EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

on common specifications in respect of the essential requirements for harmonised software componenets of electronic health record systems listed in Annex II to Regulation (EU) 2025/327

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847([1]), and in particular Article 36, paragraph (1), thereof,

Whereas:

(1) [General] Regulation (EU) 2025/327 seeks to improve access to and control by natural persons over their personal electronic health data and to facilitate the exchange of such data in the context of primary use. To this end, Article 36 of that Regulation empowers the Commission to adopt common specifications for the harmonised components of electronic health record systems (EHR systems), in respect of the essential requirements set out in Annex II to that Regulation. Where relevant, the common specifications are to consider the specificities of medical devices and high-risk AI systems referred to in Article 27(1) and (2) of Regulation (EU) 2025/327, including state-of-the-art standards for health informatics and the European electronic health record exchange format as referred to in Commission Implementing Regulation [under Article 15 EHDS - format].

(2) [Article 1, 3 and Annex I] The requirements laid down in this Regulation aim to facilitate the seamless exchange of personal electronic health data and support the rights of natural persons and health professionals under Regulation (EU) 2025/327. To this end, EHR systems placed on the market ought to comply with the requirements laid down in this Regulation to ensure the secure and free movement of personal electronic health data across the Union. To ensure proportionality, the requirements are defined with reference to the specific data operations performed by each class of EHR system and the extent to which those operations support the implementation of the rights granted to natural persons under Regulation (EU) 2025/327. This is done based on the classification of EHR systems set out in Annex I to this Regulation, which lays down different requirements per class of EHR systems. EHR system classes are not mutually exclusive in the sense that an EHR system could fall under multiple classes, depending on the data operations it is intended to perform by its manufacturer. An EHR system should comply with the respective requirements for each of the classes it falls under.

(3) [Article 1 - Scope] Requirements set out in this Regulation should not apply to EHR systems whose data operations are limited to personal details, contact information and information on insurance, as imposing such requirements on EHR systems limited to processing these main characteristics of the patient summary would be disproportionate to their operations. The requirements should not apply to national contact points for digital health as referred to in Article 23(1) of Regulation (EU) 2025/327, as requirements for national contact points for digital health are established

([1]) OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.

in accordance with rules laid down in [OP please add reference to implementing act adopted further to Article 23 of Regulation (EU) 2025/327].

(4) [Article 1 – Scope] EHR systems that generate raw measurements relating to human health, or parameters, values and indicators obtained through their analysis, should not be subject to the common specifications laid down in this Regulation. Such systems include physiological measurement devices, bedside monitoring equipment, laboratory analysers and instruments measuring biological specimens, their common distinguishing feature being that they produce uncontextualized data, which must be fed into a downstream system to be processed, contextualised, and rendered actionable for healthcare purposes. These feeder systems do not store, present or manage personal electronic health data that fall under the priority categories of Article 14(1) of Regulation 2025/327. Instead, they generate raw data at the point of measurement or analysis. Imposing the requirements laid down in this Regulation on such systems would be disproportionate and technically inappropriate.

(5) [Article 5] EHR systems that have been subject to a substantial modification should be considered to be new products. In terms of proving conformity with Regulation (EU) 2025/327, this triggers the requirement to undergo testing in a digital testing environment pursuant to Article 40 of that Regulation, and to fulfil any obligations under Chapter III thereof, including the updating of the technical documentation and registration into the EU database for EHR systems and wellness applications, referred to in Articles 37 and 49 of that Regulation respectively, as applicable. Modifications that extend the capability of an EHR system to support new priority categories of personal electronic health data referred to in Article 14(1) of Regulation (EU) 2025/327 or new main characteristics of a patient summary should be considered to be substantial. Furthermore, the introduction of new data operations, or significant changes in the technical architecture of an EHR system should be considered to be substantial modifications. Significant changes to the technical architecture of an EHR system may entail, for instance, the replacement of the underlying platform on which the EHR system operates, changes in the data storage technology, such as the replacement of the database engine, major changes in the user interface technology, or the introduction of new integrations that have a significant impact on the data processing operations. Minor modifications, such as bug fixing and security updates with the purpose of restoring functionalities rather than introducing new ones, should not be considered substantial.

