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# EHDS EHR Conformity Testing: Technical File & Test Harness

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Published by IntuitionLabs · 2026-11-25 · ehds ehr conformity testing · ehds ehr systems · european health data space · eehrxf · ehr technical documentation · eu declaration of conformity ehr · ce marking ehr systems · digital testing environment · ehr interoperability logging component

Original article: https://intuitionlabs.ai/articles/ehds-ehr-conformity-testing-technical-file-test-harness



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## Executive Summary

This report analyses what the European Health Data Space (EHDS) Regulation, Regulation (EU) 2025/327, requires of manufacturers of electronic health record (EHR) systems before they can place a product on the EU market, and translates those duties into a buildable test and evidence backlog. The regulation was published in the Official Journal on 5 March 2025 (www.sanidad.gob.es). It applies generally from 26 March 2027 (eur-lex.europa.eu), but the product obligations phase in by data category: from 26 March 2029 for patient summaries, electronic prescriptions and electronic dispensations, and from 26 March 2031 for medical imaging studies and reports, medical test results and discharge reports (www.sanidad.gob.es) (health.ec.europa.eu). The Commission's own pages describe these as "early 2029" and "early 2031".

The core duty is narrow but strict. An EHR system must contain two harmonised software components, an interoperability component and a logging component (health.ec.europa.eu). Manufacturers must test both in a European or Member State digital testing environment before market placement, include the results in technical documentation, draw up an EU declaration of conformity, affix the CE marking and register the system in a public EU database (www.sanidad.gob.es) (eur-lex.europa.eu). Passing elements are presumed conforming (eur-lex.europa.eu). The scheme is a self-assessment, not a notified-body certification (eur-lex.europa.eu).

The main uncertainty is that the detailed specifications are not final. As of 25 November 2026, draft implementing acts for the exchange format and for the digital testing environment were open for feedback until 21 and 17 December 2026 respectively (ec.europa.eu), and the common specifications for the two components were listed with Commission adoption planned for the fourth quarter of 2026 (ec.europa.eu). The statutory deadline for the common specifications is 26 March 2027 (eur-lex.europa.eu). Teams should therefore build specification-agnostic harness infrastructure now and bind test content to the final acts later.

Scope is broader than many vendors assume. The Commission calls the definition "deliberately broad" and applies it to systems that feed hospital systems as well as to the hospital systems themselves (www.sanidad.gob.es); a patient-facing app that connects to a health data access service counts (health.ec.europa.eu). A 2022 impact assessment assumed 3,800 to 5,000 products in the EHR systems

market (data.consilium.europa.eu). For planning, this report provides a labeled planning model (not a benchmark), built on hypothetical unit-effort assumptions, that yields roughly 470 person-days for an illustrative mid-size product with three interfaces, six categories, four jurisdictions and two test environments. Medical-device, in vitro diagnostic (IVD) and high-risk AI manufacturers that claim EHR interoperability face a parallel duty to prove compliance with the same essential requirements (eur-lex.europa.eu), but are not obliged to use the testing environment (www.sanidad.gob.es).

# Introduction and Background

EHR vendors, digital-health platform operators, patient-app developers, medical-device and IVD software companies, and health providers that build their own systems share one question: does the EHDS treat our product as an "EHR system", and if so, what must be built and evidenced, by when? This report addresses primary-use product conformity (the exchange of electronic health data for care), not the secondary-use data access regime in Chapter IV of the regulation.

The legal definition is functional. An EHR system is any system whose software, or combination of hardware and software, allows priority-category health data to be stored, intermediated, exported, imported, converted, edited or viewed, and that the manufacturer intends for use by healthcare providers giving care or by patients accessing their data. The Commission clarifies that a system that only handles other data, such as appointment booking, is not an EHR system (health.ec.europa.eu), and that general-purpose software used in a healthcare environment is excluded. "Manufacturer" is not separately defined; the EHDS imports the market-surveillance definition of a person who manufactures, or has designed or manufactured, a product and markets it under its own name or trademark (health.ec.europa.eu).

