SENSOPAD

SENSING ENDOMETRIOSIS ON PORTABLE AUXILIARY DEVICES

D14.2

Regulatory and Ethics I

FREDA & NTUA

28/02/2026

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Project Information

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Abbreviations

Abbreviation	Meaning
AI Act	Artificial Intelligence Act (Regulation (EU) 2024/1689)
CER	Critical Entities Resilience Directive (EU) 2022/2557
CRA	Cyber Resilience Act (Regulation (EU) 2024/2847)
CRO	Contract Research Organisation
DPIA	Data Protection Impact Assessment
EC	Electrochemical
ED	Endometriosis
EIS	Electrochemical Impedance Spectroscopy
EMC	Electromagnetic Compatibility

gFET	Graphene Field-Effect Transistor
GDPR	General Data Protection Regulation (EU) 2016/679
IFU	Instructions for Use
IVD	In Vitro Diagnostic medical device
IVDR	In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
LCA	Life Cycle Assessment
MDR	Medical Devices Regulation (EU) 2017/745
MF	Microfluidics / Microfluidic
NIS2	Network and Information Security Directive (EU) 2022/2555
POC	Proof of Concept
QMS	Quality Management System
REC/IRB	Research Ethics Committee / Institutional Review Board
REACH	Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals
RED	Radio Equipment Directive 2014/53/EU
RoHS	Restriction of Hazardous Substances Directive 2011/65/EU
SENSOPAD	Sensing Endometriosis on Portable Auxiliary Devices
s-LCA	Social Life Cycle Assessment
SOP	Standard Operating Procedure
TRL	Technology Readiness Level
UoO	University of Oxford
WEEE	Waste Electrical and Electronic Equipment Directive 2012/19/EU

Table 1: Abbreviations

Executive Summary

SENSOPAD develops a two-stage solution to shorten the diagnostic pathway for endometriosis through non-invasive analysis of menstrual fluid:

• sensoPAD: a layer pad intended for home use.

• sensoMFgFET: a point-of-care (PoC) device for improved analysis in clinical settings.

This deliverable defines an initial regulatory and ethics strategy for M1-M18 and provides a roadmap to M48. From a regulatory perspective, the consortium's current assumption is that the overall solution will be regulated primarily under the In Vitro Diagnostic Medical Devices Regulation (IVDR, Regulation (EU) 2017/746), with potential MDR implications for certain sample-collection components and EU requirements (e.g., radio equipment, chemical restrictions, and cybersecurity).

From an ethics and research integrity perspective, the strategy focuses on responsible involvement of menstruating participants, FAIR and open-science practices, careful handling of return of results and incidental findings, transparency and reproducibility, and responsible governance of any AI-enabled analytics and AI-assisted research tools.

Key outputs of this deliverable include:

• A consolidated mapping of applicable EU legislation and relevant standards across hardware, software, and materials.

• A technical documentation strategy aligned with IVDR Annex II/III, integrated with the project-level risk management and quality processes (Task 6.3).

• A roadmap for performance evidence generation (analytical performance, usability/human factors, and clinical performance) for both stages of the system.

• An ethics and data governance framework covering recruitment, consent, privacy-by-design, security, FAIR/open access, and oversight/incident handling.

• A dedicated research integrity subsection on the responsible use of AI models (e.g., large language models) in research and documentation activities.

1. Introduction to Regulatory Aspects

Endometriosis remains a condition where diagnosis often takes years, in part because symptom patterns are heterogeneous and definitive diagnosis has historically relied on invasive procedures. SENSOPAD responds to this gap by exploring a pathway in which menstrual fluid, already available during routine menstruation, becomes a specimen that can be analysed for biomarkers supporting earlier clinical suspicion. SENSOPAD's ambition is not to replace clinical evaluation, but to reduce delay in the diagnostic pathway (cover even asymptomatic women) by offering non-invasive evidence tools that can be combined with clinical decision making.

The scope of this document covers the regulatory strategy baseline established during Months 1 to 18 and the roadmap to Month 48. It interfaces directly with Task 6.3, which defines the internal project-level risk management and quality management system, by translating external regulatory requirements into concrete documentation and evidence expectations. Where Task 6.3 defines how the consortium designs and tests prototypes in a controlled manner, the present document defines what the consortium must demonstrate, and which records it must preserve, to keep later conformity assessment options open.

2. Methodology

The regulatory strategy is based on a structured partner questionnaire and on consolidated D14.2 drafting coordinated by NTUA and FREDA. Partners provided descriptions of their modules, intended purpose assumptions, standards and procedures already in use, planned verification and validation activities, expected design changes, and data flow considerations relevant to connected components.

The analysis followed a decision-driven approach. Intended purpose narratives were articulated at system and module level; regulatory qualification and preliminary classification hypotheses were examined under IVDR and, where relevant, MDR borderline logic; applicable EU legislation and guidance were mapped to the evolving system architecture; and a standards strategy and technical documentation architecture were defined in a form that partners can support through their own evidence packages. The current regulatory approach reflects the module-specific classification and evidence implications are not lost during consolidation.

3. Results

The regulatory strategy is built around a staged, risk-based path from proof-of-concept development to a market-ready in vitro diagnostic (IVD) solution. In M1-M18 the focus is on: (i) clarifying intended purpose and claims, (ii) mapping applicable legislation and standards, (iii) establishing the structure of technical documentation, and (iv) defining a performance evidence plan that can be scaled to later clinical evaluation and conformity assessment. The strategy is intentionally iterative: any change in intended use, assay chemistry, system architecture, data flows, or software functionality triggers a reassessment of classification, risk controls, and documentation needs.

3.1 System overview and intended use narrative

SENSOPAD is designed as a two-stage diagnostic support pathway for endometriosis, leveraging menstrual fluid as a non-invasive sample matrix:

• sensoPAD (wearable, home use): smart sanitary pad enabling screening/triage information during routine menstruation, intended for adult menstruating women (lay users).

• sensoMFgFET (PoC, clinical use): microfluidic processing and graphene FET sensing for confirmatory and/or extended analysis, intended to be operated by trained healthcare professionals in clinical settings.

• Digital ecosystem: mobile application (patient-facing) and secure cloud/dashboard (clinician-facing), supporting data transfer, visualisation, traceability and (potentially) decision support.

This staged approach supports a practical clinical workflow: at-home screening can reduce delays in suspicion and referral, while confirmatory testing remains under clinical oversight.

Table 2. a consolidated snapshot from partner questionnaire responses and will be updated as system architecture and responsibilities evolve.