(6) [Annex I] The EHR system classification should also determine the level at which the EHR system is required to support the European electronic health record exchange format. The support levels and the related element-level obligations should be those set out in Article 4 of Commission Implementing Regulation [under Article 15 EHDS - format].

(7) [General] The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on [XX XX 2026].

(8) [General] The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 98(1) of Regulation (EU) 2025/327,

HAS ADOPTED THIS Regulation:

Chapter 1
GENERAL PROVISIONS

Article 1
Subject matter and scope

1. This Regulation lays down common specifications for the harmonised software components of EHR systems in respect of the essential requirements laid down in Annex II to Regulation (EU) 2025/327.

2. The common specifications referred to in paragraph 1 shall not apply to EHR systems whose data operations are limited to one or more of the following main characteristics of a patient summary referred to in Annex I to Regulation (EU) 2025/327:

   (a) personal details;

   (b) contact information;

   (c) information on insurance.

3. The common specifications referred to in paragraph 1 shall not apply to the national contact points for digital health referred to in Article 23(1) of Regulation (EU) 2025/327.

4. The common specifications referred to in paragraph 1 shall not apply to feeder systems as defined in Article 2, point (o).

Article 2
Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) the definition of 'healthcare attributes' laid down in Article 2, point (1), of [OP please add reference to Commission Implementing Regulation adopted pursuant to Article 16 of Regulation (EU) 2025/327];

(b) the definition of 'identity matching' laid down in Article 3, point (55), of Regulation (EU) 910/2014;

(c) the definition of 'HL7 FHIR' laid down in Article 1, point (e), of [OP please add reference to Commission Implementing Regulation adopted further to Article 15 of Regulation (EU) 2025/327];

(d) 'store' means the act of saving or retrieving data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 to or from a storage system such as a database;

(e) 'application programming interface' or 'API' means a set of definitions and protocols for building and integrating application software to share data;

(f) 'export through API' means the act of transferring data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 from an EHR system to another EHR system through an API;

(g) ‘export through download’ means the act of creating a copy of data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 for the purpose of downloading it in the European electronic health record exchange format as referred to in Article 15(1) of Regulation (EU) 2025/327;

(h) ‘import through API’ means the act of receiving and accepting data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 from another EHR system through an API;

(i) ‘import through upload’ means the act of receiving and accepting data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 through upload;

(j) ‘intermediate’ means the act of transferring or exchanging data that belong the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 between EHR systems, including, where necessary, the temporary storage of personal electronic health data for the purposes of facilitating that transfer and without introducing any modifications to the data;

(k) ‘convert’ means the transformation, translation, or another change of data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 for the purposes of facilitating interoperability between EHR systems;

(l) ‘edit’ means the act of generating or modifying data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327;

(m) ‘display’ means the act of showing data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 on a screen of a device, enabling the user to view the data;

(n) ‘data operation’ means any act performed by an EHR system that allows data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327 to be stored, exported through an API, exported through download, imported through an API, imported through upload, intermediated, converted, edited, or displayed;

(o) ‘feeder system’ means an EHR system that:

  (i) performs automatic generation of data that belong to the priority categories of personal electronic health data under Article 14(1) of Regulation (EU) 2025/327, and;

  (ii) does not retain personal electronic health data beyond what is strictly necessary for the immediate transmission of results to a receiving system, excluding temporary buffering.

Article 3

Classification of EHR systems

1. The classification of EHR systems and the required support levels of the European electronic health record exchange format referred to in Article 4 of Commission

Implementing Regulation [under Article 15 EHDS - format] are set out in Annex I to this Regulation.

2. Where an EHR system is included in more than one class, that EHR system shall implement the support levels of the European electronic health record exchange format that are required for each of those classes, for the operations covered by each of those classes.