Two features of the legal design matter for engineering planning. First, the regulation harmonises components, not whole products. The Commission states that the EHDS requirements cover only the two harmonised components, and that Member States may keep requirements on other parts of an EHR system, including procurement rules, provided they do not interfere with those components (health.ec.europa.eu). Second, the evidence model is automated testing followed by manufacturer self-declaration. Recital 36 describes a mandatory conformity self-assessment scheme, and the Commission describes the digital testing environments as an automated means of verifying the harmonised components (health.ec.europa.eu).

This report does not include a product comparison table. It is an analytical reading of public sources as of 25 November 2026 and is not legal advice; teams with borderline products should obtain qualified regulatory counsel and check final implementing acts when published.

# Scope Decision and Effective-Date Roadmap

## Scope decision tree

A practical triage uses four questions, each tied to the definition. First, does the product process any of the six priority categories (patient summaries, electronic prescriptions, electronic dispensations, imaging studies and reports, medical test results, discharge reports)? If not, it is outside the EHR-system definition (health.ec.europa.eu). Second, does the manufacturer intend it for use by healthcare providers in patient care,

or by patients to access their data? Intended purpose, as documented by the manufacturer, drives the answer; the regulation also bars marketing text that suggests uses other than those in the technical documentation. Third, is it general-purpose software? Standard text-processing software is not specifically intended for patient care and does not count (www.sanidad.gob.es). Fourth, is it already a medical device, IVD or high-risk AI system claiming interoperability? Then the parallel Article 27 route applies.

Two scoping subtleties deserve early legal review. Systems manufactured and used within health institutions in the Union, and systems offered as a service, are treated as "put into service", and Chapter III applies to those from 26 March 2031. The Commission also does not require systems to use the exchange format internally; the requirement is the capability to import and export it (www.sanidad.gob.es).

*Table 1* below applies the Commission's published examples to typical product types.

| Product type | Likely status | Basis and caveat |
|---|---|---|
| Pharmacy system reading e-prescriptions and issuing dispensations | In scope | Listed as an in-scope example (www.sanidad.gob.es) |
| Patient portal giving access to prescriptions, imaging reports and lab results | In scope | Listed as an in-scope example (www.sanidad.gob.es); apps connecting to the patient access service count (health.ec.europa.eu) |
| Converter turning legacy EHR output into the exchange format | In scope | Listed as an in-scope example (www.sanidad.gob.es) |
| GP appointment scheduling system | Out of scope | The report's reading of the Commission's out-of-scope examples; confirm against the Commission Q&A |
| Billing system | Out of scope unless it processes diagnosis, medication or other priority-category data to prepare bills | Commission example (www.sanidad.gob.es) |
| Smart thermometer with app, wellness app on non-medical data | Out of scope | The report's reading of the Commission's out-of-scope examples; confirm against the Commission Q&A |
| Smartwatch letting users view their health data | Not an EHR system | Operates outside care provision (www.sanidad.gob.es) |
| Medical device or IVD claiming EHR interoperability | Parallel duty | The report's reading of Article 27: such products must prove compliance with the Annex II interoperability and logging requirements that apply to EHR systems |

Table 1 shows that the dividing line is data category plus intended use, not product label. The most common misjudgements are likely to be middleware and integration engines that "feed" EHR systems, which the Commission's "deliberately broad" reading pulls in, and billing or analytics modules that quietly ingest diagnosis or medication fields.

### Effective-date roadmap

The roadmap has three layers: statutory application dates, implementing-act deadlines and product-side milestones. The regulation applies from 26 March 2027. The product-facing articles (including Articles 25, 26, 27 and 49) apply from 26 March 2029 to the first category group and from 26 March 2031 to the second group (eur-lex.europa.eu). The Commission summarises the practical effect: from 26 March 2029 manufacturers may place on the market only systems complying with the common specifications for the first group.