System element	Main function	Examples of responsible partners (from questionnaire)	Regulatory relevance (illustrative)
sensoPAD materials and absorbent layers	Comfortable and safe fluid handling; controlled delivery to sensor areas	NTUA (SAPs), BIOG3D (electrospun cellulose nanofibers), UNIBO/UDC (sensor chemistry/inks), IRES (hazard/exposure assessment)	Biocompatibility, chemical safety, user comfort; contributes to safety and performance claims.
Autonomous biofuel-cell based sensing and electrochromic read-out	Self-powered measurement element and visual read-out supporting IL-6 related sensing in menstrual fluid	UoC (paper-based glucose fuel cell biosensor, electrochromic read-out, molecular imprinting polymer approach)	IVDR relevance as an in vitro measurement element; material safety for catalysts and polymers; stability and shelf-life evidence; usability of result interpretation.
sensoPAD sensing + electronics + app	Electrochemical measurement (e.g., EIS), data transmission (BLE/NFC), user interface	SG (readout, transmission, power management, firmware, mobile app), SG(integration)	IVDR/MDR (depending on intended use), RED/EMC, cybersecurity, usability/human factors.
sensoMFgFET platform (microfluidics, gFET, electronics)	Menstrual sample processing and DNA extraction; gFET sensing; instrument control and reporting	INL (MF modules), GSEMI (gFET fabrication, ISO 13485), UDC/UNIBO (functionalisation/assay development), SG (readout/transmission, cloud)	IVDR likely applies; analytical/clinical performance, software lifecycle, cybersecurity, electrical safety.

Sample collection / specimen interface	Collection and safe transfer of menstrual effluent for analysis	GLB (Tulipon menstrual effluent collection device), UOXF (clinical workflow and recruitment via CRO)	Potential MDR and/or IVDR relevance (borderline: collection device vs specimen receptacle); usability, safety, IFU.
Transversal evidence and governance inputs	User needs, risk and exposure assessment, social and environmental evaluation	CBS (user research), IRES (occupational safety and LCA planning), WR (advisory and governance), NTUA/FREDA (consolidation)	Inputs that shape intended use, foreseeable misuse, risk controls, and acceptability of claims; supports technical documentation and benefit-risk rationale.

3.2 Regulatory qualification and preliminary classification hypothesis

The system-level regulatory hypothesis is that SENSOPAD will be primarily regulated as an in vitro diagnostic medical device under Regulation (EU) 2017/746. This follows directly from the core medical purpose: analysis of human specimens, outside the body, to provide information concerning a disease state. The consortium treats this as a working assumption because the final intended purpose statement and claim wording are still being refined as prototype results accumulate.

Within that hypothesis, three classification drivers require early attention. ***The first*** is the possibility of genetic or SNP-based testing within the sensoMFgFET pathway, which under the IVDR classification framework is typically associated with higher-risk classes. ***The second*** is the way in which results are communicated to lay users in the home-use pathway: the more the system behaves as a self-test that can drive medical decisions without professional mediation, the more the evidence and usability obligations will intensify. ***The third*** is software, including any data-driven predictive tool, because software that drives or influences IVD results must be governed as part of the device and will normally inherit the device risk class. Module-level partner inputs show variations in emphasis that must be reconciled into a single system story. The University of Coimbra module, for example, proposes a disposable, self-powered IL-6-related biosensor integrated into the pad and suggests that IVDR Annex VIII Rule 3 may apply, with a preliminary view toward Class C depending on the clinical relevance of the marker and how results may influence patient management. Other partners describe components as parts of an IVD system rather than as standalone devices, and some modules sit at the MDR-IVDR border, such as specimen collection devices. The regulatory strategy, therefore, recommends treating classification as an evolving hypothesis that will be revisited in the next updated version of the Ethics and Regulatory Strategy (i.e., Tasks 15.3 & 16.3, and D15.2 & D16.2).3.4 Applicable EU legislation and compliance requirements

Beyond IVDR, SENSOPAD must comply with EU requirements that apply to connected electronics, materials, and data processing. These requirements shape design decisions such as whether a wearable module contains a battery, how wireless connectivity is implemented, where cloud services are hosted, and how chemical substances in inks and catalysts are selected. Because SENSOPAD is a connected system, compliance must be handled coherently across partners rather than as isolated component checklists.

The current register is intentionally conservative and will be refined as the SENSOPAD Project implementation progresses. The table below summarises the baseline mapping used during M1 to M18.

Table 3. Baseline mapping during M1 to M18.

EU instrument	Compliance topic	Primary SENSOPAD touchpoints (examples)
Regulation (EU) 2017/746 (IVDR)	IVD safety and performance, technical documentation, performance evaluation, post-market processes	System intended purpose, assay performance, software influencing results, clinical performance planning, traceability to risk controls.
Regulation (EU) 2017/745 (MDR)	Medical device obligations for components that qualify as devices or accessories	Specimen collection and interface devices, potential accessories, labelling and IFU decisions for borderlines.
Regulation (EU) 2016/679 (GDPR)	Lawful processing of personal data, transparency, rights, security, accountability	User studies, clinical studies, connected device data flows, cloud platform storage, audit logs and retention rules.
Directive 2014/53/EU (RED) and EMC rules	Radio safety, EMC, spectrum use, and security-related requirements for radio equipment	Wearable BLE/NFC communication, clinician device Wi-Fi/Bluetooth, antenna design, interference risk, secure pairing.
Regulation (EC) No 1907/2006 (REACH) and Directive 2011/65/EU (RoHS)	Restricted substances, chemical safety, declarations for electrical and electronic equipment	Electronics, inks, adhesives, catalysts, and any user-exposed materials in pads or collection devices.
Directive 2012/19/EU (WEEE) and Regulation (EU) 2023/1542 (Batteries)	End-of-life obligations, battery handling, removability and replaceability expectations	Disposable electronics strategy, battery-less design exploration, disposal instructions, and environmental documentation.
Regulation (EU) 2024/2847 (Cyber Resilience Act)	Security by design, vulnerability handling, documentation for products with digital elements	Firmware, mobile application, cloud platform, dashboards, software update mechanisms and vulnerability disclosure process.
Regulation (EU) 2024/1689 (AI Act) and medical device software guidance	Obligations for high-risk AI and transparency requirements where applicable	Any predictive analytics influencing clinical interpretation, governance of training data provenance and monitoring.
Worker protection and laboratory safety directives and national rules	Biosafety, chemical exposure, occupational health and safety	Manufacturing and laboratory activities; handling of menstrual fluid, reagents, and nanoparticles; exposure assessment work.

