COLABMO TECHNICAL GUIDANCE

Medical Electrical Device Regulatory Guidance

Current U.S. and European requirements for Class II, Class IIa and Class IIb medical electrical equipment

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Technical guidance; not a substitute for the approved certification basis, regulatory pathway or contract.

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Purpose and use

This document provides a practical framework for planning U.S. and European regulatory, safety, performance, quality, and lifecycle evidence for Class II, Class IIa, and Class IIb medical electrical equipment, including products with displays, touchscreens, software, wireless functions, and accessories.

The primary audience is the manufacturer, product and systems engineering team, regulatory and quality organization, safety and risk-management team, human-factors and software specialists, test laboratories, suppliers, and conformity-assessment partners. The guidance supports requirements development, evidence planning, design reviews, supplier flowdown, submission readiness, and certification coordination.

> **U.S. and EU regulatory basis.** 21 CFR § 820.10 is the specific Quality Management System Regulation provision requiring a medical-device quality management system; design and development controls flow through § 820.10(c) and incorporated ISO 13485:2016 Clause 7.3. For a traditional Class II premarket notification, 21 CFR Part 807, Subpart E, including § 807.87, defines the required 510(k) information. The EU counterpart is Regulation (EU) 2017/745 (MDR): Article 10(9) requires the manufacturer's quality management system, Annex I defines the General Safety and Performance Requirements, Annexes II and III define technical documentation and post-market documentation, and Annexes IX, X, and XI define conformity-assessment routes. Classification rules and special controls remain product-specific in both markets.

Normative language

Must. Identifies a binding regulatory, approval-basis, certification or contractual obligation once applicable to the product and market.

Shall. Identifies an example requirement that becomes mandatory only when incorporated into an approved product specification, quality-system record, test plan or contract.

Should. Identifies recommended regulatory or engineering practice that requires product-specific tailoring and documented rationale.

Applicability decision

Confirm intended use, users, environments, claims, accessories, software and connectivity, U.S. product code and classification regulation, EU MDR classification rule, applicable standards, and the roles of FDA, the Notified Body, accredited laboratories, and certification bodies before freezing the evidence plan.

Contents

1. Regulatory framing and classification

Medical electrical equipment is not regulated as a separate global regulatory class. It is regulated as a medical device according to intended purpose and risk, then evaluated against safety, performance and lifecycle requirements that are typical for devices containing electrical/electronic circuitry. For most moderate-risk equipment, the regulatory burden comes from the intersection of device classification, general/special controls or GSPRs, quality system obligations, consensus or harmonised standards, and product-specific evidence.

Area	United States	European Union	Requirement consequence
Legal basis	FD&C Act and 21 CFR medical-device regulations, including Parts 801, 803, 806, 807, 812, 814, 820 and 830. [S2]	Regulation (EU) 2017/745 (MDR), especially Articles 10, 51, 52, 61, 83-92 and Annexes I-III, VIII-XI, XIV-XV. [S12]	The regulatory file must map claims and intended use to the applicable legal obligations before test planning begins.
Classification	Class I, II or III by product code, regulation and risk. Class II uses general and special controls. [S3]	Class I, IIa, IIb or III by MDR Annex VIII classification rules. [S12]	Classification sets pathway, depth of review, clinical evidence burden, QMS scrutiny and post-market reporting cadence.
Moderate-risk focus	Class II devices usually require 510(k), unless exempt; De Novo is available for novel low/moderate-risk devices without a predicate. [S4]	Class IIa/IIb require notified-body involvement and technical-documentation assessment, with IIb generally receiving deeper review. [S12]	A moderate-risk electrical device should still be managed as a full technical-file project, not just a test-report project.
Standards role	FDA-recognized consensus standards may support declarations of conformity when edition and extent of recognition match the device. [S5]	Harmonised standards cited in the OJEU provide presumption of conformity only for the covered requirements. [S13]	Every standard claim needs edition control, applicability rationale, deviations, acceptance criteria and traceability to risks and requirements.

1.1 Class differences

Risk band	U.S. class	Typical U.S. route	EU MDR class	Typical EU route	Practical evidence delta
Low	Class I; general controls; many 510(k)-exempt.	Registration/listing, labeling, QMSR where applicable, complaint files and postmarket controls.	Class I; self-declaration unless sterile, measuring or reusable surgical instrument aspects require notified body.	Technical documentation, EU Declaration of Conformity and CE mark.	Lower premarket review, but technical evidence still needed to support claims, safety and labeling.
Moderate	Class II; general + special controls.	510(k), De Novo or exemption check; special controls and consensus standards often central.	Class IIa.	Notified-body QMS and sampled technical documentation review.	Formal risk, V&V, labeling, PMS and clinical evaluation are expected; FDA predicate logic differs from EU GSPR logic.
Moderate/ high	Higher-risk Class II or De Novo Class II.	510(k)/De Novo with deeper performance, software, cyber, clinical or postmarket commitments.	Class IIb.	Notified-body review by generic device group; IIb implantables generally receive device-level technical-documentation review.	Clinical evidence, PMCF, risk controls and essential-performance evidence require stronger justification.
High	Class III.	PMA or other high-risk pathway; IDE for significant-risk investigations.	Class III.	Full notified-body design/technical review; possible expert-panel/clinical consultation for selected devices.	Clinical evidence and lifecycle control are central; equivalence and literature-only strategies are much harder.

2. U.S. Class II pathway and FDA evidence package

The controlling U.S. question is whether the device is legally marketable for the intended use and technological characteristics. For most Class II medical electrical equipment, this means a 510(k) showing substantial equivalence to a predicate, unless the device is exempt or better suited for De Novo. The submission should read like a coherent safety and performance argument, not a bundle of unrelated reports.

FDA workstream	Requirement-level expectation	Evidence artifact	Owner
Classification	Manufacturer shall identify device type, regulation number, product code, panel, class, special controls and exemption status before freezing the regulatory path.	Classification memo, product-code screen, 513(g) or Q-sub record if uncertainty remains.	RA
Predicate strategy	Manufacturer shall compare intended use and technological characteristics against one or more legally marketed predicates.	Substantial-equivalence matrix, differences/risk analysis, performance bridging rationale.	RA / Systems
Special controls	Each special control shall be mapped to design inputs, testing, labeling or postmarket commitments.	Special-controls compliance table.	RA / QA
510(k) / eSTAR	Submission shall include device description, indications, labeling, standards, performance data, software/cyber/HF sections as applicable and administrative content.	eSTAR package, attachments, declarations of conformity, test summaries.	RA

FDA workstream	Requirement-level expectation	Evidence artifact	Owner
QMSR readiness	Manufacturer shall implement design/development, purchasing, production, complaint, CAPA and postmarket processes aligned to QMSR/ISO 13485.	QMS procedures, design records, supplier controls, complaint/MDR procedures.	QA
Postmarket	Manufacturer shall maintain complaint files, MDR reporting, corrections/removals records, registration/listing and UDI/GUDID data.	Procedures, logs, decision trees, reportability records, GUDID entries.	QA / RA

2.1 510(k) evidence depth for medical electrical equipment

- Electrical safety evidence shall identify the tested configuration, accessories, applied parts, power sources, software version, operator/patient environment and essential performance evaluated under IEC 60601-1 and applicable collateral/particular standards.
- EMC evidence shall define intended electromagnetic environments, emissions/immunity test levels, essential-performance acceptance criteria, wireless coexistence assumptions and labeling mitigations.
- Software documentation shall scale to risk and follow FDA software guidance; the file should include software description, architecture, risk analysis, requirements, verification/validation, unresolved anomalies and release version.
- For cyber devices, the premarket file shall include secure design documentation, threat modeling, vulnerability management, SBOM, security architecture, labeling and update/patch strategy consistent with FDA's February 2026 cybersecurity guidance.
- Usability evidence shall justify whether human factors validation is required and, where required, shall include critical-task analysis, formative work, validation protocol, representative users/environments and residual-risk conclusions.
- Biocompatibility shall be risk-based and tied to direct or indirect contact type and duration; unnecessary testing may be avoided only with scientifically supported material, chemical or prior-use rationale.