Article 4
Common specifications

1. The general requirements for the harmonised software components of EHR systems referred to in Annex II of Regulation (EU) 2025/327 are set out in Annex II.
2. The requirements for the interoperability component of EHR systems referred to in Annex II of Regulation (EU) 2025/327 are set out in Annex III.
3. The requirements for the security and logging component of EHR systems referred to in Annex II of Regulation (EU) 2025/327 are set out in Annex IV.
4. Where requirements refer to personal electronic health data, these shall apply to all priority categories of personal electronic health data referred to in Article 14(1) of Regulation (EU) 2025/327 that are processed by an EHR system.

Article 5
Substantial modifications

1. An EHR system shall be considered to be a new product when it has undergone any of the following substantial modifications:
    a) an addition of a functionality for processing a new priority category of personal electronic health data referred to in Article 14(1) of Regulation (EU) 2025/327;
    b) an addition of a functionality for processing a new main characteristic of a patient summary referred to in Annex I, point (1), of Regulation (EU) 2025/327;
    c) an introduction of a new data operation;
    d) a significant change in the technical architecture of the EHR system or in the technology used to perform data operations.

Article 6
Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 26 March 2029.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President

Annex I
Classification of EHR systems and data level obligation requirements

Class identifier	**EHR systems included in the class**	**Required level of support of the European electronic health record exchange format as referred to in Article 4 of [Implementing act under Article 15 EHDS]**
EHR-Store	EHR systems that perform the '**store**' data operation	Full
EHR-ExportAPI	EHR systems that perform the '**export through API**' data operation.	Full
EHR-ExportDownload	EHR systems that perform the '**export through download**' data operation.	Full
EHR-ImportAPI	EHR systems that perform the '**import through API**' data operation.	Basic
EHR-ImportUpload	EHR systems that perform the '**import through upload**' data operation.	Basic
EHR-Intermediate	EHR systems that perform the '**intermediate**' data operation.	N/A The EHR system shall transfer personal electronic health data without introducing any modifications.
EHR-Convert	EHR systems that perform the '**convert**' operation.	Full

Class identifier	EHR systems included in the class	Required level of support of the European electronic health record exchange format as referred to in Article 4 of [Implementing act under Article 15 EHDS]
EHR-Edit	EHR systems that perform the '**edit'** operation.	Full
EHR-Display	EHR systems that perform the '**display'** operation.	Basic

Annex II
General requirements

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Topic	Requirement	Explanation

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Topic	Requirement	Explanation
Gen-Installation	**1.2**	All classes of EHR systems set out in Annex I.	**Installation Design & Integrity - Installation**	The harmonised software components of the EHR system shall be designed and developed in such a way that the EHR system can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use.	
Gen-Documentation	**1.2**	All classes of EHR systems set out in Annex I.	**Installation Design & Integrity - Documentation**	The harmonised software components of the EHR systems shall be supplied to their operators with detailed documentation of the installation procedure and configuration.	The documentation may contain prerequisites, step-by-step instructions with or without screenshots, configuration instructions, recommendations for secure operation, verification methods and post-installation tests, troubleshooting and uninstallation procedures.

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Topic	Requirement	Explanation
Gen-PerformanceSafety	**1.1**	All classes of EHR systems set out in Annex I.	**Performance and Patient Safety**	The harmonised software components of EHR systems, during normal conditions of use, shall not prevent the EHR system being used for its intended purpose, shall not have a significant negative impact on the EHR system's performance, and shall not put at risk patient safety.	'Normal conditions of use' means the anticipated operational loads and typical clinical workflows, including expected peak periods in the intended deployment environment. The requirement applies to: (a) the effect of the harmonised software component on the EHR system (performance, responsiveness, availability); (b) the direct safety implications on patient care (loss, corruption, or delay of information). Manufacturers of components intended for high-acuity use should demonstrate capacity and resilience appropriate to that claimed use. 'Not put at risk patient safety' means the avoidance of risk that exceeds the maximum acceptable risk related to the use of harmonised software components, consistent with a high level of protection for the safety and health of patients and established through a documented risk assessment.