3.3 Standards strategy and quality system alignment

The consortium applies a standards-led approach to make evidence generation predictable and to reduce later rework. Partners report different organisational baselines, ranging from ISO 13485-certified manufacturing environments to research-oriented laboratories operating under internal SOPs and academic governance. The standards baseline below is therefore expressed as a strategy: which standards matter now for M1 to M18 evidence, and which standards must be progressively adopted as prototypes move toward clinical validation and market readiness.

Table 4. Standards baseline

Standard or guidance	Why it matters for SENSOPAD	M1-M18 focus and evidence examples
ISO 13485	Quality management system expectations for medical devices and IVDs	Applied by certified partners such as gFET manufacturing; informs system-level documentation handover format and change control expectations.
ISO 14971	Risk management framework linked to safety and performance	Hazard identification and risk controls across materials, electronics, biosafety, cybersecurity and usability; interface to Task 6.3 risk file.
IEC 62304	Medical device software lifecycle processes	Foundation for governing mobile app, cloud services and firmware documentation; supports traceability, maintenance planning and problem resolution.
IEC 62366-1	Usability engineering linked to safety	User needs and foreseeable misuse inputs from user research translated into usability requirements, critical tasks and evaluation endpoints.
ISO 10993-1 and ISO 10993-5	Biological evaluation and cytotoxicity principles for user-contact materials	In vitro screening of pad layers, inks and related materials; supports safety-by-design and justification of material choices.
IEC 60601-1 and IEC 60601-1-2 (as applicable)	Electrical safety and EMC for medical electrical equipment	Relevant for clinician-operated point-of-care instrument as it matures; supports design constraints and verification planning.
IEC 81001-5-1 and ISO/IEC 27001 (as applicable)	Cybersecurity and information security management practices	Supports security-by-design, secure development practices, and governance of sensitive health data in connected systems.
ISO 20916 and ICH GCP E6 (for later phases)	Good practice for clinical performance studies and clinical research governance	Used to plan later clinical performance evidence; informs protocol structure, data quality and participant protection.

3.4 Technical documentation strategy (IVDR Annex II/III oriented)

A central output is a technical documentation architecture that can absorb partner evidence without losing traceability. The architecture is aligned to IVDR Annex II (technical documentation) and Annex III (post-market surveillance documentation) and is designed to be modular. Partners provide controlled extracts of documentation, test reports, and design descriptions, which are consolidated into a coherent system-level technical file.

At this stage, technical documentation is treated as a living structure rather than a frozen submission package. The emphasis is on the evidence chain. A design choice is only defensible if it can be traced to a requirement, a hazard or risk control, and a verification or validation result, and if changes are controlled so that evidence remains valid. The architecture, therefore, includes device description and intended purpose, design and manufacturing information, GSPR mapping, risk management documentation, performance evaluation documentation, software and cybersecurity documentation, usability documentation, and post-market planning appropriate to the maturity level.

Because SENSOPAD is distributed across multiple organisations, document control interfaces matter. The regulatory strategy recommends that each module provide a minimum evidence package with stable identifiers and version history. Certified partners can leverage existing document control processes, while research partners can align through project-level templates and shared repositories. The practical goal is to make evidence portable across partners, not to standardise everyone's internal systems.

3.5 Minimum evidence set for M1-M18

Evidence generation under IVDR is framed by performance evaluation, which includes scientific validity, analytical performance, and clinical performance. In M1 to M18, the project is necessarily focused on feasibility and analytical verification rather than formal clinical performance. Even so, it is possible to structure M1 to M18 evidence so it remains usable later, provided that protocols, acceptance criteria, and traceability are recorded early.

Partner inputs provide concrete examples of M1-M18 evidence that can feed into the technical file. Microfluidic modules are benchmarked against target endpoints for red blood cell removal, cell sorting efficiency, lysis success, and DNA capture and recovery. Pad materials and inks are evaluated through absorbency and mechanical tests, combined with in vitro toxicological screening aligned to internationally recognised thresholds. The University of Coimbra module reports bench testing focused on analytical performance parameters such as linearity, limit of detection, and selectivity for IL-6 in buffer and synthetic menstrual fluid, with additional checks for interference from blood components and linkage to an electrochromic colour-change read-out.

In parallel, system integration evidence is generated for electronics, connectivity, and software, including energy budgets, internal communication integrity, data transfer reliability, and clarity of user-facing outputs. The regulatory strategy treats this evidence as essential because, for connected IVDs, failures in data handling and user guidance can become safety issues even when the underlying sensor chemistry performs well. The evidence checklist in the table below summarises the minimum evidence package expected from each module at this stage.

Table 5. minimum evidence package expected from each module at this stage.

Evidence item	Purpose	Examples of sources in M1-M18
Component descriptions and interfaces	Define system architecture and regulatory scope	Partner questionnaires; CAD/BoM extracts; integration notes. NTUA electrospinning in silico modelling approach.
Material safety and biocompatibility screening	Support safe-by-design and user-contact safety	BIOG3D in vitro assays; IRES hazard/exposure assessment; material datasheets. NTUA materials synthesis.
Prototype verification testing	Demonstrate basic functional performance against requirements	INL microfluidic module performance; SG electronics integration tests; GLB mechanical tests.
Cybersecurity baseline and data flow mapping	Establish security-by-design foundations and privacy-by-design alignment	Architecture descriptions for app/cloud; encryption/authentication approach; initial threat analysis.
User needs and usability inputs	Support usability engineering and intended user definition	CBS qualitative study outputs; preliminary user stories and requirements. UoO pilot study clinical protocol.
Change control log (high level)	Ensure traceability of significant design choices	UNIBO chemistry changes; SG kit selection; GSEMI ISO 13485 change control; IRES iterative risk reassessment.

3.6 Digital components, cybersecurity and interoperability strategy

SENSOPAD includes firmware, mobile software, cloud services and clinician-facing dashboards. The regulatory strategy therefore treats cybersecurity and interoperability as core safety and performance topics. This is reinforced by horizontal cybersecurity legislation, but it is also a direct IVDR concern: results must not be altered in transit, access must be controlled, and auditability must allow investigation of anomalies and complaints.

In M1 to M18, the strategy focuses on establishing baseline digital architecture decisions that can scale. These include authenticated access for clinician-facing components, controlled pairing and authorisation for patient devices, encryption of data in transit and at rest, logging of relevant events for auditability, and definition of a vulnerability management process that covers third-party software and dependencies. Interoperability is treated as a planned capability rather than an immediate deliverable, because premature integration with external clinical systems can create uncontrolled data flows and undermine traceability.