2.2 U.S. Class II submission readiness checklist

Gate	Pass condition	Typical failure mode
Classification gate	Product code, special controls and exemption status are documented.	Team assumes Class II 510(k) without checking special controls or exemption limitations.
Predicate gate	Predicate differences are tied to risk and performance testing.	Predicate table says 'same' while technology, use environment or software function differs materially.
Standards gate	FDA recognition number, edition and extent of recognition are checked.	Test report uses a newer/older edition without transition rationale.
Risk gate	Risk controls are traceable to verification, labeling and postmarket monitoring.	Risk file exists but does not drive test acceptance criteria.
Submission gate	eSTAR attachments are complete and internally consistent.	Software, cyber, EMC or labeling sections conflict on device version or intended environment.

3. EU MDR Class IIa/IIb pathway and technical documentation

The EU route is not predicate-based. The manufacturer must demonstrate conformity with the MDR General Safety and Performance Requirements (GSPRs), supported by technical documentation, QMS processes, clinical evaluation, PMS/PMCF, UDI and notified-body certification where required. The notified body expects a structured, traceable technical file rather than a collection of test reports.

MDR element	Class IIa expectation	Class IIb expectation	Evidence file
Classification	Annex VIII rule rationale; active therapeutic/diagnostic devices commonly fall into IIa unless higher-risk conditions apply.	Escalation where hazardous energy/substances, vital-parameter monitoring danger, implantability, software rule severity or other rules apply.	Classification memo, intended-purpose statement, rule-by-rule analysis.

MDR element	Class IIa expectation	Class IIb expectation	Evidence file
Conformity route	Article 52 route with notified-body QMS and technical documentation sampling.	Article 52 route with deeper notified-body technical-documentation review per generic device group; IIb implantable review expectations are higher.	Conformity assessment plan, notified-body application, certificate scope.
GSPR evidence	Annex I GSPR checklist mapped to standards, tests, risk controls, clinical evidence and labeling.	Same, with stronger scrutiny for benefit-risk, clinical evidence and risk control verification.	GSPR checklist with objective evidence references.
Technical documentation	Annex II technical documentation and Annex III PMS documentation.	Same, generally with deeper review and higher expectation for representative device justification.	Technical file index, design/manufacturing description, verification, validation, PMS.
Clinical / PMCF	Clinical evaluation required; PMCF required unless justified.	Higher depth, especially for novel, active, implantable, high-risk or claim-heavy devices.	CER, clinical evaluation plan, PMCF plan/report, literature/equivalence/data files.
EUDAMED	Actor, UDI/device, notified-body/certificate and market-surveillance modules mandatory from May 28, 2026 where applicable. [S14]	Same, with certificate and surveillance data particularly relevant.	SRN, Basic UDI-DI, UDI-DI, certificate and registration records.

3.1 EU technical file index

Section	Minimum contents	Common expansion for electrical devices
Device description	Intended purpose, users, patients, variants, accessories, principles of operation, UDI, Basic UDI-DI.	Block diagram, power architecture, applied parts, software architecture, network interfaces, accessories and system configuration.
Design and manufacturing	Specifications, materials, drawings, critical suppliers, manufacturing processes, process validation.	PCB/enclosure/power-supply specs, insulation system, cable/accessory definitions, firmware release control, calibration and servicing processes.
GSPR checklist	Each applicable GSPR, method of conformity, evidence reference and justification for non-applicability.	Tie IEC 60601 clauses, EMC results, software/cyber, usability, biocompatibility and clinical evidence to Annex I.
Risk management	Risk-management plan/report and residual risk/benefit-risk conclusion.	Essential performance, single-fault conditions, electromagnetic disturbances, network hazards, alarm hazards and foreseeable misuse.
Verification/validation	Bench, electrical, EMC, software, cyber, usability, biological, sterilization, packaging, shelf-life and clinical evidence.	Complete configuration control and acceptance criteria linked to GSPRs and risk controls.
PMS documentation	PMS plan, PMCF plan, PSUR/PMS report, vigilance/trend process.	Cyber vulnerability monitoring, field software update monitoring, complaint coding for use error and essential-performance degradation.

4. Quality system, design control and lifecycle requirements

As of February 2, 2026, FDA's QMSR is effective and incorporates ISO 13485:2016 with FDA supplemental requirements. The EU MDR also expects a QMS under Article 10. For a device team, the practical result is a single lifecycle system that can support both U.S. and EU evidence needs when configured carefully.

Lifecycle phase	Requirement statement	Records / objective evidence
Intended purpose	Manufacturer shall define intended purpose, indications, users, patients, clinical environment, operating environment, contraindications and claims before classification is finalized.	Intended-use statement, claims matrix, user/patient profiles, use-environment analysis.

Lifecycle phase	Requirement statement	Records / objective evidence
Design planning	Manufacturer shall plan design stages, reviews, responsibilities, verification/validation, regulatory submissions, risk management and design transfer.	Design and development plan, regulatory plan, V&V plan, clinical plan.
Design inputs	Inputs shall include regulatory requirements, standards, risk controls, usability needs, software/cyber needs, performance claims, service life, packaging, labeling and production constraints.	Input requirements specification, standards matrix, risk-control list.
Design outputs	Outputs shall be sufficient for purchasing, production, servicing, verification and traceability.	Drawings, BOM, software build, specifications, labeling, manufacturing instructions.
Design review	Reviews shall be planned, documented and include representatives of functions concerned with the stage reviewed.	Design review minutes, action logs, unresolved issue records.
Verification	Verification shall confirm outputs meet inputs using predefined acceptance criteria.	Protocols, raw data, reports, deviations, trace matrix.
Validation	Validation shall confirm device conforms to user needs and intended use in representative or simulated conditions.	Clinical/performance validation, usability validation, process validation, packaging validation.
Design transfer	Transfer shall ensure production specifications can repeatedly make conforming product.	DMR/production specifications, inspection plans, process validations, training records.
Changes	Changes shall be assessed for regulatory submission impact, risk impact, verification/validation, labeling, UDI and PMS impact.	Change order, regulatory assessment, V&V regression plan, release notes.

4.1 Design history / technical file crosswalk

Design-control artifact	FDA / QMSR relevance	EU MDR relevance	Supplier flowdown trigger
Design input requirements	Supports design and development planning and 510(k)/De Novo consistency.	Feeds GSPR checklist and Annex II technical documentation.	Inputs that allocate design responsibility to suppliers must become purchasing requirements.
Risk file	Supports performance testing, special controls, labeling and CAPA/complaint links.	Core Annex I risk-management evidence and PMS feedback loop.	Supplier hazards and controls must appear in supplier specifications and quality agreements.
V&V matrix	Supports submission summaries and inspection readiness.	Supports GSPR evidence and notified-body review.	Supplier test reports must be controlled for configuration and acceptance criteria.
Labeling	21 CFR Part 801, UDI and special-control labeling.	MDR Annex I Chapter III and language/UDI requirements.	Accessories, reusable parts, servicing and IT-network instructions may require supplier data.
Postmarket plan	Complaint/MDR/CAPA/recall and cyber vulnerability procedures.	PMS/PMCF/PSUR/vigilance/ trend reporting.	Supplier notification and field action cooperation obligations.

5. Standards architecture for medical electrical equipment

A standards plan should be built at the architecture stage. The plan should identify general, collateral, particular, process, software, cyber, usability, biological, labeling and product-specific standards. It should also distinguish regulatory recognition from state-of-the-art expectations.