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Topic	Requirement	Explanation
Gen-NoUndueBurden	**2.5**	EHR-Store EHR-ExportAPI EHR-ExportDownload EHR-Intermediate EHR-Convert	**No Undue Burden on Access**	The harmonised software components of the EHR system shall not include features that prohibit, restrict or place an undue burden on authorised access, personal electronic health data sharing or use of personal electronic health data for permitted purposes	
Gen-SystemReplacement	**2.6**	EHR-Store	**System Replacement**	The harmonised software components of the EHR system shall allow the authorised export of the personal electronic health data it stores in the European electronic health record exchange format, for the reasons of replacing the EHR system by another product, within a reasonable timeframe and without any technical or procedural impediments that would constitute undue burden.	This requirement focuses on preventing procedural or other functional impediments to data export for the purposes of system replacement.

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Topic	Requirement	Explanation
Gen-Retention	**3.4**	EHR-Store	**Retention**	The harmonised software components of an EHR system that store personal electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.	Different retention periods may apply depending on applicable legislation. The ability to configure retention per data category and origin is necessary to support compliance across different legal frameworks.

Annex III
Requirements for interoperability

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Push and pull				
Iop-Api-Producer-PullGeneral	2.1	EHR-Store EHR-ExportAPI EHR-Intermediate EHR-Convert	The EHR system shall enable other EHR systems to **retrieve** personal electronic health data that it processes through an API that shall comply with the technical interoperability and exchange specifications, and data content specifications laid down in [OP please add reference to the implementing act adopted further to Article 15 of Regulation (EU) 2025/327].	The Commission, in cooperation with the EHDS Board, may publish implementation guides in the form of an 'EHDS API' composed of a set of specific transactions that define how personal electronic health data flows between actors.

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Producer-PushGeneral	2.1	EHR-Store EHR-ExportAPI EHR-Intermediate EHR-Convert	The EHR system shall be able to **submit** the personal electronic health data that it processes to other EHR systems through an API that shall comply with the technical interoperability and exchange specifications, and data content specifications laid down in [OP please add reference to the implementing act adopted further to Article 15 of Regulation (EU) 2025/327].	
Iop-Api-Consumer-PullGeneral	2.2	EHR-Store EHR-ImportAPI EHR-Intermediate EHR-Convert	The EHR system shall be able to **retrieve** personal electronic data through an API that shall comply with the technical interoperability and exchange specifications, and data content specifications laid down in [OP please add reference to the implementing act adopted further to Article 15 of Regulation (EU) 2025/327].	

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Consumer-PushGeneral	2.2	EHR-Store EHR-ImportAPI EHR-Intermediate EHR-Convert	The EHR system shall be able to **receive** personal electronic health data through an API that shall comply with the technical interoperability and exchange specifications, and data content specifications laid down in [OP please add reference to the implementing act adopted further to Article 15 of Regulation (EU) 2025/327].	
Download and upload				
Iop-Producer-Download	**1.3** **2.1**	EHR-ExportDownload	The electronic copy of personal electronic health data for download shall comply with the European electronic health record exchange format. The electronic copy shall be signed by the EHR system.	The Commission, in cooperation with the EHDS Board, may publish implementation guides laying down technical specifications for the electronic signature.

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Consumer-Upload	**1.3** **2.2**	EHR-ImportUpload	Where personal electronic health data uploaded is signed by the issuer using a qualified electronic signature in accordance with Regulation (EU) 910/2014, the EHR system shall verify the electronic signature and accept the data in accordance with Article 7(4) of Regulation (EU) 2025/327. In other cases, the EHR system shall accept the personal electronic health data as data inserted by natural persons or their representatives referred to in Article 5 of Regulation (EU) 2025/327.	Personal electronic health data downloaded in accordance with requirement Iop-Producer-Download shall be accepted by the receiving system as data originating from a healthcare provider if it has been signed by the issuer using a qualified electronic signature in accordance with Regulation (EU) 910/2014. Personal electronic health data which has not been downloaded in accordance with Iop-Producer-Download shall be accepted as data inserted by natural persons or their representatives.
Authorisation				