A specific risk for later phases is the introduction of predictive analytics. The regulatory strategy recommends that any model that influences interpretation be governed as a controlled design item. Training and validation datasets must be documented, subgroup performance must be monitored, explainability must align with user group needs, and model updates must trigger a formal change impact

assessment. Treating models as research-only artefacts would create high regulatory and reputational risk once clinical decision-making is involved.3.11 Configuration management, changes and regulatory impact assessment

Iterative optimisation is expected for a project at this maturity, but it creates a regulatory hazard if changes are not controlled. The regulatory strategy therefore formalises configuration management principles that apply across modules: definition of configuration items at system and module level, recording of changes with rationale and evidence impact, and decision gates aligned with project milestones where classification and documentation assumptions are reviewed.

Configuration control is particularly important for changes that affect intended purpose, clinical claims, specimen type, assay chemistry, algorithmic processing, or safety-critical functions such as wireless communication and power supply. Introducing a battery into a disposable wearable module, for example, may materially change environmental and safety obligations and may trigger additional test evidence. Changing catalyst materials in a self-powered biosensor can alter toxicological assumptions and stability. In each case, the regulatory impact must be assessed before the change becomes embedded in the system3.12 Regulatory roadmap (M1-M48)

The roadmap below summarises how the regulatory strategy evolves across the three project phases. It is intended as a planning tool and will be updated as the device design and clinical strategy mature.

Table 6. Regulatory Roadmap

Phase	Primary regulatory outputs	Key dependencies and decisions
M1-M18 (current deliverable scope)	Regulatory hypothesis and classification rationale; legislation/standards register; technical file structure; initial risk management integration; prototype verification evidence planning.	Clarify intended purpose and claims; define device boundaries (sensoPAD vs sensoMFgFET vs accessories); initial cybersecurity architecture; confirm sample-collection regulatory pathway.
M18-M36	Expanded technical documentation; performance evaluation plans and interim reports; usability engineering evidence; cybersecurity validation plan; supplier and manufacturing controls.	Clinical study design finalisation (CRO); selection of harmonised standards; decisions on sensoPAD power strategy and end-of-life model; confirmation of software roles (decision support vs information) and in silico modeling.
M36-M48	Clinical performance evaluation reports; consolidated technical file; PMS/PMPF plans; conformity assessment readiness package (notified body engagement as needed).	Final intended purpose/claims; final algorithm governance; deployment model (home vs clinician mediated); data retention and post-market monitoring approach.

3. Conclusions

The first 18 months of SENSOPAD established a credible regulatory baseline by converging on an IVDR-oriented system narrative, clarifying module boundaries, and building a living compliance register that includes both medical-device specific and EU requirements.

For the next phase, the consortium will **identify** the intended purpose of the SENSOPAD devices, avoiding over-claiming; **operationalise** traceability across modules so that requirements, hazards, and evidence remain connected as prototypes evolve; and **implement** a unified software and cybersecurity lifecycle that is compatible with IVDR expectations and the broader EU landscape for products with digital elements. If the above elements are addressed early, later clinical performance work can build on a stable regulatory foundation.

4. Introduction to Ethics and Research Integrity

Ethics work in SENSOPAD has three intertwined goals. The first is participant protection in research activities, including respectful recruitment, informed consent, minimisation of burden, and safeguards for vulnerable or stigmatised groups. The second is trustworthy data governance, meaning GDPR-aligned roles, security-by-design, controlled sharing, and clear retention and deletion rules. The third is research integrity, meaning reproducible methods, transparent reporting, and governance that keeps scientific claims proportional to the available evidence.

5. Methodology

The ethics synthesis is based on partner questionnaire inputs coordinated by NTUA and on consolidated D14.2 drafting. Partners described whether and how they involve human participants, which data streams they handle, what safeguards they implement, and how they ensure research integrity and reproducibility. The aim was to surface shared obligations and dependencies without reproducing local ethics application texts.

The analysis followed a risk-based approach. Research activities involving humans were mapped, distinguishing user research, prototype evaluations, and future clinical specimen workflows. Data flows were mapped at a governance level, separating identifiers from analytic datasets and identifying where controller or processor roles will need formal definition. Safeguards were assessed against core principles: autonomy and respect for persons, beneficence and proportionality, justice and non-discrimination, security and confidentiality, and transparency and accountability.

6. Results

6.1 Ethics governance, roles, and accountability

SENSOPAD uses a layered governance model. Local Research Ethics Committees or Institutional Review Boards retain authority over participant-facing studies at each recruiting site. Project-level coordination, led by NTUA, consolidates shared requirements so that participant protection remains consistent even when data and specimens flow across partners. Data protection oversight is implemented through partner institutional policies and Data Protection Officers where applicable, with project-specific decisions documented through consortium governance.

A practical governance point emerging at M18 is the need to keep ethics and regulatory logic aligned. Performance evidence required for IVDR readiness often relies on access to specimens and metadata. The ethics strategy, therefore, emphasises that protocol design, consent language, and data governance must anticipate future reuse of datasets for verification and validation without turning participants into passive data sources. When data are to be reused, transparency and purpose limitation remain essential, and the governance model must make responsibilities explicit rather than assumed.

6.2 Human participants: involvement, recruitment, inclusion and safeguards

During M1 to M18, direct involvement of human participants was primarily concentrated in user research exploring needs, expectations, and acceptance factors among menstruators and clinicians (Task 6.4 – CBS). These activities inform user-centred design decisions, including comfort requirements, communication preferences, and the kinds of support users would expect from a technology dealing with intimate bodily data. Participation is voluntary, supported by clear information materials, and designed to minimise burden through remote options where appropriate.

Clinical specimen workflows are being prepared for later phases. Recruitment of healthy volunteers and endometriosis patients, and collection of menstrual fluid, are expected to be conducted under ethically approved protocols led by our clinical partner (UoO) and supported by a Contract Research Organisation where appropriate. Technical partners that process specimens (NTUA, INL, UoC, UNIBO), such as microfluidic developers (INL) and biosensor laboratories (UoCoimbra, UNIBO), expect to receive anonymised or coded specimens without direct identifiers. For example, the University of Coimbra, as well as NTUA, reports laboratory validation using synthetic menstrual fluid provided by other INL, without directly engaging in recruitment or consent processes.