Standard family	Examples	When applicable	Evidence expectation
Quality / lifecycle	ISO 13485, ISO 14971, ISO/TR 24971.	All medical-device programs; risk management is universal.	Procedures, plans, risk file, traceability, management review/CAPA feedback.
Medical electrical safety	IEC 60601-1 Ed. 3.2, AAMI ES60601-1, EN 60601-1.	Medical electrical equipment and systems.	Accredited test report, clause-by-clause checklist, construction review, risk-management file.
Collaterals	IEC 60601-1-2 EMC, -1-6 usability, -1-8 alarms, -1-11 home healthcare, -1-12 emergency, -1-10 physiologic closed-loop controllers.	Based on environment, alarms, controller function, home/emergency use and usability risks.	Applicability rationale, test reports, labeling, essential-performance criteria.
Particular standards	IEC 60601-2-x or ISO/IEC 80601-2-x standards for device type.	When a device-specific standard exists and applies.	Particular standard normally modifies/supplements general IEC 60601 requirements.
Software	IEC 62304, IEC 82304-1, FDA software guidance.	Software of unknown provenance, embedded firmware, SaMD/SiMD, apps and cloud functions.	Software safety class, architecture, SOUP, V&V, anomaly and maintenance evidence.
Cybersecurity	IEC 81001-5-1, AAMI TIR57/TIR97, UL 2900 family, FDA cybersecurity guidance.	Network-connectable or otherwise cyber devices.	Threat model, SBOM, vulnerability process, secure update, security risk controls.
Usability / HFE	IEC 62366-1, IEC 60601-1-6, AAMI HE75, FDA HF guidance.	Use-related risk, critical tasks, alarms, lay users, home use or novel interface.	Use specification, user-interface risk analysis, formative/summative validation.
Biocompatibility	ISO 10993 series.	Direct or indirect body contact.	Biological evaluation plan/report, chemical characterization, toxicological risk or tests.
Labeling	ISO 15223-1, ISO 20417, IEC 60601 marking/accompanying documents.	Labels, IFU, symbols, warnings and technical manuals.	Labeling specs, symbol rationale, IFU validation where needed, UDI records.

5.1 Standards control requirements

- The standards matrix shall identify edition, national adoption, FDA recognition number or EU harmonisation/OJEU status, transition period, applicability and deviations.
- The project shall not assume a standard is acceptable for a submission solely because a test laboratory offers it; regulatory recognition and state-of-the-art status must be checked separately.
- Where a newer non-harmonised standard is used in the EU, the technical file shall justify state of the art and map evidence to MDR GSPRs.
- Where a recognized standard is used in the U.S., the declaration of conformity shall respect FDA's extent of recognition and any limitations.

6. IEC 60601 electrical safety and essential performance requirements

IEC 60601-1 is the backbone safety standard for medical electrical equipment. It evaluates basic safety and essential performance under normal and single-fault conditions. The design team must define essential performance early; it becomes the acceptance criterion for many electrical, EMC, software and usability tests.

Requirement area	Detailed requirement / design implication	Evidence
Essential performance	Manufacturer shall identify performance necessary to avoid unacceptable risk. If no essential performance exists, the rationale shall be documented.	Essential-performance analysis, risk file, test acceptance criteria.
Applied parts	Manufacturer shall classify applied parts and patient connections; BF/CF assumptions shall be justified.	Applied-part list, insulation diagram, leakage current tests.

Requirement area	Detailed requirement / design implication	Evidence
Means of protection	Design shall define MOOP/MOPP, insulation, creepage/clearance and protective earth strategy.	Insulation coordination review, construction checklist, dielectric tests.
Power and energy	Power supply, battery, charging, internal electrical power source and thermal hazards shall be controlled.	Power architecture, battery safety tests, temperature measurements.
Mechanical hazards	Moving parts, instability, handles, enclosures and mounting shall be evaluated.	Mechanical tests, risk-control verification.
Thermal hazards	Accessible surfaces and applied parts shall remain within allowed limits under intended use.	Temperature test report, thermal analysis.
Alarms	Alarm systems shall comply with applicable collateral requirements when alarms are used as risk controls.	Alarm priority, audibility/visibility, usability and IEC 60601-1-8 evidence.
Programmable systems	Software-controlled safety functions shall connect IEC 60601 programmable electrical medical system expectations to software lifecycle evidence.	Software architecture, risk control verification, release records.
Accompanying documents	Instructions shall describe installation, operation, maintenance, warnings, EMC environments and service limits.	IFU, technical manual, labeling review.

6.1 IEC 60601 deliverable package

Deliverable	Must include	Review question
Test plan	Standards, edition, national deviations, model/serial/software version, accessories, test configuration and acceptance criteria.	Does it match the device that will be submitted and sold?
Construction review	Enclosure, insulation, PCB spacing, components, fuses, grounding, cables, connectors and markings.	Are critical components controlled in the BOM and supplier specs?
Risk link	Hazards and risk controls referenced to clauses and tests.	Are test failures linked back to risk acceptability and design changes?
Test report	Raw observations, pass/fail results, deviations, photos, test setup and unresolved issues.	Can a reviewer reproduce the configuration and conclusion?
Labeling links	Warnings, environmental limits, installation/service conditions, accessories and EMC precautions.	Do instructions reflect actual test limitations?

7. EMC, wireless, interoperability and environmental requirements

EMC and wireless evidence should be treated as safety evidence, not merely compliance testing. The device must remain safe and perform essentially in the intended electromagnetic environments. If wireless or network connections are involved, coexistence, interoperability and cybersecurity claims must also be controlled.

Topic	Requirement statement	Evidence / acceptance
Intended environments	Manufacturer shall define professional healthcare, home healthcare, emergency, transport, RF-rich or special environments.	Use-environment specification and EMC test-level rationale.
Essential performance	EMC pass/fail criteria shall be based on essential performance and safety risk, not cosmetic behavior alone.	EMC protocol with essential-performance monitoring method.
Emissions	Device shall not create unacceptable electromagnetic disturbances in intended environments.	IEC 60601-1-2 emissions results, deviation handling.
Immunity	Device shall remain safe and essentially performant during expected disturbances.	Immunity test results and observed degradations.
Wireless coexistence	Wireless functions shall be evaluated for coexistence and loss/interruption effects when wireless performance affects safety or effectiveness.	Coexistence assessment, risk controls, labeling.

Topic	Requirement statement	Evidence / acceptance
Interoperability	Interfaces shall specify purpose, data, timing, failure modes, user responsibilities and compatible systems.	Interface control document, validation, labeling.
Environmental	Transport, storage, humidity, vibration, ingress, cleaning, altitude and service-life assumptions shall be controlled.	Environmental test plan, packaging/transport tests, shelf/service life evidence.

7.1 EMC labeling requirements

- Labeling shall identify intended electromagnetic environments and any exclusions or restrictions.
- Labeling shall identify cables, accessories, power supplies or configurations required for EMC compliance.
- Labeling shall describe warnings for portable RF communications equipment, wireless coexistence limitations and observed performance degradations when relevant.
- Service instructions shall control replacement parts, cable lengths, shielding, grounding and software versions that affect EMC performance.

8. Risk management and traceability requirements

Risk management is the organizing spine of the requirements file. ISO 14971-style risk management should begin at concept and continue through production and post-market surveillance. For electrical devices, the risk file must integrate hazards from energy, software, cyber, use error, alarms, accessories, patient contact, essential performance and foreseeable misuse.

Risk file element	Requirement	Evidence
Risk management plan	Define scope, responsibilities, criteria for risk acceptability, review points and production/post-production data sources.	Approved plan and risk acceptability policy.
Hazard identification	Identify hazards from electrical energy, thermal effects, software faults, electromagnetic disturbances, biological contact, use error, cleaning, servicing and cyber compromise.	Hazard analysis, preliminary hazard analysis, FMEA/FTA as appropriate.
Risk estimation	Estimate severity and probability using defined scales and available evidence.	Risk table with rationale and assumptions.
Risk control	Apply inherent safety by design, protective measures and information for safety in that order where practicable.	Risk-control matrix, design inputs, labeling controls.
Verification	Verify each risk control with objective evidence and acceptance criteria.	Traceability matrix, V&V reports.
Residual risk	Evaluate residual risks individually and overall; document benefit-risk where needed.	Risk management report, clinical benefit-risk link.
Production/PMS feedback	Use complaints, service data, MDR/vigilance, CAPA, PMCF and cyber signals to update risk management.	PMS inputs, CAPA records, periodic review.