Implementing acts are the dependency. The Commission must adopt common specifications for the essential requirements by 26 March 2027, and must by implementing act lay down common specifications for the digital testing environment (ec.europa.eu). The required registration data are to be set by delegated act. The status snapshot as of 25 November 2026 is:

- **Exchange format (EEHRxF) implementing act:** draft open for feedback from 23 November to 21 December 2026 (ec.europa.eu); the initiative covers all six priority categories (ec.europa.eu).
- **Digital testing environment specifications:** draft open for feedback from 19 November to 17 December 2026 (ec.europa.eu). The Commission will provide the environment as an open-source reference implementation and Member States will deploy and operate their own (ec.europa.eu).
- **Common specifications for the two components:** the Commission lists adoption as planned for the fourth quarter of 2026 (ec.europa.eu).
- **Registration data (delegated act):** no adopted act was located in the sources reviewed for this report; treat the data schema as unfixed.
- **Already adopted, adjacent acts:** the MyHealth@EU implementing regulation of 18 September 2026 (Implementing Regulation (EU) 2026/2083) and the EHDS Board implementing regulation of 7 April 2026 (Implementing Regulation (EU) 2026/771). An independent tracker shows the EHDS Committee held its eleventh meeting on 22 October 2026 (ehdsexplorer.eu).

These drafts are the specifications that this report labels "not yet fixed". Everything below that depends on test content, data formats or registration fields should be read as design guidance to be re-bound once the acts are final.

## Key Changes: Article-by-Article Conformity Duties

### Change 1: Two harmonised components become a market-access condition

Article 25 requires EHR systems to include a European interoperability software component and a European logging software component (health.ec.europa.eu). The definitions state that each component is independent of the other, which has an architectural consequence: the two should be separately testable, versioned and documentable. Article 30 adds that the components must not be adversely affected by other software components of the same EHR system, and that procedures must ensure continuing compliance as design changes. In practice that is a regression-testing obligation across the whole product, not only inside the components.

Annex II sets the essential requirements. For interoperability, a system designed to store or intermediate data must provide an interface giving access to the data in the exchange format (eur-lex.europa.eu); structured-entry functionality must capture data with sufficient granularity to produce it; and the components must not impede authorised export for the purpose of replacing the product. For security and logging, systems must provide reliable authentication of health professionals, log at least who accessed the data and when (eur-lex.europa.eu), offer tools to review log data or support external tools, and support different retention periods and access rights by origin and category.

### Change 2: Digital testing environments replace self-chosen test evidence

Article 40 has four parts: the Commission develops a testing environment and publishes its software as open source; Member States operate their own environments; manufacturers must use them before market placement, and elements with positive results are presumed conforming; and the Commission sets common specifications by implementing act. The EU database platform page says the environments provide automated testing and that manufacturers will access them through the platform (health.ec.europa.eu).

The Commission's Q&A adds operating detail: a failed test yields feedback on which parts failed and the manufacturer may retry; only the final, successful report must be made available; and a system that fails the tests may not be placed on the market (www.sanidad.gob.es). For engineering, this means the official environment is a release gate, and the internal harness is a pre-gate whose purpose is to make the official run boring.

### Change 3: Technical documentation becomes a living evidence file

Article 37 requires technical documentation drawn up before market placement and kept up to date, containing at least the Annex III elements and a reference to the digital testing environment results (eur-lex.europa.eu). Annex III requires, among other items, a system architecture description showing how components feed into each other and the results and critical analyses of all verification and validation tests (eur-lex.europa.eu). Manufacturers must keep the file, and the declaration, for 10 years after placing the system on the market (eur-lex.europa.eu), and must produce it to a market surveillance authority within 30 days of a request. If a manufacturer does not comply, the authority may require an independent-body test at the manufacturer's expense. Source code or programming logic must be made available to authorities on reasoned request where necessary to check compliance.

**Public or confidential?** The sources differ. The Commission's certification page says test results are to be included "in public technical documentation" (health.ec.europa.eu), whereas Article 37 as published speaks of supplying the file to market surveillance authorities and the Q&A says only the successful test report has to be made available. Until implementing acts or guidance settle this, a prudent design separates a publishable summary (intended purpose, supported standards and versions, test result summary) from a confidential engineering annex (architecture detail, source references, internal analyses).