The ethics strategy recognises foreseeable vulnerabilities even when participation is formally voluntary. Endometriosis can be associated with pain, fatigue, and prior negative experiences with healthcare, which may increase susceptibility to undue influence or misunderstanding of the purpose of an investigational device. Recruitment and communication, therefore, need to avoid therapeutic misconception by clearly separating research participation from clinical diagnosis and by making it clear what the technology can and cannot conclude at each maturity stage.

6.3 Informed consent and withdrawal

Informed consent practices reported by partners (UoO) follow a layered logic: participants receive a clear explanation of the study aim and what participation involves, supported by a more detailed information sheet for those who want to read further. Consent is obtained before any data collection begins and is documented in a form appropriate to the study modality, including remote participation where applicable.

A key point for future phases is consent for secondary use. Even when early user studies are not medical tests, the connected-device architecture and planned analytics create pressure to reuse datasets to improve algorithms or refine communication. The ethics strategy recommends that secondary use is handled explicitly, with optional consent choices where feasible, and with clear explanation of what withdrawal can and cannot achieve. Where datasets are fully anonymised, withdrawal may not be technically possible, which needs to be explained honestly in participant-facing materials.

6.4 Data protection, privacy and data governance

SENSOPAD processes data streams that are sensitive by nature. These include user research data, clinical study data linked to specimens, and device-generated data from connected electronics and software. The ethics strategy therefore treats GDPR compliance as a design requirement. This means data minimisation is enforced at the level of study and app design, identifiers are separated as early as feasible, access is role-based and auditable, and retention periods are defined before data collection scales.

At M18, partners report that user research data are stored on secure institutional systems with restricted access and that consortium sharing is primarily done through anonymised or aggregated outputs. Clinical recruitment and specimen collection are expected to remain under the control of authorised clinical sites, which retain the ability to re-identify participants when clinically justified under protocol, while downstream technical partners work on coded material. The University of Coimbra reports generating laboratory datasets from electrochemical measurements and storing them under institutional control, while receiving only anonymised specimens for validation.

For the connected device pathway, the strategy anticipates a controller and processor mapping that will need to be formalised per study and per deployment model. A practical deliverable for the next phase is a harmonised data flow diagram and study-specific data processing agreements that clarify which partner is controller, joint controller, or processor in each context, how long data are retained, where they are stored, what security measures apply, and how data subject rights are operationalised.

Table 7. Summary of SENSOPAD data streams, outlining typical content, controller context, and key data protection safeguards.

Data stream	Typical content	Primary controller context (illustrative)	Key safeguards and constraints

User research datasets	Demographics, attitudes, usability feedback, interview transcripts or coded themes	Academic research partner conducting the study (e.g., CBS) as controller for its own processing	Informed consent, minimisation, early pseudonymisation, restricted access, aggregation for sharing, careful quote handling to avoid indirect identification.
Clinical specimen-linked datasets	Coded specimen IDs, clinical metadata, assay results, potentially biomarkers and outcomes	Recruiting clinical partner (UoO) or CRO as controller or joint controller (defined per protocol)	Separation of identifiers at site, coded transfer, defined retention, DPIA where required, protocol governance for re-identification and incidental findings.
Device-generated and platform datasets	Sensor measurements, timestamps, app interactions, error logs, potentially dashboard outputs	Deployment-dependent; likely joint controller arrangements for multi-partner platform operation	Security by design, encryption, authentication and authorisation, audit logs, incident response, minimised telemetry, defined update and vulnerability handling process.
Laboratory and engineering datasets	Bench test results, calibration curves, materials characterisation, electrochemical traces	Technical partners for their own datasets (generally non-personal)	Controlled access, versioning, traceability to protocols, careful separation from any personal metadata, open access only for non-personal and non-identifying content.

3.5 Security of systems and incident handling

Security is treated as an ethical safeguard because breaches of sensitive women's health data can cause harm that is not easily reversed. Partners report baseline physical and digital security controls for laboratories and institutional storage. For connected software, security controls are developed in parallel with architecture decisions and include authentication, authorisation, encryption, and access logging.

Incident handling must exist before it is needed. This includes procedures for adverse events in participant-facing studies, data breaches and near misses, cybersecurity vulnerabilities affecting connected components, and research integrity concerns such as protocol deviations or data quality problems. Incidents should be documented, assessed for impact, and used to update risk controls and participant communication, with clear reporting lines to NTUA and to relevant institutional oversight.

3.6 FAIR data, open access, and return of results

SENSOPAD aligns with open science obligations by applying FAIR principles to non-sensitive research outputs while protecting privacy and confidentiality. Partners anticipate using trusted repositories for non-personal datasets and metadata, with persistent identifiers and clear documentation to support reuse and reproducibility. For personal-level datasets involving health information, public release is not appropriate; instead, findings are disseminated in aggregated form and, where necessary, as controlled-access datasets under governance.

Return of results is ethically delicate for a project that includes a home-use sensing stage. A screening output can create anxiety if presented without context, and it can create harm through false reassurance if uncertainty is not communicated. The ethics strategy recommends clinician mediation for outputs with clinical interpretation and a staged communication approach where early prototypes are framed as investigational. If incidental findings arise in clinical performance evaluation, their handling must be protocolised and clinically anchored, rather than improvised by technical teams.

3.7 Responsible use of AI and algorithmic governance

AI-related ethics in SENSOPAD has two dimensions. The first concerns algorithmic analytics embedded in the device ecosystem, such as predictive models supporting triage or decision support. The second concerns AI-assisted tools used during research and documentation, such as language models for drafting or coding support. Both dimensions require explicit guardrails because both can introduce subtle errors and accountability gaps.

At M18, predictive analytics are a planned later-stage activity (based on the data that we can collect and analyze) rather than a deployed system, which allows governance to be designed before deployment. Any future model is treated as a controlled design item. Training and validation data must have documented provenance; representativeness and subgroup performance must be assessed to avoid discrimination across age, symptom profiles, and diverse menstrual health experiences; explainability must be adapted to user group needs; and model updates must trigger change impact assessment and monitoring for drift and systematic error.

For AI-assisted research tools, the baseline safeguards are practical. No personal data or confidential clinical information should be entered into public AI services. Outputs are treated as drafts requiring expert review, with factual claims verified against primary sources. When AI assistance materially influences a deliverable, the process should be documented to preserve transparency and reproducibility rather than undermine them.