8.1 Sample requirement traceability format

ID	Requirement	Source	Risk link	Verification
ME-001	Device shall maintain essential performance during normal and single-fault electrical safety testing.	IEC 60601-1 / risk file	Hazard: loss of therapy/monitoring	60601 report, essential-performance monitoring.
EMC-002	Device shall remain safe and meet defined essential-performance criteria during immunity testing for intended environments.	IEC 60601-1-2 / FDA EMC guidance	Hazard: performance degradation under disturbance	EMC protocol/report.
SW-003	Software safety controls shall be traced from hazards to requirements, architecture, tests and release anomalies.	IEC 62304 / FDA software guidance	Hazard: software failure causing harm	Software trace matrix.

ID	Requirement	Source	Risk link	Verification
CY-004	Cybersecurity controls shall include secure update, authentication, vulnerability management and SBOM maintenance where device is a cyber device.	FDA cyber guidance / IEC 81001-5-1	Hazard: unauthorized access or unsafe modification	Threat model, SBOM, penetration/security testing.
HF-005	Critical tasks shall be validated with representative users in representative use environments when use error could cause harm.	FDA HF guidance / IEC 62366-1	Hazard: use error	HF validation report.

9. Software, AI and cybersecurity requirements

Software and cybersecurity are now core regulatory topics for connected or software-dependent medical electrical equipment. Documentation depth should scale with risk, but the file must always establish what the software does, how it is controlled, what hazards it can create, how it was verified, and how it will be maintained after release.

Software area	Requirement statement	Evidence
Software scope	Manufacturer shall identify all device software functions, firmware, mobile apps, cloud components, libraries, OTS/SOUP and non-device functions that may affect safety.	Software description, architecture and bill of software components.
Safety classification	Software shall be classified by potential contribution to hazardous situations and harm.	IEC 62304 safety classification rationale.
Architecture	Architecture shall identify segregation, interfaces, safety controls, cybersecurity controls, data flow and failure handling.	Architecture diagrams, interface specifications.
Requirements	Software requirements shall be testable and trace to system requirements, risk controls and user needs.	Software requirements specification and trace matrix.
Verification	Verification shall include unit, integration and system testing appropriate to risk and architecture.	Protocols, automated/manual test results, coverage rationale.
Validation	Software validation shall show the device meets intended use in the final or representative configuration.	System validation, usability/clinical/performance links.
Anomalies	Unresolved anomalies shall be assessed for risk, release acceptability and labeling impact.	Bug list, anomaly assessment, release notes.
Maintenance	Maintenance shall control updates, patches, regression testing, complaint feedback and regulatory change assessment.	Maintenance procedure, change-control records.

9.1 Cybersecurity evidence package

Artifact	Expected content	Why it matters
Cyber applicability rationale	Whether the device is a cyber device and what connectivity, data, update and network features exist.	Determines whether section 524B and FDA cyber premarket content apply.
Threat model	Assets, trust boundaries, attack surfaces, threats, controls and residual risks.	Shows security is designed in, not added as a label warning.
SBOM	Software components, versions, suppliers and known vulnerability handling.	Supports vulnerability management and customer transparency.
Security architecture	Authentication, authorization, encryption, logging, secure boot, update mechanism, hardening and data protection.	Links security controls to safety and performance.
Vulnerability management	Intake, triage, coordinated disclosure, patching, monitoring and field update processes.	Supports total product lifecycle cybersecurity.
Security labeling	IT requirements, supported configurations, update responsibilities, backup/restore and secure disposal.	Prevents unsafe deployment in real healthcare networks.

9.2 AI/ML-enabled software notes

- AI/ML-enabled device functions shall define the locked or adaptive behavior, model inputs/outputs, intended users, clinical role and human oversight expectations.
- Training, tuning and validation datasets shall be characterized for representativeness, bias, independence and relevance to intended use.
- Performance shall be evaluated against clinically meaningful acceptance criteria, including failure modes, subgroups and out-of-distribution limitations where relevant.
- Planned model changes shall be assessed under FDA and EU change-control expectations; predetermined change-control concepts may apply where appropriate.

10. Usability, labeling, UDI and information supplied with the device

Usability and labeling are risk controls. They should be designed and validated as part of the device, especially for critical tasks, alarms, setup, home use, cleaning, accessories, software configuration and network deployment.

Area	Requirement statement	Evidence
Use specification	Manufacturer shall define intended users, use environments, patient populations, training assumptions and operating scenarios.	Use specification, user profiles, environment analysis.
Critical tasks	Critical tasks shall be identified from risk analysis and user-interface analysis.	Critical-task list, task-hazard analysis.
Formative evaluation	User-interface designs shall be iterated using formative evaluations where use-related risk warrants it.	Formative plans, findings, design changes.
Validation	HF validation shall use representative users, tasks and environments when use error could cause harm or FDA/product guidance expects it.	HF validation protocol/report.
Labeling	Labeling shall support safe installation, operation, maintenance, cleaning, accessories, warnings, contraindications, EMC/cyber limits and residual risks.	IFU, quick guides, technical manuals, label artwork.
UDI	UDI and Basic UDI-DI/UDI-DI requirements shall be planned with device variants, kits, software versions and direct marking needs.	UDI plan, GUDID records, EU UDI/device registration.

10.1 Labeling content matrix

Labeling topic	U.S. expectation	EU MDR expectation
Intended use / purpose	Consistent with cleared/authorized indications and 21 CFR labeling rules.	Consistent with MDR intended purpose, classification, clinical evaluation and GSPRs.
Warnings / precautions	Special controls, risk controls, EMC/cyber/HF limitations and contraindications.	Residual risks, precautions, contraindications and information needed for safe use under Annex I.
Electrical / EMC	Accessories, cable limits, electromagnetic environments and performance degradation information per FDA EMC guidance.	Information needed to maintain conformity and safe performance in intended environments.
Software / cyber	Supported configurations, update process, network requirements, security features and vulnerability disclosure path.	IT security measures, operating environment, update responsibilities and residual risks.
UDI	UDI on label/package and GUDID data where required; direct marking where applicable.	UDI carrier, Basic UDI-DI, device registration and language requirements.

11. Biocompatibility, cleaning, sterilization and material safety

Medical electrical devices often include patient-applied parts, wearable sensors, handheld accessories, cables, electrodes, probes, carts, reusable surfaces or fluid-contacting components. Body-contacting materials must be evaluated using a risk-based biological evaluation, not merely a default test battery.

Topic	Requirement statement	Evidence
Contact characterization	Manufacturer shall identify nature, duration and body site of direct and indirect contact for every patient/user-contacting component.	Contact matrix, material list, patient-contact diagram.
Material characterization	Materials, additives, colorants, processing aids, adhesives and suppliers shall be controlled.	BOM, material certifications, chemical characterization.
Biological evaluation	Biological endpoints shall be selected based on ISO 10993-1 contact category and risk information.	BEP/BER, toxicological risk assessment, test reports.
Cleaning / disinfection	Reusable or cleanable components shall have validated instructions compatible with materials and performance.	Cleaning validation, disinfection validation, usability assessment.
Sterilization	Sterile devices/accessories shall define sterilization method, SAL, packaging, shelf life and residuals.	Sterilization validation, packaging validation, aging, EO residuals if applicable.
Production changes	Material, supplier, cleaning, sterilization or manufacturing changes shall trigger biological and regulatory impact assessment.	Change-control records and bridging rationale.

11.1 Material safety flowdown examples

- Supplier shall notify manufacturer before changing material formulation, resin grade, colorant, adhesive, processing aid, surface treatment or manufacturing location for patient-contacting components.
- Supplier shall provide material certificates, biocompatibility history, chemical composition information or extractables/leachables support as contractually required.
- Manufacturer shall not rely solely on supplier 'medical grade' statements without mapping material evidence to device contact type, duration, processing and intended use.
- Cleaning/disinfection instructions shall be validated on aged or worst-case representative devices where degradation could affect safety, performance or biocompatibility.