### Change 4: EU declaration, information sheet and CE marking

The EU declaration states that the essential requirements in Annex II have been fulfilled, and where other Union acts also require a declaration, a single declaration covers them all (eur-lex.europa.eu). By issuing it, the manufacturer assumes responsibility for compliance of the harmonised components; a digital declaration

must stay online for the expected lifetime of the system and at least 10 years. Annex IV requires the declaration to be complemented by the testing-environment result. The information sheet (Article 38) may be replaced by entering its content in the EU database. The CE marking must be affixed visibly, legibly and indelibly to the accompanying documents before market placement (eur-lex.europa.eu). The Commission notes that CE marking helps providers identify systems that can support citizens' rights under the EHDS (health.ec.europa.eu).

### Change 5: Registration in the EU database

Before placing a system on the market or putting it into service, the manufacturer or authorised representative must enter the required data, including the Article 40 results, into the EU database; the Commission maintains that database as publicly available. The platform page lists registration as the step that allows a system to be placed on the market (health.ec.europa.eu). Medical devices, IVDs and high-risk AI systems claiming interoperability must also be registered in their own databases, with the data forwarded to the EHDS database.

### Change 6: Ongoing manufacturer duties and updates

Beyond the launch gate, manufacturers must run complaint channels and keep registers of complaints and of non-conforming systems. Updates trigger re-assessment only if they are a "substantial change", which the Commission describes by three cumulative conditions borrowed from other product legislation (www.sanidad.gob.es). A pragmatic reading is to re-run the full conformance suite on every release that touches the components, and to document a substantial-change decision record for the rest.

## Reference Architecture: Test Harness and Evidence Pipeline

### System components and data flow

A buildable architecture separates five layers. (1) **Product boundary**: the EHR system's internal stores and user interfaces, which the EHDS does not require to use the exchange format internally. (2) **Interoperability component**: a mapping and serialisation service that exports and imports priority-category data in the exchange format. (3) **Identity and access layer**: health-professional authentication, which Annex II requires. (4) **Logging component**: an access-event recorder with a review capability. (5) **Evidence layer**: a requirements and test management store that links Annex II clauses to test cases and results.

The exchange format itself is defined by the Commission as including harmonised datasets, coding systems and technical interoperability specifications (health.ec.europa.eu), and the draft specifications are being published as HL7 Europe FHIR implementation guides. As of the dates shown on their pages, the Laboratory Report guide is at version 2.1.0 (hl7.eu), the Hospital Discharge Report guide at 1.0.0 (hl7.eu), the Medication Prescription and Dispense guide at 1.0.0 (hl7.eu), the European Patient Summary guide at 1.0.0-ballot (hl7.eu), the imaging report guide in ballot form (build.fhir.org) and an EU Health Data API guide in ballot form (build.fhir.org). These are industry and project specifications, not yet the legal exchange format; the binding content will come from the implementing act.

## Test design principles from the draft conformity scheme

The Xt-EHR joint action's draft conformity assessment scheme is the most detailed public design for what testing may look like. Its principles translate directly into harness requirements: the full test plan should cover 100% of identified requirements (ncez.mzcr.cz); test cases are uniquely identified and versioned, grouped by feature, with the test tools and their versions listed (ncez.mzcr.cz); and if test cases are automated the applicant can self-assess, otherwise review by a neutral third party is recommended (ncez.mzcr.cz). The draft includes dedicated test-case sections for the logging component (ncez.mzcr.cz) and for content producers of laboratory results (ncez.mzcr.cz). It is a draft for stakeholder consultation and not a legal text, so any test identifiers below are illustrative.

Industry has organised around this. The IHE Europe industry group (X-Net) has produced comments on the Xt-EHR deliverables including the conformity scheme (www.ihe-europe.net), and an Xt-EHR Projectathon organised by Xt-EHR and IHE-Europe provided a hands-on environment for vendors to test the proposed specifications (connectathon.ihe-europe.net).