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Producer-AuthDiscovery	2.1	EHR-Store EHR-ExportAPI	The EHR system shall enable discovery of its authorisation server information so that a consumer can obtain authorisation from the appropriate endpoint. The referenced authorisation server may be integrated in the EHR system or be external to the EHR system.	The discovery of the authorisation server may be achieved through machine-discoverable metadata or through out-of-band administrative configuration. When out-of-band administrative configuration is used, it is the EHR system operator’s responsibility to establish appropriate secure administrative processes to avoid misconfiguration.
Iop-Api-Producer-AuthProvideToken	2.1	EHR-Store EHR-ExportAPI	The EHR system with an integrated authorisation server shall support the issuance of authorisation tokens to consumers using the consumer's registered credentials and scopes of access.	
Iop-Api-Consumer-AuthObtainToken	2.2 2.3	EHR-Store EHR-ImportAPI	The EHR system shall be able to obtain an authorisation token from the producer's designated authorisation server.	

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Producer-AuthRequireToken	2.1	EHR-Store EHR-ExportAPI	The EHR system shall require a valid authorisation token from the consumer. A valid authorisation token shall include at least: 1) Token issuer; 2) Token issuance time; 3) Token expiration time; 4) Token subject, including identification of the healthcare provider and of the natural person (health professional or another authorised user) authorised to access personal electronic health data; 5) Identification of the natural person whose personal electronic health data is authorised to be accessed; 6) Scope of access, such as a transaction type or categories of data authorised to be accessed; 7) Endpoints authorised to be accessed; 8) Electronic signature.	

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Consumer-AuthPresentToken	2.2 2.3	EHR-Store EHR-ImportAPI	The EHR system shall present a valid authorisation token to the producer.	
Natural person lookup and identity matching				
Iop-Api-Producer-NaturalPerson	2.1	EHR-Store EHR-ExportAPI	The EHR system shall implement a natural person lookup API sufficient for a consumer to unambiguously identify the natural person whose personal electronic health data are processed in the EHR system, using the natural person's healthcare attributes as search parameters. The API shall comply with the European electronic health record exchange format.	

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Consumer-NaturalPerson	2.2 2.3	EHR-Store EHR-ImportAPI	The EHR system shall implement a natural person lookup API to unambiguously identify the natural person whose personal electronic health data it processes in an external EHR system, using the natural person's healthcare attributes as search parameters. The API shall comply with the European electronic health record exchange format.	
Iop-IdentityAssociation	1.3	EHR-Store	The EHR system shall store electronic health data under the healthcare attributes of the natural person issued by the Member State of affiliation.	Personal electronic health data stored by the EHR system should be associated to the natural person's healthcare attributes supplied with it, to enable identity matching for any future imports.
Iop-Api-Consumer-IdentityMatch	2.2	EHR-Store EHR-ImportAPI EHR-ImportUpload	The EHR system shall import the personal electronic health data under the healthcare attributes of the natural person regardless of their Member State of affiliation.	The EHR system may need to perform identity matching to correctly associate the imported personal electronic health data to the natural person whose data may already be processed by the EHR system.

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Producer-EntryIdentity	2.4	EHR-Edit	The EHR system shall enable the registration of electronic health data under the healthcare attributes of the natural person issued by the Member State of affiliation.	The EHR system should allow the selection of the Member State of affiliation as part of its functionalities enabling the entry of administrative information about the natural person. Depending on the selection, the EHR system should enable entry of relevant healthcare attributes.
Personal electronic health data search and retrieval				
Iop-Api-Producer-Document	2.1	EHR-Store EHR-ExportAPI	The EHR system shall implement an API that enables an external EHR system to search and retrieve personal electronic health data processed by it as HL7 FHIR Documents in accordance with the European electronic health record exchange format.	