12. Clinical evidence, PMS, PMCF and vigilance

Clinical evidence expectations differ between FDA and EU MDR. FDA Class II 510(k) submissions often rely on non-clinical performance and predicate comparison unless clinical data are needed. EU MDR requires clinical evaluation for all devices, with PMCF unless justified. Both systems expect postmarket feedback to update risk and benefit-risk conclusions.

Clinical / postmarket topic	Requirement	Evidence
Clinical evaluation	Manufacturer shall evaluate whether clinical data are needed to support intended purpose, claims, benefit-risk and safety/performance.	Clinical evaluation plan/report, literature search, equivalent/comparable device rationale.
Clinical investigation	Clinical investigation shall be planned where existing clinical and non-clinical evidence cannot adequately support claims and GSPRs.	Protocol, approvals, monitoring plan, report.
PMCF	EU MDR PMCF shall proactively collect clinical data after market unless a documented justification supports no PMCF.	PMCF plan, PMCF evaluation report, CER updates.
PMS plan	PMS shall define data sources, responsibilities, indicators, review cadence and links to risk/CAPA/clinical evaluation.	PMS plan, PMS report or PSUR.
Vigilance / MDR reporting	Reportable adverse events, serious incidents, FSCAs, corrections/removals and trends shall be assessed under jurisdictional rules.	MDR/vigilance decision records, FSN/recall records.

Clinical / postmarket topic	Requirement	Evidence
Cyber postmarket	Cyber vulnerabilities shall be monitored, assessed for safety/performance impact and handled through update/field action processes.	Vulnerability logs, patch records, customer notices.

12.1 Postmarket signal sources

Signal source	What to monitor	Possible action
Complaints	Malfunctions, adverse events, use errors, labeling confusion, essential-performance loss.	MDR/vigilance assessment, CAPA, labeling update, design change.
Service data	Repeated repairs, calibration drift, battery issues, connector failures, environmental damage.	Supplier corrective action, preventive maintenance update, design change.
Cyber intelligence	Known vulnerabilities, exploit reports, SBOM component alerts, customer IT incidents.	Patch, compensating control, security notice, regulatory reporting assessment.
Clinical literature	New safety/performance data, competitor events, state-of-the-art changes.	CER/PMCF update, risk update, labeling or design change.
Regulatory surveillance	FDA recalls, MAUDE, EU safety notices, MDCG/FDA guidance, standards transitions.	Regulatory plan update, PMS trend review, standards gap assessment.

13. Supplier, accessory and production flowdown requirements

Medical electrical equipment depends heavily on suppliers: power supplies, batteries, displays, sensors, electrodes, enclosures, carts, cables, connectors, PCBs, software components, cloud services, sterilization/packaging vendors and test laboratories. Supplier controls should translate regulatory requirements into purchasing controls and quality agreements.

Supplier category	Flowdown requirements	Records
Power supplies / batteries	Safety certification, rated use, leakage/temperature constraints, change notification, traceability and end-of-life controls.	Certificates, test reports, BOM controls, supplier agreement.
Cables / connectors	Shielding, length, materials, patient-contact status, cleaning compatibility, strain relief and EMC configuration control.	Drawings, specs, inspection plans, EMC test configuration.
Sensors / applied parts	Biocompatibility data, electrical classification, essential-performance tolerances and calibration needs.	Material files, calibration records, V&V reports.
Software / cloud suppliers	Security controls, SBOM, vulnerability notification, change notification, validation support and uptime/data integrity expectations.	Supplier risk assessment, quality/security agreement, SOC/security evidence.
Sterilization / packaging	Validated process, load configuration, change notification, residuals, shelf life and shipping configuration.	Validation reports, batch records, certificates.
Test labs	Accreditation scope, test standards/editions, deviations, configuration control and raw data retention.	Quotes, protocols, reports, accreditation records.

13.1 Example supplier shall statements

- Supplier shall not change materials, design, firmware, manufacturing process, manufacturing location, critical sub-supplier or inspection method without prior written notification and approval when the item affects safety, performance, regulatory evidence or labeling.
- Supplier shall maintain traceability for critical components and provide lot, serial, firmware or configuration identifiers as specified by the purchasing specification.
- Supplier shall support regulatory submissions and audits by providing certificates, test data, risk information, cybersecurity vulnerability information and change-impact evidence as contractually required.

- Supplier shall notify manufacturer of field issues, recalls, vulnerabilities, nonconformities or regulatory notices that could affect supplied components or services.
- Manufacturer shall classify suppliers by risk and control them through qualification, purchasing data, monitoring, incoming acceptance, quality agreements and corrective action.

14. Integrated requirement matrices and gap checklist

14.1 Master evidence matrix

Evidence package	FDA Class II use	EU Class IIa/IIb use	Must be traceable to
Classification memo	Confirms pathway, product code and special controls.	Confirms Annex VIII rule and Article 52 route.	Intended purpose, claims, risk.
Risk management file	Supports special controls, performance testing, labeling, CAPA and MDR decisions.	Supports GSPRs, PMS, clinical evaluation and benefit-risk.	Hazards, design inputs, V&V, PMS.
IEC 60601 report	Supports safety/effectiveness and standards declaration.	Supports GSPR conformity and state of the art.	Essential performance, configuration, labeling.
EMC report	Supports FDA EMC guidance and submission labeling.	Supports electromagnetic safety/performance GSPRs.	Intended environments and essential performance.
Software file	Supports FDA software guidance and eSTAR sections.	Supports Annex II software description and GSPR 17.	Software requirements, risks, tests, anomalies.
Cyber file	Supports FDA section 524B and cyber guidance.	Supports MDR security/state-of-the-art expectations.	Threat model, SBOM, risk file, labeling.
Usability file	Supports FDA HF expectations and critical-task safety.	Supports GSPR risk reduction and information supplied.	Use-related hazards, critical tasks, IFU.
Biological evaluation	Supports ISO 10993-1 risk-based biocompatibility.	Supports material and biological safety GSPRs.	Contact matrix, materials, cleaning/sterilization.
Clinical evaluation	Supports clinical/performance claims when needed.	Required MDR clinical evaluation and PMCF rationale.	Claims, benefit-risk, PMS/PMCF.
Labeling/UDI	Supports 21 CFR Part 801, UDI/GUDID and special controls.	Supports Annex I Chapter III, UDI/Basic UDI-DI and EUDAMED.	Claims, risks, V&V limitations.

14.2 Common gap checklist

- Classification rationale does not match actual claims, indications, accessories, software functions or use environment.
- IEC 60601, EMC and software reports use different device configurations or software versions.
- Essential performance is undefined or inconsistent across risk, electrical safety, EMC, software and labeling.
- Standards matrix omits FDA recognition extent, EU harmonisation/OJEU status or transition dates.
- Risk controls are listed but not verified, or verification reports do not cite the controlled requirement.
- Cybersecurity documentation lacks SBOM maintenance, vulnerability disclosure, secure update or threat modeling.
- Human factors file lacks representative users, critical-task linkage or validation rationale.
- Clinical evaluation is written like a U.S. predicate comparison rather than an MDR benefit-risk and GSPR argument.
- PMS/PMCF plan does not define measurable signals, review cadence or update triggers for risk and clinical evaluation.
- Supplier quality agreements omit change notification for materials, firmware, process, cybersecurity or critical sub-suppliers.

15. Display-specific guidance and human interface requirements

This section expands the requirements guide for devices that contain displays. It applies broadly to medical electrical equipment with screens, visual indicators, touchscreens, graphical user interfaces, alarm displays, mobile companion displays, wearable displays, service screens and diagnostic image displays. The intent is general medical-device guidance focused on display-containing devices, not only standalone diagnostic monitors.