## Test catalogue

*Table 2* proposes a catalogue of test families for the two components. It is a design proposal derived from Annex II and the draft scheme's structure, not an official test list, and every row must be rebound to the final common specifications.

| Family | What to automate | Annex II anchor | Status of the underlying specification |
|---|---|---|---|
| Export conformance | Generate documents or resources for each priority category and validate against the profile | Section 2.1 | Not fixed: awaiting EEHRxF implementing act (ec.europa.eu) |
| Import conformance | Ingest conformant and edge-case payloads, confirm lossless storage or display | Section 2 (receipt of data) | Not fixed |
| Entry granularity | Trace structured-entry fields to exchange-format elements, flag unmappable fields | Section 2.4 | Not fixed |
| Export without lock-in | Bulk export test: full patient record exported for system replacement | Section 2.6 | Requirement fixed; test method not fixed |
| Authentication | Health-professional login events bound to identities | Section 3.1 | Identity specifications pending |
| Access-event logging | Each read creates a log record with who, which person, which categories, when, origin | Section 3.2 | Minimum content fixed; format via common specification |
| Log review | Query and analysis function, or external tool connection | Section 3.3 | Requirement fixed |
| Retention and access rights | Per-origin, per-category retention and role rules | Section 3.4 | Requirement fixed |
| Component isolation | Regression tests proving other modules do not impair the components | Article 30(1)(b) | Requirement fixed |

Table 2 separates what is already legally fixed (the existence and minimum content of logging, the export and entry requirements) from what is not (profiles, value sets and the exact test oracle). The practical consequence is that logging tests can be written substantially now, while export and import tests should be built as parameterised suites with the profile as an input.

### Evidence lifecycle

The evidence pipeline should run in six stages: requirement baseline (Annex II clauses and, later, common specification clauses, each with a version); test implementation (unique test IDs, tool versions, test data); continuous integration (every build runs the internal suite and stores signed results); release candidate run against the official or a Member State environment; technical-file assembly (Annex III items 1 to 6 populated from the evidence store); and declaration and registration. The key design choice is immutability: results should be stored as versioned, hash-linked artefacts, because the file must be kept for 10 years and produced within 30 days.

## Cross-Regulation Overlap: MDR, IVDR, AI Act and Cyber Resilience Act

Products may have parts under different frameworks, and each part must meet its own regime (www.sanidad.gob.es). The Commission also notes that the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) are undergoing a targeted revision, so cross-references may change.

**AI Act timing.** Regulation (EU) 2026/1744, the "Digital Omnibus on AI", moves the application date for high-risk obligations under Article 6(2) and Annex III to 2 December 2027 (eur-lex.europa.eu) and for Article 6(1) and Annex I systems to 2 August 2028 (eur-lex.europa.eu). Under our reading, AI embedded in medical devices falls in the Annex I category, but classification of any specific system needs legal analysis.

**Cyber Resilience Act (CRA).** The CRA's main obligations apply from 11 December 2027, with reporting obligations from 11 September 2026 (digital-strategy.ec.europa.eu); manufacturers must now report actively exploited vulnerabilities (digital-strategy.ec.europa.eu). The CRA does not apply to products covered by the MDR or the IVDR (eur-lex.europa.eu), so an EHR system that is not itself a medical device may face both the EHDS and the CRA. That is an inference to confirm with counsel, not a Commission statement.

*Table 3* summarises reuse opportunities.

| Evidence item | EHDS use | Reuse in other regimes |
|---|---|---|
| Architecture description | Annex III item 1(g) | Likely reusable in MDR software documentation and CRA technical documentation (to be confirmed) |
| Verification and validation results | Annex III item 4 | Reusable where the same interoperability tests support a device's interoperability claims (Article 27) |
| Single EU declaration | Combined declaration where several Union acts apply | Same document can cover multiple acts |
| Registration data | EU database for EHR systems | Data forwarded from MDR, IVDR or AI registrations |

| Evidence item | EHDS use | Reuse in other regimes |
|---|---|---|
| Common specifications conformity | Presumption of conformity | Applies equally to devices and AI systems under Article 36 |

Table 3 shows the largest saving is in documentation architecture rather than in tests: one traceability model can feed several technical files. The main exception is the testing environment: device and AI manufacturers are not obliged to use it, whereas EHR-system manufacturers are.

