability; 9.3 metrological traceability; 9.4 self-testing and near-patient performance	Performance evaluation (one row per 9.1 parameter)	Scientific validity report; analytical and clinical performance reports; stability reports; calibrator and control traceability; lay-user or near-patient study
10	Chemical, physical and biological properties; compatibility with specimens and analytes	Material characterization; verification	Material specifications; biological safety assessment; residue and leachables data; interference studies
11	Infection and microbial contamination; sterile supply	Sterilization validation; contamination control	Sterilization validation; bioburden and packaging integrity data; handling instructions
12	Materials of animal, human or microbial origin	Sourcing and processing controls	Sourcing records; inactivation and processing validation; supplier certificates
13	Construction and interaction with the environment; compatibility; EMC; specimen receptacles	Design verification; compatibility testing	Compatibility and interoperability reports; EMC report; mechanical design verification
14	Diagnostic or measuring function: accuracy, precision, stability, units, display	Measurement performance verification	Accuracy and precision data; measuring range and units specification; display verification
15	Protection against radiation	Radiation safety verification	Radiation emission test report; shielding documentation; or documented non-applicability
16	Electronic programmable systems and software: 16.1 reliability and single fault; 16.2 lifecycle, security, V&V; 16.3 mobile platforms; 16.4 IT requirements	Software lifecycle process; cybersecurity risk management	Software development plan; requirements and architecture; V&V; reports; cybersecurity risk assessment; anomaly list; minimum hardware and IT specification
17	Devices connected to or equipped with an energy source	Electrical safety testing	Electrical safety test report; battery and power supply verification; alarm verification
18	Protection against mechanical and thermal risks	Design verification	Mechanical hazard assessment; surface temperature testing; guarding of moving parts
19	Self-testing and near-patient testing: performance suited to the user, reduced use error, understandable results	Usability and lay-user performance evaluation	Lay-user study; near-patient environment data; result interpretation verification; usability file
20	Label and IFU: 20.1 general; 20.2 label; 20.3 sterile packaging; 20.4.1 IFU; 20.4.2 self-testing and near-patient IFU content	Labeling review against each lettered subclause	Label specifications; IFU with clause-by-clause checklist; symbol check; translations; sterile packaging label

IVD-only entries. Section 9.3: calibrator and control values traceable to reference measurement procedures or reference materials.
Section 9.4: performance checked with lay users (self-testing) or in the actual use setting (near-patient testing).
Class D devices in a group covered by Regulation (EU) 2022/1107 cite the common specification annex in rows 9.1(a), 9.1(b), 9.3 and 9.4(a).

IVDR GSPR Evidence Matrix: Working Rows and Pre-Submission Check

Nine columns that satisfy Annex II Section 4 (a) to (d). Copy the row structure for every applicable subclause.

GSPR and subclause	Requirement (short)	Applies? Y / N / P	Justification (device property)	Conformity method	Standard, CS or other solution (edition)	Evidence document (number, title, rev)	Location (section / folder)	Status / notified body query
9.1(a) precision	Precision (repeatability, reproducibility) achieved as claimed	Y	Quantitative immunoassay; listed 9.1(a) parameter	Performance evaluation	Internal protocol based on CLSI EP05 (other solution)	APR-0117 Rev 03, Sect 6.2, Tables 6 to 8	TD Sect 6.1.2, folder 06	Complete

Row 1 is a worked example (document numbers illustrative). Column 4 names the device property behind every applicable and not-applicable decision.

Pre-submission check

- ☐ Every Annex I section and subclause has a row; Section 9.1 has one row per listed parameter and 20.2 and 20.4.1 one row per lettered item.
- ☐ Every not-applicable or partially applicable row names the device property behind the decision.
- ☐ Every applicable row states the conformity method.
- ☐ Every standard is cited with edition and year, and its harmonized status is confirmed from the Official Journal list under the IVDR.
- ☐ Where the listed edition differs from the edition applied, a gap assessment is referenced.
- ☐ Class D devices in a group covered by Regulation (EU) 2022/1107 cite the common specification annex and the data against each criterion.
- ☐ Every evidence reference gives document number, revision and section; no reference reads "see technical file".
- ☐ Sections 2 to 5 and 8 reference the hazard analysis, risk control table, verification records and benefit-risk determination.
- ☐ Every residual risk in the risk management file has a matching warning or limitation in the IFU, and every IFU warning has a source risk.
- ☐ Every performance claim in the IFU matches the performance evaluation report cited under Section 9.
- ☐ Section 16 rows cite lifecycle plan, requirements, V&V; reports, cybersecurity assessment, anomaly list and the 16.4 IT requirements statement.
- ☐ The matrix is under document control, dated after the latest design, standard, CS, labeling or performance evaluation change, with a revision history.