Display/HMI planning principle
A display is part of the medical device user interface and often becomes a risk control. Treat screen content, visual hierarchy, alarms, controls, color, contrast, data freshness, touchscreen behavior and display degradation as design inputs with verification evidence, not as late cosmetic choices.

15.1 Display use-case classification

Display use case	Typical examples	Regulatory/HMI concern	Evidence emphasis
Status and setup display	Power state, battery, calibration, sensor connection, therapy readiness, self-test.	Incorrect status interpretation can lead to delayed use, wrong setup or missed faults.	Critical-task analysis, status-state matrix, usability validation, fault-injection tests.
Control display / touchscreen	Dose, therapy settings, mode selection, start/stop, menu navigation.	Use error may directly change therapy, monitoring, diagnosis or alarm behavior.	UI requirements, confirmation logic, lockouts, error prevention, HF validation.
Monitoring display	Vitals, trends, waveforms, numeric results, device-generated decisions.	Data freshness, scale, units, trend compression and alarm priority can affect clinical decisions.	Display accuracy tests, alarm and trend interpretation validation, labeling.
Alarm and alert display	Visual alarm banners, color-coded priorities, alarm lists, silencing status.	Users must perceive, understand and act on alarm conditions in the intended environment.	IEC 60601-1-8 applicability, alarm risk analysis, visual/alarm validation.
Diagnostic image display	Radiology soft-copy display, medical-grade monitor, image review display.	Image quality may affect diagnostic interpretation.	FDA diagnostic-radiology display guidance, IEC 62563-1, DICOM PS3.14, display QA plan.
Patient-facing display	Home-use therapy guidance, wearable readings, mobile app screens.	Lay users may misunderstand instructions, warnings, icons or trend data.	Lay-user HFE, language/health-literacy review, accessibility and environmental testing.
Service / maintenance display	Calibration, logs, firmware update, service menus.	Service errors can create hidden safety/performance problems.	Service-mode access controls, procedure validation, training and service manual evidence.

15.2 Display standards and guidance matrix

Source	Primary display relevance	When to apply
FDA Human Factors and Medical Devices pages and August 2026 HFE guidance [S8, S21]	User interface includes displays, GUI logic, feedback, alarms, packaging, labeling and training; HFE focuses on perception, interpretation, decision-making and manipulation.	All devices where a display affects setup, operation, maintenance, clinical interpretation or risk controls.
FDA Content of Human Factors Information in Marketing Submissions, May 2026 [S22]	Risk-based framework for what HFE information should be submitted in 510(k), De Novo, PMA and HDE submissions.	U.S. marketing submissions, especially if the display creates or modifies critical tasks.
IEC 62366-1 / ANSI AAMI IEC 62366-1:2015+AMD1:2020 [S18, S23]	Usability engineering process for safety-related user interfaces, including screen-based interactions.	Safety-related display functions, critical tasks, warnings, prompts, alarms and user decisions.
IEC 60601-1 / IEC 60601-1-8 [S16, S24]	Medical electrical equipment display markings, accompanying documents and visual alarm signals; alarm displays may need priority, legibility and perceptibility evidence.	Medical electrical equipment with screen-based status, warnings, alarms or essential-performance indicators.
FDA Display Devices for Diagnostic Radiology guidance, September 2022 [S25]	510(k) recommendations for diagnostic radiology display devices under 21 CFR 892.2050/product codes.	Standalone or integrated displays intended for diagnostic radiology interpretation.

Source	Primary display relevance	When to apply
IEC 62563-1 medical image display systems [S26]	Evaluation methods for medical image display systems used for diagnostic or medical viewing purposes.	Medical image display systems where image quality is a safety/performance claim.
DICOM PS3.14 Grayscale Standard Display Function [S27]	Defines grayscale display behavior to support consistent medical image presentation.	Devices that display grayscale medical images where diagnostic or clinical viewing consistency matters.
AAPM display QA reports, including Report 270/TG18 lineage [S28]	Display quality assurance for flat-panel medical displays, including acceptance and periodic quality control concepts.	Clinical deployment, acceptance testing, service and maintenance planning for medical image displays.

15.3 Display and HMI requirement matrix

ID	Requirement	Risk / rationale	Verification evidence
DISP-001	Manufacturer shall classify each display function by user, environment, clinical role and consequence of incorrect perception or action.	Display risk differs greatly between decorative, informational, control, alarm and diagnostic use.	Display-function inventory and HMI risk classification.
DISP-002	Display content shall use unambiguous units, labels, state names, timestamps and data-source indicators where misunderstanding can affect safety or effectiveness.	Wrong unit, stale data or ambiguous state can drive wrong clinical action.	Requirements review, simulated-use validation, fault-state tests.
DISP-003	Critical values, alarms and actionable prompts shall remain legible at intended viewing distance, angle, ambient light and user posture.	Poor legibility can delay response or cause use error.	Legibility protocol, human factors validation, environmental readability tests.
DISP-004	Color shall not be the sole means of communicating safety-critical state, priority or user action.	Color vision deficiency, glare, display drift and cultural conventions can impair interpretation.	UI design review, accessibility check, formative/summative HF evidence.
DISP-005	Screen hierarchy shall make the current device state, patient/device risk state, active therapy/monitoring mode and required user action immediately clear.	Users must know what the device is doing and what they need to do next.	Critical-task validation, state-transition tests, use-scenario review.
DISP-006	Touch targets and controls shall be sized, spaced, labeled and protected against inadvertent activation for intended users and environments.	Gloves, motion, stress, cleaning and small screens increase touch error.	Touchscreen usability tests, mis-touch/fault-injection tests.
DISP-007	High-consequence actions shall use appropriate confirmation, cancellation, lockout, timeout or undo design controls.	Accidental start/stop, dose/mode changes and alarm silencing can harm patients.	Risk-control verification, HF validation.
DISP-008	Display refresh, latency, smoothing, averaging and trend compression shall be specified and validated when clinical decisions depend on real-time or trend information.	Users can over-trust delayed, averaged or stale values.	Performance tests, data-freshness indication, labeling review.
DISP-009	Visual alarms shall be coordinated with audible/tactile alarms and shall identify alarm condition, priority and user action where applicable.	Alarm management failure is a known source of delayed response and alarm fatigue.	IEC 60601-1-8 analysis, alarm validation, use-error testing.
DISP-010	Display degradation, stuck pixels, backlight failure, burn-in, contrast loss, calibration drift and touchscreen failure modes shall be risk-assessed.	Display hardware aging can silently reduce safety or diagnostic quality.	Design FMEA, service diagnostics, display self-test, maintenance plan.

15.4 Human-interface design controls for display devices

- The HMI specification should describe information architecture, screen map, navigation model, modes, states, controls, alerts, alarms, trend views, data-entry fields, error messages and service screens.

- Critical screens should have explicit design inputs for viewing distance, viewing angle, ambient light, language, units, numeric precision, icon meaning, alarm priority, color use, touchscreen conditions and user training assumptions.
- Display validation should include representative users, representative environments and realistic workflow pressures. For hospital use, consider interruptions, PPE/gloves, competing alarms and multi-device clutter. For home use, consider lay users, low light, mobility, noise, cleaning and limited training.
- For international markets, do not assume English text, color conventions or icon meaning will transfer safely. Language expansion, translation, symbol comprehension and local labeling requirements should be managed as design changes.
- Screen captures in submissions should match the released software version and be controlled as labeling or design outputs where they instruct or constrain use.