# Implementation Considerations and Process Changes

## Article-to-control traceability and build backlog

*Table 4* converts the five articles into a backlog.

| Article | Duty | Engineering and quality backlog item | Owner |
|---|---|---|---|
| Art. 30 | Conformity, isolation, complaints, 10-year retention | Component isolation tests; complaint register; retention policy for evidence | Quality and engineering |
| Art. 37 | Technical documentation | Evidence store populated from CI; Annex III index | Regulatory affairs |
| Art. 39 | EU declaration | Declaration template; version binding to release | Regulatory affairs |
| Art. 40 | Digital testing | Pre-gate harness; official run in release checklist | Engineering |
| Art. 41 | CE marking | Marking in documentation set before release | Regulatory affairs |
| Art. 49 | Registration | Registration data feed; delegated-act schema adapter | Product and regulatory |

Table 4 deliberately maps every article to a named owner so that no duty is left without an accountable function. The unfixed items are the Article 49 schema and the Article 40 environment specification.

## Procurement and vendor-assessment questions

Providers buying systems can rely on what the Commission says buyers will see: CE marking (www.sanidad.gob.es) and a publicly accessible database entry. Recommended questions to vendors: Which priority categories and which EHR-system functions are declared? Which component versions and common-specification versions were tested, and when? Where is the database entry? How are log data exposed for review? What is the substantial-change policy? What happens to the evidence on version updates? Providers building in-house systems must ask the same questions of their own teams, since such systems are treated as put into service.

A simple scorecard for build, refactor or vendor-assess decisions rates each of the six categories 1 to 5 on four criteria: export/import maturity, logging maturity, test automation maturity and documentation maturity. Scores of 1 or 2 on export or logging suggest refactoring the component rather than wrapping it.

### Planning model (not a benchmark)

The model below is an illustrative calculation. All unit effort values are assumptions made for this report, with no public benchmark behind them. **(Hypothetical Example)** A mid-size product has three interfaces (legacy inbound feed, internal store, outbound API), six priority categories, four national deployments, and two test environments.

- **Mapping:** 12 person-days per interface per category: 12 × 3 × 6 = 216
- **Logging component:** 40 person-days base plus 5 per interface: 40 + 15 = 55
- **Jurisdiction variants:** 4 person-days per category per jurisdiction: 4 × 6 × 4 = 96
- **Test environment runs:** 5 person-days per environment per category: 5 × 2 × 6 = 60
- **Technical file, declaration and registration:** 45 person-days

The total is 472 person-days, roughly 2.2 full-time-equivalent years at 215 productive days. The first wave (three categories) would carry about half of the mapping, jurisdiction and test costs. Teams should replace each constant with measured values from a spike on one category.

### Phased readiness plan

- **Now to the specification adoption window (Q4 2026 to March 2027):** classify products against Table 1; build the evidence store; write logging tests; submit feedback on draft acts (feedback closes 17 and 21 December 2026) (ec.europa.eu).
- **2027:** bind test suites to final common specifications; run pilots in a Member State environment when available; define the substantial-change policy.
- **2028 to early 2029:** complete the first-group categories, assemble the technical file, issue the declaration, register, CE mark.
- **2029 to early 2031:** extend to the second group and to in-house or service-based systems.

## Data Analysis and Evidence

The quantitative evidence on EHDS conformity is thin, which is itself a finding. No public benchmark of per-product conformity cost under the adopted self-assessment scheme was found. The only official cost figures predate the final design.

The 2022 impact assessment assumed 3,800 to 5,000 products in the EHR systems market (data.consilium.europa.eu) and, for a mandatory certification option, costs of EUR 20,000 to 50,000 per EHR product, half internal costs and half certification fees (data.consilium.europa.eu). A separate third-party certification option was estimated at EUR 0.6 to 2.9 billion of total compliance cost for market operators (data.consilium.europa.eu). The final regulation instead adopts self-assessment, so these numbers are best read as order-of-magnitude context, not a budget. The same assessment cited studies suggesting interoperability could generate potential savings of EUR 4.6 billion per year for health services (data.consilium.europa.eu).