3.8 Research integrity, transparency and reproducibility

Research integrity in SENSOPAD is anchored in documented protocols, traceable datasets, and transparent reporting, aligned with partner institutional policies and European research integrity guidance. Partners report that experimental work is documented through SOPs, data sheets, and versioned records, and that progress is reviewed in internal and consortium meetings. These practices are essential because regulatory readiness later depends on whether early feasibility evidence can be trusted and re-used.

As integration increases, reproducibility becomes a system property. Small changes in assay chemistry, microfluidic flow conditions, firmware timing, or data preprocessing can change outcomes. Beyond M18, the consortium should strengthen cross-partner conventions for metadata, protocol versioning, and software version control. These controls reduce the risk of unintentional bias and make it easier to explain results to clinicians and participants in a transparent, non-defensive way.

3.9 Societal values, equity, and sustainability

SENSOPAD's societal promise is to reduce the diagnostic time even for asymptomatic women. The ethics strategy emphasises equity and non-stigmatising communication. User research helps identify language that feels respectful and does not reinforce stereotypes or imply blame. Material and design choices, including scalable low-cost manufacturing and comfort-driven design, are treated as part of equitable access rather than as purely technical concerns.

Environmental sustainability is treated as both compliance and ethics. Partners report early exploration of biodegradable or biobased materials for pad layers, efforts to reduce reagent volumes through microfluidic processing, and analysis of disposal and end-of-life implications for electronics. Life cycle assessment activities planned beyond M18 can provide evidence to support decisions that balance safety, performance, and environmental burden.

3.10 Roadmap to M48

The ethics roadmap mirrors the technical and regulatory roadmap because participant involvement and data governance obligations scale with device maturity. In M1 to M18, the focus is on the consolidation of requirements, baseline GDPR-aligned practices for user research, early data flow mapping, and initial guardrails for AI tool use. In M18 to M36, the focus shifts to ethics approvals for expanded studies, DPIAs where required, refined policies for return of results and incidental findings, and strengthened security controls and access logging for connected systems. The table below summarises the roadmap and highlights dependencies that need early decision-making to avoid late-stage ethical bottlenecks.

Table 8. Ethics roadmap to M48, outlining phase-specific outputs and key dependencies aligned with the project's technical and regulatory progression.

Phase	Primary ethics outputs	Key dependencies and decision points
M1-M18 (baseline)	Consolidated ethics requirements; consent and participant communication principles; baseline GDPR practices for user research; high-level data flow mapping; initial FAIR and open access plan; AI tool use guardrails.	Define study modalities and data categories; clarify controller and processor roles for early studies; agree on what can be shared across partners and in what form.

M18-M36	REC/IRB approvals for expanded studies; DPIAs as needed; operational policies for return of results and incidental findings; strengthened security controls and access logging; publication and repository plan for non-sensitive outputs.	Finalise clinical study design; decide how home-use outputs are communicated; confirm cloud architecture and any international transfer implications; define governance for predictive analytics before deployment.
M36-M48	Ethics monitoring reports; final retention and deletion decisions; long-term governance for connected platform; ethics contributions to post-market style monitoring and complaint handling.	Deployment model choices; sustainability trade-offs; agreed routes for user and clinician feedback, correction and contestation; ongoing vulnerability and incident handling commitments.

5. Conclusions

The current ethics strategy makes explicit that ethics is not only about compliance; it is about protecting trust and scientific validity in a domain where people are understandably sceptical after years of delayed diagnosis and stigma.

6. Next steps

There will be two consecutive and related tasks (Task 15.3 and Task 16.3) following, as well as two corresponding reports, D15.1 “Ethics and Regulatory II” and D16.1 “Ethics and Regulatory III”

Appendix A – Questionnaire

1. Regulatory Strategy Input

The current section is intended to collect from each partner all information relevant to the regulatory strategy of the SENSOPAD system and its modules. FREDA will use the information requested below to analyse the regulatory classification, identify applicable legislation and standards, plan the content of the technical documentation, and assess the impact of any proposed changes to components, modules, or software. **Please answer only regarding the components and activities that fall within your project responsibilities.**

Partner role, tasks and contributions relevant to the SENSOPAD system

Please describe, in concrete terms, the work packages, tasks, and deliverables for which you are responsible (as each partner) that relate to the SENSOPAD devices (sensoPAD and/or sensoMFgFET) or their components. Indicate which hardware modules, software components, data sets, clinical activities or other contributions you provide, their current technology readiness level, and how they integrate into the overall system architecture.

Partner response:

Components, modules and software under your responsibility

For each component, module or software element that you develop, supply or manage, provide a concise description of its function, interfaces, primary materials, key technical specifications, and whether it is intended to be used by patients, healthcare professionals, or only in laboratory or development settings. Clarify whether it will be part of the final SENSOPAD (sensoPAD or sensoMFgFET) product, a prototype used only in research, or a supporting tool.

Partner response:

Intended purpose, target users and use environment

Based on your current understanding, describe the intended purpose of the component(s) you contribute to, for example, screening, diagnosis, monitoring or decision support, the target population, such as adult women with specific conditions or healthy volunteers, and the intended users (such as clinicians, trained technicians or lay users). Describe the expected use environment, for example, hospital, clinic, home or laboratory, and any foreseeable misuse or off-label use that should be taken into account.

Partner response:

Preliminary view on regulatory qualification and classification

For the purposes of SENSOPAD, the overall solution is treated as a candidate in vitro diagnostic medical device under IVDR (EU) 2017/746, consistent with Task 6.3. In this section, you are not asked to make a final system-level regulatory conclusion. Instead, provide component-level input only.

Indicate whether, in your view, the components that you are responsible for are likely to be considered a medical device, an in vitro diagnostic medical device, an accessory, software as a medical device, or a non-medical research tool. Briefly explain your reasoning, including any borderline use cases. If you are already applying a specific classification rule or risk class under Regulation (EU) 2017/745 or Regulation (EU) 2017/746, describe it and identify any uncertainties.

If you are already applying a specific IVDR/MDR classification rule or risk class, cite the rule and explain the reasoning, including borderline use cases and uncertainties. Do not introduce a conflicting overall classification narrative in partner responses.

Partner response:

Applicable EU legislation, guidance and national requirements

Identify any EU regulations, directives, guidance documents or national requirements that you already consider relevant for your components, even if they are not yet fully applied. This can include medical device and in vitro diagnostic regulations; general product safety; radio equipment; electromagnetic compatibility; electrical safety; chemical substances; environmental restrictions; data protection and cybersecurity; and any national ethical or professional rules. Indicate where you see potential gaps or open questions that require further analysis.