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Consumer-Document	2.2 2.3	EHR-Store EHR-ImportAPI	The EHR system shall implement an API that enables it to search and retrieve personal electronic health data from an external EHR system as HL7 FHIR Documents in accordance with the European electronic health record exchange format.	
Iop-Api-Producer-Resource	2.1	EHR-Store EHR-ExportAPI	The EHR system shall implement an API that enables an external EHR system to search and retrieve personal electronic health data processed by it as individual HL7 FHIR Resources or DICOM objects in accordance with the European electronic health record exchange format.	
Iop-Api-Consumer-Resource	2.2 2.3	EHR-Store EHR-ImportAPI	The EHR system shall implement an API that enables it to search and retrieve personal electronic health data from an external EHR system as individual HL7 FHIR Resources or DICOM objects in accordance with the European electronic health record exchange format.	

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Iop-Api-Encryption	1.4	EHR-Store EHR-ExportAPI EHR-ImportAPI EHR-Intermediate	The EHR system shall implement transport-level encryption in data exchange.	Transport-level encryption may be replaced, where appropriate, by alternative security measures within the EHR system or within the infrastructure in which the EHR system is intended to be operated, such as through the use of private networks and firewalls, to ensure an equivalent level of protection.
Iop-Terminology	2.1	EHR-Store EHR-Edit EHR-ExportAPI EHR-ExportDownload EHR-Convert	The EHR system shall implement retrieval of code systems and value sets from a terminology server and shall be able to include the code, the identifier of the code system and the display name in accordance with the European electronic health record exchange format	There is no requirement to provide a terminology server as part of the EHR system, however the EHR system should be able to use external terminology servers and correctly process all code systems and value sets required by the European electronic health record exchange format.

Annex IV
Requirements for security and logging

Identifier	Essential requirement (Annex II of Regulation (EU) 2025/327)	Applicability	Requirement	Explanation
Sec-UserID	3.1	EHR-Display	Electronic identification implemented by the EHR system shall follow requirements on assurance levels set out in [implementing act under Article 16 EHDS].	
Log-AccessEvent	3.2	EHR-ExportAPI EHR-Intermediate EHR-Convert EHR-Edit EHR-Display	The EHR system shall produce logs for all events in which personal electronic health data are accessed by health professionals or other users of the EHR system. Each log shall record at least the following information on every access event or group of access events. The following information shall be recorded: The identification of the organisation: • organisation name(s); • organisation identifier(s). In case of access by a natural person or health professional: • the specific individual accessing the data,	Access can be enabled by direct access within an EHR system, or by exporting data to another EHR system by submission of data or by enabling the retrieval of data. In situations where a healthcare provider is using a service provider enabled to access the EHR system of the healthcare provider, both organisations shall be identified. In some cases, such as infection control reporting, pharmacovigilance or reimbursement purposes, there may be no natural person accessing the

			identified through a unique identifier; • the role of the individual (e.g. physician, nurse, patient). The purpose of data access: healthcare, reimbursement, statistical purposes, etc. The categories of data accessed. The time and date of access. The origin of data: Identification of the organisation(s) from which the accessed data originates.	data. In such cases, only the organisation is identified.
Log-NaturalPersonAccess	3.2, 3.3	EHR-ExportAPI EHR-Intermediate EHR-Convert EHR-Edit EHR-Display	The EHR system shall include a mechanism for supplying log data to an electronic health data access service. The information made available shall include at least the data referred to in requirement Log-AccessEvent.	A health data access service may be provided directly by the EHR system or by an external electronic health data access service. The data displayed to the natural person by the electronic health data access service may exclude details on the specific individual accessing the data.
Log-Review	3.3	EHR-ExportAPI EHR-Intermediate EHR-Convert EHR-Edit	The EHR system shall include tools or mechanisms to review and analyse the log data, or shall support the connection and use of external software for the same purposes. The access to log review tools shall itself be subject to appropriate access controls.	EHR systems should enable the review and analysis of logs by providing built-in tools to display log data or by providing an API enabling authorised users or external applications to review

		EHR-Display		access events.
Log-Retention	3.4	EHR-ExportAPI EHR-Intermediate EHR-Convert EHR-Edit EHR-Display	The EHR system shall support configurable log retention periods and differentiated user access rights that take into account the origins and categories of electronic health data to which the log entries relate.	Different retention periods may apply depending on applicable legislation. The ability to configure retention per data category and origin is necessary to support compliance across different legal frameworks.