15.5 Display performance requirements

Performance area	General devices with displays	Diagnostic or image-review displays
Luminance / brightness	Specify operating range, automatic brightness behavior and minimum readable state in intended environments.	Define luminance response, calibration, acceptance and QC process using IEC 62563-1/DICOM/AAPM where applicable.
Contrast / grayscale	Specify contrast sufficient for text, icons, waveforms, alarms and disabled/enabled states.	Control grayscale behavior, JND/GSDF conformance, black/white levels and image-presentation pipeline.
Resolution / scaling	Verify text, icons, plots and waveforms remain legible after scaling, localization and software updates.	Verify pixel pitch, resolution, interpolation, image scaling and artifacts relative to diagnostic/viewing claims.
Color	Use color redundantly with text, shape or position for safety-critical states.	If color affects clinical interpretation, specify color behavior, calibration and profile management.
Ambient light / glare	Evaluate readability under intended clinical, transport, home and service lighting conditions.	Control reading-room or viewing-environment assumptions; evaluate reflections and ambient illumination.
Viewing angle / distance	Define operator position, patient-facing orientation, team viewing and mounted/cart use.	Define primary/secondary viewing roles and reading geometry.
Latency / refresh	Specify acceptable update rate, stale-data indicators and transition behavior.	Specify image load, window/level interaction, pan/zoom behavior and display pipeline latency where relevant.
Cleaning / durability	Verify screen coatings, touch response and readability after cleaning/disinfection and service life.	Include calibration/QA after service, replacement display modules or display controller changes.

15.6 Touchscreen and GUI risk controls

Risk scenario	Preferred design controls	Evidence
Inadvertent actuation	Spacing, guard zones, press-and-hold, confirmation, lockout, physical separation for emergency controls.	Mis-touch testing, HF validation, risk-control verification.
Wrong mode / wrong patient	Persistent mode banner, patient/device identifiers, context checks, confirmation before action.	Scenario validation, state-transition verification.
Alarm silencing confusion	Clear silence/pause countdown, persistent alarm state, escalation, separate acknowledge vs silence logic.	Alarm workflow validation, IEC 60601-1-8 analysis.
Stale or delayed data	Timestamp, data-quality indicator, loss-of-signal state, explicit disconnected/invalid state.	Data-loss tests, simulated use, software V&V.
Localization text overflow	Dynamic layout checks, abbreviation control, reviewed translation, no truncation of safety text.	Localization screenshots, regression tests, translation verification.
Software update UI change	Change-impact assessment for critical tasks and training/labeling effects.	Change-control record, HFE impact analysis, regression testing.

15.7 Display verification and validation package

Evidence item	Include for general display-containing device	Add for diagnostic/image display
Display requirements specification	Screen inventory, user roles, states, controls, warnings, alarms, units and environment assumptions.	Image presentation claims, modality compatibility, DICOM/GSDF assumptions.
Display risk analysis	Use errors, misinterpretation, critical tasks, display failure modes, alarm fatigue and service errors.	Clinical impact of luminance, contrast, grayscale, artifacts, calibration drift and ambient light.
Bench verification	Brightness, contrast, readability, touch response, latency, fault states, screen transitions and data freshness.	IEC 62563-1/DICOM/AAPM display measurements, calibration and QA limits.
Human factors validation	Representative users and critical display tasks with released UI or high-fidelity equivalent.	Representative diagnostic/viewing workflows where display interpretation affects clinical decisions.
Labeling	Operating environment, warnings, symbols, display limitations, cleaning, troubleshooting and service/calibration.	Reading environment, calibration/QC instructions, intended diagnostic/viewing use and limitations.
Postmarket monitoring	Complaints for display confusion, alarms, touchscreen failure, localization, brightness/contrast, software UI changes.	Display QA failures, calibration drift, image-quality complaints and field-service replacements.

15.8 Display/HMI source addendum

ID	Authority	Source	URL
S21	FDA	Human Factors and Medical Devices; device-user interface includes displays, GUI logic, feedback, auditory and visual alarms, labeling and training	https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/human-factors-and-medical-devices
S22	FDA	Content of Human Factors Information in Medical Device Marketing Submissions, final guidance, May 2026	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions
S23	FDA recognized standards database	IEC 62366-1 Edition 1.1 / ANSI AAMI IEC 62366-1:2015+AMD1:2020 recognition information	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=41235
S24	IEC	IEC 60601-1-8 alarm systems for medical electrical equipment and systems	https://webstore.iec.ch/
S25	FDA	Display Devices for Diagnostic Radiology, final guidance, September 2022	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/display-devices-diagnostic-radiology
S26	IEC	IEC 62563-1:2009+AMD1:2016+AMD2:2021 CSV, Medical image display systems - Evaluation methods	https://webstore.iec.ch/en/publication/7209
S27	DICOM / NEMA	DICOM PS3.14 2026c, Grayscale Standard Display Function	https://dicom.nema.org/medical/dicom/current/output/chtml/part14/ps3.14.html
S28	AAPM	AAPM Report No. 270, Display Quality Assurance	https://www.aapm.org/pubs/reports/detail.asp?docid=183

Appendix A. Current standards snapshot

This planning snapshot is current to 16 August 2026. Always verify the product classification and conformity-assessment basis, controlled standard revisions, FDA recognition and limitations, EU harmonised-standard status, common specifications, transition dates and Notified Body position before use.

Domain	Document/revision	Status/use note
U.S. quality system	21 CFR Part 820 (QMSR); ISO 13485:2016	QMSR effective 2 February 2026; apply FDA supplemental provisions and product-specific requirements.
EU quality system and conformity	Regulation (EU) 2017/745, Article 10(9), Annexes I-III and IX-XI	Binding MDR framework; classification and the Notified Body route remain product-specific.
Risk management	ISO 14971; ISO/TR 24971	Lifecycle process; confirm FDA recognition and EU harmonisation or state-of-the-art use.
Basic safety / essential performance	IEC 60601-1 Ed. 3.2; U.S. and EN national adoptions	Define essential performance and test the released configuration under normal and single-fault conditions.
EMC and use environments	IEC 60601-1-2 Ed. 4.1; applicable -1-11 and -1-12 collaterals	Select environments, immunity levels and essential-performance criteria; control accessories and labeling.
Alarms and usability	IEC 60601-1-8; IEC 60601-1-6; IEC 62366-1; FDA HFE guidance (May/Aug. 2026)	Apply by alarm and use-related risk; link critical tasks and user-interface risk controls to validation.
Software	IEC 62304; IEC 82304-1; FDA device-software guidance	Control safety classification, architecture, SOUP, requirements, V&V, anomalies and maintenance.
Cybersecurity	IEC 81001-5-1; FDA cybersecurity guidance (Feb. 2026); UL 2900 family as applicable	For cyber devices, maintain threat modeling, SBOM, secure update and vulnerability-management evidence.
Biological evaluation	ISO 10993 series; FDA ISO 10993-1 guidance	Base the strategy on contact type and duration, materials, processing and chemical information.
Cleaning / sterilization / packaging	ISO 17664-1; ISO 11135, ISO 11137 or ISO 17665; ISO 11607 as applicable	Validate only the processes and claims applicable to the released reusable or sterile configuration.
Labeling and symbols	21 CFR Parts 801 and 830; MDR Annex I; ISO 15223-1; ISO 20417	Control UDI, symbols, IFU, languages, warnings and installation/service information as applicable.
Clinical and postmarket	MDR Article 61, Annex XIV, Articles 83-86 and Annex III; FDA product-specific pathway	Evidence depth is device- and claim-specific; feed surveillance into risk, CAPA and benefit-risk.
Particular and display standards	Applicable IEC/ISO 60601-2-x or 80601-2-x; IEC 62563-1 and DICOM PS3.14 where relevant	Particular standards modify the general standard; display standards depend on the intended imaging and use case.

Appendix B. Supplier data-item checklist

Use this checklist to define contractual data deliverables and acceptance evidence for each supplier or external service. Tailor it by supplier risk, device configuration, intended use, regulatory pathway and lifecycle phase; identify the required revision, format, approval status, retention and delivery milestone in the purchasing specification or quality agreement.