Partner response:

Standards, specifications and internal procedures currently followed

Describe the international, European or national standards, technical specifications, corporate policies or internal procedures you currently use or plan to use when designing, developing, testing or validating your components. Examples include risk management, software lifecycle, usability, electrical safety, biocompatibility, information security and quality management. State whether your organisation is already certified to any relevant standard and to which scope and indicate what documentation can be shared within the project. State whether your organisation’s standards and procedures undergo regular updates and how often these updates are made.

Partner response:

Technical documentation, design control and traceability

Explain what technical documentation you currently maintain, or will maintain, for your components, such as design requirements, architecture and design descriptions, drawings, bills of materials, change logs, test plans and reports, verification and validation evidence, and traceability between requirements, risks and tests. Clarify (i) where these documents are stored, (ii) how versions are controlled, and (iii) how you will provide access or extracts to FREDA for the overall technical documentation of SENSOPAD.

Partner response:

Software development, AI or ML lifecycle and data used for algorithms

If you develop software, data processing pipelines, artificial intelligence or machine learning models, describe your development lifecycle, including requirements definition, coding practices, code review, testing, documentation and release management. Specify what data you use for training, validation and testing, how these data sets are curated and documented, how you address potential bias and performance across relevant subgroups of women, how you deal with explainability, and how model changes will be managed over time. Indicate any regulatory or ethical constraints you foresee for your algorithms.

Partner response:

Cybersecurity, connectivity and interoperability

For components that communicate with other devices, systems or cloud services, describe the connectivity architecture, communication protocols and interfaces you foresee. Explain how you plan to manage cybersecurity risks, including user authentication, access control, encryption of data in transit and at rest, vulnerability management, logging and monitoring, and dependencies on third-party software or cloud providers. Identify any interoperability standards or profiles you intend to use.

Partner response:

Verification, validation, performance and usability evaluation

Describe the bench tests, laboratory experiments, simulated use, usability evaluations, clinical performance studies or other forms of verification and validation that you plan to conduct within your tasks. Clarify the objectives, endpoints, success criteria and relevant standards or guidance you intend to follow. Indicate how the results will be documented and made available to FREDA to support the regulatory strategy and, where applicable, future conformity assessment.

Partner response:

Anticipated changes, configuration variants and impact on regulatory strategy

Identify any foreseeable design changes, configuration variants, optional features or alternative materials that may be explored during the project and that could affect the regulatory classification, risk profile or technical documentation of the SENSOPAD system. Describe how you plan to manage these changes in a controlled way, how you will assess their impact, and how you will communicate them to FREDA and the consortium.

Partner response:

Labelling, user documentation, warnings and training

If you are responsible for any instructions for use, user manuals, on-device labelling, electronic information or training materials, describe their planned scope and content. Explain which warnings, precautions, contraindications, maintenance instructions and limitations you expect to be required for safe use, and how you will involve users or clinicians in reviewing the clarity and usability of this information.

Partner response:

Interface with Task 6.3 risk management and Quality Management System

Briefly explain how your current development and testing practices align with, or differ from, a formal medical device or in vitro diagnostic quality management system. Indicate what additional process descriptions, work instructions, records or risk analyses you will provide under Task 6.3, and how they relate to the technical and regulatory information described in this section. Highlight any support you expect from FREDA to adapt your internal processes to the project-level quality management system.

Partner response:

Ethics and research integrity input

This part of the template is intended to collect from each partner all information needed to support the ethical, legal, social and research integrity analysis in Task 14.1. NTUA will use the information to identify ethical challenges, assess compliance with applicable regulations and guidelines, and propose appropriate safeguards and governance measures. Please answer only for the activities, data, and participants that fall within your project responsibilities.

Overview of ethical, legal and social issues in your tasks

Provide an overview of the main ethical, legal, and social issues you anticipate in the tasks you lead or contribute to, including aspects related to the recruitment and involvement of women as participants or users, data protection and privacy, fairness and non-discrimination, the use of artificial intelligence, the return of results, open science, and environmental impact. Indicate whether these issues have already been discussed with local ethics committees or data protection authority officers.

Partner response:

Human participants, recruitment strategies and inclusion criteria

Describe whether and how you will involve human participants or users, including patients, healthy volunteers or professionals, in your tasks. Explain the recruitment pathways, inclusion and exclusion criteria, any vulnerable groups involved, and the measures you will take to avoid undue influence and to ensure fair, transparent and non-discriminatory recruitment of women from diverse backgrounds.

Partner response:

Informed consent process, materials and withdrawal

Explain how informed consent will be obtained from participants or users, including who will obtain consent, at what stage, in which setting and using which information materials. Describe how you will ensure that consent is truly informed, freely given and documented, how you will handle consent for secondary use of data or samples, and how participants can withdraw consent and what the consequences of withdrawal are for data already collected.

Partner response:

Data protection, privacy and data governance

Describe in a step-by-step manner how personal data, including omics data and other sensitive health-related data, will be collected, recorded, stored, accessed, analysed, shared and ultimately archived or deleted in your tasks. Specify the data sources, formats, identifiers, locations of storage, retention periods and who will have access under which conditions. Clarify whether you act as controller, joint controller or processor, and how data protection responsibilities are allocated and documented. Include information on your data management protocols, pseudonymisation keys, back-up procedures, disaster recovery and your policies on data sharing within the consortium and with third parties, if any.

Partner response:

Technical and organisational measures to safeguard rights and freedoms

Describe the technical and organisational measures you will implement to safeguard the rights and freedoms of data subjects and research participants, such as data minimisation, purpose limitation, access control, staff training, documented procedures, privacy by design measures and data protection impact assessments where relevant. Explain how participants will be informed about these safeguards.

Partner response:

Security of systems and equipment used for data processing

Describe the security measures in place to prevent unauthorised access to personal data or to the equipment and systems used for processing, including physical security, user authentication, authorisation concepts, password policies, encryption, network security, logging and monitoring, back-ups and incident response. Indicate whether you apply any specific information security standards or certifications.

Partner response:

Anonymisation, pseudonymisation and re-identification risk

Explain which anonymisation or pseudonymisation techniques you will apply to the different data sets you handle, including omics data, imaging data and sensor data, and at which stage of the data flow they are used. Describe how the key code is managed, who can re-identify data, and under what conditions. If specific data cannot be anonymised or pseudonymised, justify and describe the compensating safeguards you will implement.