A peer-reviewed policy analysis in Frontiers in Medicine concludes that meeting the deadlines presents significant challenges, particularly regarding the scope of EHR systems and specification development (pmc.ncbi.nlm.nih.gov). It warns that constant specification changes can disrupt long development cycles (pmc.ncbi.nlm.nih.gov) and that delays will hit smaller manufacturers hardest (pmc.ncbi.nlm.nih.gov).

Key figures to track are summarised in the lists above and in the tables; the principal quantities are the 10-year retention period, 30-day documentation response time, two harmonised components, six priority categories and two phase dates. These are legal parameters, not measurements. The planning model produces a single illustrative output (472 person-days) and should not be quoted as a market estimate.

## Implications and Future Directions

Three implications follow. First, procurement will likely become the enforcement multiplier: providers can read CE marks and database entries, so vendors without visible conformity will face questions before regulators ask. Second, test tooling is converging on shared specifications; the Commission is producing an open-source reference testing environment and Member States will operate their own (ec.europa.eu), which favours harnesses that can run the same suite against several endpoints. Third, governance is being built in parallel: the Commission established an EHDS Stakeholder Forum and Community in October 2026 (health.ec.europa.eu), and an EHDS Board implementing regulation was adopted in April 2026.

Open questions to monitor: the final content of the exchange format and testing-environment acts; the Article 49 data schema; the exact meaning of "public" technical documentation; interplay with revised MDR/IVDR text; and the national market surveillance designations. On the analysis in this report, a requirements-to-test traceability model, maintained as a living artefact and rebound as acts are finalised, is the lowest-regret investment.

## Frequently Asked Questions (FAQs)

**What technical documentation does the EHDS require for EHR systems?** Article 37 requires documentation containing the Annex III elements and a reference to the digital testing environment results; Annex III includes system description, architecture, test results and analyses, information sheet and declaration copy.

**Is EHDS conformity a self-certification?** Recital 36 describes a mandatory conformity self-assessment scheme; the manufacturer issues the EU declaration and assumes responsibility.

**What are the essential requirements in Annex II?** General, interoperability, and security and logging requirements; see the traceability and test tables above, including export, import, authentication, access logging, review tools and retention.

**How will conformity with the European EHR exchange format be tested?** Through automated testing in European or Member State environments (health.ec.europa.eu); the specification of those environments is still in draft (ec.europa.eu).

**What do the interoperability and logging component tests cover?** Annex II sections 2 and 3 (Table 2). Logging must record who accessed data, which person, categories, time and origin.

**What is in the EU declaration of conformity?** The Annex IV content, including the testing-environment result, in a single declaration where several Union acts apply.

**Do manufacturers need CE marking?** Yes, affixed before market placement.

**What are the manufacturer timelines?** 26 March 2029 for the first group of categories and 26 March 2031 for the second.

**Can an automated FHIR harness replace the official environment?** No. Manufacturers must use the digital testing environments before market placement; an internal harness is a pre-gate only.

## Conclusion

EHDS conformity for EHR products reduces to two testable software components, an automated pre-market assessment, a technical file kept for 10 years, a single EU declaration, CE marking and public registration. The legal skeleton is fixed; the test content is still in draft, with feedback windows closing in December 2026 and a statutory deadline of March 2027 for common specifications. Teams that classify scope now, build a traceable evidence store, automate logging tests first and parameterise export and import tests will be placed to adopt the final specifications with limited rework. The conservative reading of scope, the separation of public and confidential documentation, and the use of the planning model as a template to be replaced with measured effort are the three practical recommendations of this report.

## Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.


1. https://www.sanidad.gob.es/areas/saludDigital/espacioEuropeoDS/docs/ehealth_ehds_qa_en_20260326.pdf
2. https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng
3. https://health.ec.europa.eu/ehealth-digital-health-and-care/certification-ehr-systems_en
4. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/17512-European-Health-Data-Space-specifications-for-the-European-electronic-health-exchange-format-EEHRxF-_en
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# About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

### AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

### Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

### Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

### Work with IntuitionLabs

Explore AI enablement, pharma and biotech software development, data engineering and BI, and Veeva services. Contact IntuitionLabs to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

**Website:** https://intuitionlabs.ai

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