- Approved product specification, drawings, interfaces, configuration baseline and bill of materials
- Risk-based supplier classification, qualification records, audit status and quality agreement
- Critical-component, material, formulation, manufacturing-site and critical sub-tier source data
- Material certificates and biological, chemical, extractables/leachables or toxicological support as allocated
- IEC 60601 construction data, critical-component certifications, CB reports and certificates as applicable
- Accessory, applied-part, power-supply, battery, cable and connector specifications
- Software/firmware release records, SOUP/OTS inventory, SBOM and vulnerability-notification commitments
- Allocated risk controls, requirement traceability and verification evidence
- Electrical safety, EMC, wireless-coexistence and interoperability evidence for the exact tested configuration
- Display, GUI, alarm and usability evidence when the supplier controls user-interface behavior
- Cleaning, disinfection, reprocessing, sterilization and packaging-validation inputs as applicable
- Manufacturing-process validation, special-process controls, work instructions and production test evidence
- Acceptance criteria, inspection/test methods, sampling rationale, calibration and measurement uncertainty
- Certificates of conformance, lot/serial traceability, deviations, nonconformities and corrective-action records
- Advance change notification with regulatory, risk, verification and requalification impact assessment
- Complaint, field issue, recall, cybersecurity and regulatory-notice escalation commitments
- Obsolescence, last-time-buy, service, repair, spare-parts and lifecycle-continuity plan

Appendix C. Glossary and abbreviations

Term	Meaning
Basic safety	Freedom from unacceptable risk directly caused by physical hazards when equipment is used under normal and single-fault conditions.
Essential performance	Performance of a clinical function, other than basic safety, where loss or degradation beyond limits results in unacceptable risk.
GSPR	MDR General Safety and Performance Requirement in Annex I.
ME equipment	Medical electrical equipment under IEC 60601: equipment with an applied part or that transfers energy to/from the patient, or detects such energy transfer, and has not more than one connection to a supply mains.
ME system	Combination of equipment, at least one item of which is ME equipment, interconnected by functional connection or multiple socket-outlet.
QMSR	FDA Quality Management System Regulation, effective February 2, 2026, incorporating ISO 13485:2016 with FDA supplemental provisions.
PMS / PMCF / PSUR	Post-market surveillance, post-market clinical follow-up and periodic safety update report.
UDI / Basic UDI-DI	Unique device identification carrier/database identifiers; Basic UDI-DI is the EU primary identifier for a device model family in regulatory documentation.
SOUP / OTS	Software of unknown provenance / off-the-shelf software.

Appendix D. Colabmo and FPD.DEV client support services

Colabmo supports product teams from early concept through market entry and lifecycle change. Engagements may be advisory, embedded within the client team, or organized as a defined work package. FPD.DEV, Colabmo's sister company, extends this support with specialized flat-panel display, optical, touch, electronics, supplier-development, and manufacturing capabilities.

> **Role boundary.** Colabmo and FPD.DEV do not issue regulatory approvals, certifications, or marks. They support the manufacturer or applicant in preparing evidence and coordinating with regulators, accredited laboratories, Nationally Recognized Testing Laboratories (NRTLs), certification bodies, and EU Notified Bodies, as applicable. The manufacturer retains responsibility for regulatory strategy, declarations, product conformity, and use of marks.

D.1 Product development and requirements

- Clarify intended use, users, operating environments, system boundaries, interfaces, and measurable acceptance criteria.
- Translate stakeholder and regulatory needs into requirements baselines, traceability, interface controls, supplier flowdowns, and verification plans.
- Facilitate architecture and design reviews, risk-based trade studies, design-for-compliance decisions, and evidence-focused readiness reviews.
- Support configuration control, supplier change assessment, obsolescence planning, prototype maturation, and transfer to repeatable production.
- Integrate essential performance, electrical safety, EMC and wireless, usability, software and cybersecurity, biocompatibility, cleaning or sterilization interfaces, and supplier controls into a coherent product baseline.

D.2 Regulatory navigation and evidence readiness

- Develop a market-entry roadmap covering product classification, approval or conformity-assessment routes, authorities and bodies, program gates, and decision owners.
- Build and maintain standards-applicability, revision, recognition or harmonisation, and transition matrices tailored to the product and target markets.
- Perform evidence-gap assessments and organize compliance matrices, technical documentation, design-history records, test reports, declarations, and supplier evidence.
- Plan pre-compliance and formal testing, review submission or certification packages, and help teams prepare clear responses to reviewer questions and nonconformities.

D.3 Certification and conformity-assessment coordination

- Help identify and coordinate the appropriate regulator, accredited laboratory, UL or other NRTL route, certification body, and EU Notified Body when required by the product and market.
- Develop test scopes, evidence matrices, sample and configuration definitions, submission schedules, and responsibility assignments before formal engagement.
- Coordinate technical exchanges, test witnessing, findings, corrective actions, retesting, and closure records with the selected bodies and laboratories.
- Support readiness for UL certification and mark authorization, and for CE marking through the applicable EU conformity-assessment route, including declaration, labeling, and technical-file checks.

D.4 Sister-company support through FPD.DEV

- Provide display-platform and component selection, custom display and electronics development, optical-stack and touch integration, backlight solutions, ruggedization, prototyping, and supplier development.
- Coordinate display-specific requirements and evidence with the broader Colabmo regulatory, systems-engineering, quality, and certification workstream.
- Support sourcing, manufacturer engagement, first-article and pilot-build readiness, production transfer, and lifecycle continuity for display-intensive products.
- Define ownership, milestones, interfaces, deliverables, assumptions, and acceptance criteria for each Colabmo and FPD.DEV engagement in the client statement of work.

References

Sources are authoritative regulatory, standards-body or testing/certification references. Standard names and scopes are referenced for planning; this document does not reproduce copyrighted standard text.

ID	Authority	Source	URL
S1	FDA	Quality Management System Regulation (QMSR), update February 2, 2026	https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr
S2	eCFR / CFR	21 CFR Parts 800-898, including 801, 803, 806, 807, 812, 814, 820 and 830	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H
S3	FDA	Classify Your Medical Device and Regulatory Controls	https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
S4	FDA	Premarket Notification 510(k), De Novo Classification Request, PMA and eSTAR resources	https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission
S5	FDA	Recognized Consensus Standards database, page last updated May 25, 2026	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
S6	FDA	Cybersecurity in Medical Devices: QMS Considerations and Content of Premarket Submissions, final guidance, February 2026	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket
S7	FDA	Content of Premarket Submissions for Device Software Functions, final guidance, June 2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions
S8	FDA	Applying Human Factors and Usability Engineering to Medical Devices, final guidance, August 2026	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices
S9	FDA	Electromagnetic Compatibility (EMC) of Medical Devices, final guidance, June 2022	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices
S10	FDA	Use of International Standard ISO 10993-1, final guidance, September 2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and
S11	FDA	UDI Basics and Device Registration and Listing resources	https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-basics
S12	EUR-Lex	Regulation (EU) 2017/745 on medical devices, consolidated MDR text	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
S13	European Commission	Harmonised standards under MDR and IVDR, OJEU list through 2026 updates	https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
S14	European Commission	EUDAMED overview and first four mandatory modules from May 28, 2026	https://health.ec.europa.eu/medical-devices-eudamed/overview_en
S15	European Commission	MDCG endorsed guidance index for MDR, software, cybersecurity, clinical, PMS and PRRC topics	https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

ID	Authority	Source	URL
S16	IEC	IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV, basic safety and essential performance	https://webstore.iec.ch/en/publication/2606
S17	IEC	IEC 60601-1-2:2014+AMD1:2020 CSV, electromagnetic disturbances	https://webstore.iec.ch/en/publication/2590
S18	ISO	IEC 62366-1:2015, usability engineering for medical devices	https://www.iso.org/standard/63179.html
S19	UL Solutions	IEC 60601 testing and certification; IEC/AAMI/UL 60601, UL 2900, IEC 62304 references	https://www.ul.com/services/iec-60601-testing-and-certification
S20	FDA	Computer Software Assurance for Production and QMS Software, final guidance, February 2026	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software

Revision control reminder
Standards and regulations change. Confirm the current controlled revision, amendments, notices, authority acceptance and contract invocation before placing requirements on a drawing, purchase order or compliance matrix.