Partner response:

International data transfers and collaboration with other partners

If you plan to transfer personal data to any other organisation located outside the EU or EEA, describe the nature and categories of data transferred, the purposes of the transfer, the legal basis, and the transfer mechanism used under Chapter V of the GDPR, such as adequacy decisions, standard contractual clauses, or other appropriate safeguards. Explain how data subjects are informed about such transfers and how you verify and document compliance.

Partner response:

Use of humans and other regulatory approvals

If your tasks involve work with humans, describe the procedures and endpoints, and provide an overview of the ethical approvals, facility authorisations and project authorisations required. Indicate the status

of these approvals and how copies of the authorisations and related protocols will be made available to the consortium. If no animal work is involved, state this explicitly.

Partner response:

FAIR data principles, open access and return of results

Describe how you will apply the FAIR principles, findable, accessible, interoperable and reusable, to the data generated in your tasks while protecting privacy and confidentiality. Explain which data, code or materials you plan to make openly accessible, under which licences and at which stage of the project. Describe whether and how individual or aggregate results will be returned to participants, clinicians or the wider public, and how you will handle incidental findings that may have clinical relevance.

Partner response:

AI ethics, transparency, explainability and accountability

If you use artificial intelligence or machine learning methods, describe how you will address key ethical dimensions such as transparency of the algorithms and processing logic, explainability of outputs for clinicians and users, avoidance of bias and discrimination, robustness and reliability, human oversight and the possibility to contest decisions. Indicate whether you map your approach against existing AI ethics guidelines or regulatory proposals, and how responsibilities for AI-related decisions are allocated within your organisation.

Partner response:

AI/ML (or other algorithmic) analytics used in SENSOPAD

If your SENSOPAD tasks include AI/ML or other algorithmic analytics, describe how you will apply the ALTAI self-assessment together with a Fundamental Rights and Algorithmic Impact Assessment (FRAIA) to identify and mitigate any reasonably foreseeable impacts on fundamental rights. In particular, explain how you will prevent discrimination and bias (including across age and diverse menstrual health profiles), protect privacy and data protection given the sensitivity of women's health data, preserve user autonomy through clear information and meaningful human oversight, and ensure users and clinicians can challenge or correct outputs. Indicate the concrete safeguards you will implement (e.g., traceability and audit logs, transparency/explainability, performance monitoring for systematic errors, incident handling and complaint/correction routes) and who is accountable for these measures within your organisation.

Partner response:

Societal impact, gender and diversity, and democratisation of women's health

Reflect on the broader societal implications of your contribution to SENSOPAD, particularly in promoting equitable access to women's health technologies, avoiding the reinforcement of stereotypes or structural discrimination, and ensuring that the system's benefits are available to diverse groups of

women without unjustified restrictions. Describe any planned activities to involve patients, citizens or civil society organisations in the design, evaluation or dissemination of your work.

Partner response:

Environmental and sustainability aspects of your tasks

Describe the environmental aspects associated with your tasks and components across their life cycle, including the selection of materials and chemicals, manufacturing or laboratory processes, energy consumption, transport and logistics, waste generation, disposal of reagents, cartridges or devices, and end-of-life management. Indicate how you will comply with relevant environmental directives and restrictions, such as those on hazardous substances, packaging and electronic waste, and how you will minimise your environmental footprint and support circularity wherever feasible.

Partner response:

Research integrity, transparency and reproducibility

Explain how you will ensure research integrity and reproducibility in your tasks, including robust study design, appropriate sample sizes where applicable, pre-specification of analysis plans, transparent reporting of methods and results, management of conflicts of interest and clear authorship criteria. Describe how you will document protocols, versions of software and models, parameter settings and analysis scripts to allow verification and, where appropriate, reuse by others.

Partner response:

Ethical oversight, monitoring and incident handling

Describe the mechanisms you will use to monitor ongoing ethical compliance in your tasks, including roles and responsibilities, internal or external oversight, reporting lines to ethics committees or data protection officers, and how deviations, adverse events, data breaches or ethical incidents will be detected, documented, reported and corrected. Indicate how you will keep NTUA and the consortium informed about any significant ethical issues that arise.

Partner response:

Research Ethics Committees (RECs) and Institutional Review Boards (IRBs)

State whether your organisation’s organisational chart includes a Research Ethics Committee or an Institutional Review Board. State whether your project activities require ethics approval/clearance from this REC/IRB, and how this will be obtained.

Appendix C – Bibliography (selected key references)

The references below include key EU legal instruments, guidance documents and standards relevant to the regulatory and ethics strategy. Where ISO/IEC standards are referenced, the latest applicable editions should be consulted through official standardisation bodies.

1. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR).

2. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

3. Regulation (EU) 2016/679 (General Data Protection Regulation, GDPR).

4. Directive 2014/53/EU (Radio Equipment Directive, RED).

5. Regulation (EU) 2023/1542 concerning batteries and waste batteries (Battery Regulation) and Commission Notice C/2025/214 on removability and replaceability guidance.

6. Directive 2011/65/EU (RoHS) and Regulation (EC) No 1907/2006 (REACH).

7. Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

8. Regulation (EU) 2024/2847 (Cyber Resilience Act).

9. Regulation (EU) 2024/1689 (Artificial Intelligence Act).

10. MDCG 2020-16 (rev.) Guidance on classification rules for in vitro diagnostic medical devices under Regulation (EU) 2017/746.

11. ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes.

12. ISO 14971: Medical devices - Application of risk management to medical devices.

13. ISO 10993-1 and ISO 10993-5: Biological evaluation of medical devices (selected parts).

14. IEC 62304: Medical device software - Software life cycle processes.

15. IEC 62366-1: Medical devices - Application of usability engineering to medical devices.

16. IEC 60601-1: Medical electrical equipment - General requirements for basic safety and essential performance.

17. IEC 81001-5-1: Health software and health IT systems safety, effectiveness and security (selected requirements).

18. ISO/IEC 27001: Information security management systems - Requirements.

19. European Commission High-Level Expert Group on AI: Ethics Guidelines for Trustworthy AI and ALTAI self-assessment tool.

20. ALLEA: The European Code of Conduct for Research Integrity (revised edition).

21. FAIR principles: Wilkinson et al. (2016) The FAIR Guiding Principles for scientific data management and stewardship, Scientific Data.

22. ICH E6(R2). Guideline for Good Clinical Practice (GCP).

23. World Medical Association. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (latest revision).

24. ISO 20916: In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice.

25. MDCG 2019-16. Guidance on Cybersecurity for Medical Devices.

26. MDCG 2019-11. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR).

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