TECHNICAL COMPLIANCE

PRACTICAL GUIDE · 2026 EDITION

Medical Devices Registration in Russia and the EAEU

A comprehensive handbook for manufacturers, exporters and product managers



CLASSIFICATION · REGISTRATION · MARKET ACCESS
TESTING · DOCUMENTATION · CHECKLISTS

As of 11 October 2026

ac-inorms.com

PRACTICAL GUIDE

How to use this handbook

Classify, register and support medical devices in the market.

This handbook addresses manufacturers, exporters, importers and regulatory and quality managers. It covers medical devices including in vitro diagnostics, active equipment, software and sterile products. It focuses on Russia and the common registration route in the Eurasian Economic Union comprising Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan. Both language editions contain the same chapters and worksheets.

Registration is the central decision

Medical-device registration assesses safety, quality and effectiveness for a defined intended purpose. It is not an ordinary EAC certificate or general sanitary SGR registration. Assess additional product requirements separately. Medicines follow their own authorisation rules; a pharmaceutical GMP certificate does not replace medical-device registration.

Pages 4-13 explain classification, routes and responsibilities. Pages 14-30 address dossiers, testing and quality management. Marking, decisions and lifecycle follow on pages 31-40. Costs, a case study, FAQs and worksheets appear on pages 41-46. Terminology, sources and contact details conclude the guide.

Edition 1.0 · As of 11 October 2026

Based on the AC Inorms sector page and regulations archive, supplemented by official EAEU and Russian sources. Includes the transition through the end of 2027 and QMS amendment No. 43/2026. Explanations are not official translations. The selected route and actual product dossier determine requirements.

Sources: [1]-[8]

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Contents

Linked chapters and official sources for everyday project work.

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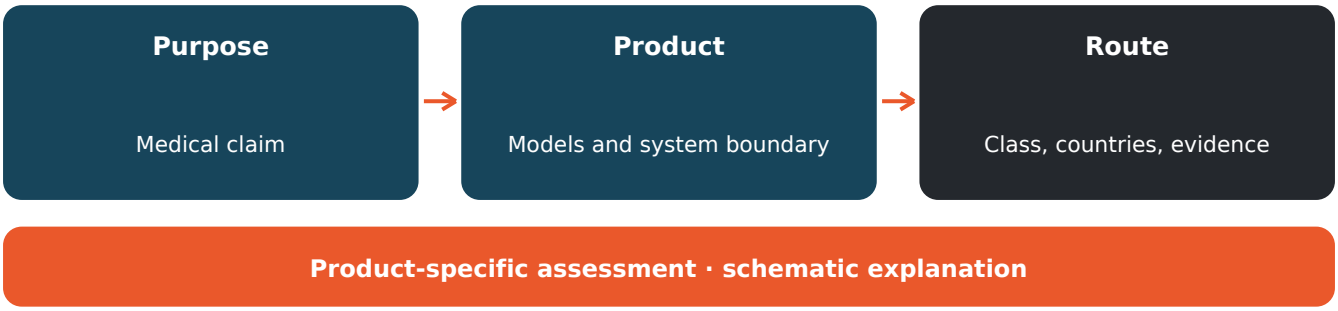
Suggested starting point

Prepare a model list covering intended purpose, risk classification, patient contact, software, sterility and destinations. Then choose the registration route. Existing CE evidence is a valuable dossier source but does not automatically provide Russian or EAEU approval.

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Quick start: seven decisions

A clear product description precedes schedule and cost commitments.



Assessment area	Project implementation
01 · Product	Identify models, accessories, sets and manufacturer.
02 · Purpose	Define indication, users, patients and use environment.
03 · Class	Justify the classification rule; assess IVDs separately.
04 · Countries	Specify Russia alone or further EAEU markets.
05 · Route	Compare national and common routes objectively.
06 · Evidence	Collect reports, clinical data, QMS and labelling.
07 · Operation	Organise changes, complaints and representative support.

The description “medical technology” alone does not determine the route. A laboratory instrument may support general research or a medical diagnosis. The same hardware with a different intended purpose may therefore receive a different classification. Keep claims in websites, sales materials, labels and instructions consistent. A customs code supports import assessment but replaces neither the device definition nor risk classification. Start with a version-controlled product list showing all variants and their differences.

In practice

Maintain a responsible dossier owner, destination status and open action plan for each product.

Sources: [1], [3], [5]

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Device, medicine or borderline product?

Intended purpose and principal mode of action determine qualification.

Assessment area	Project implementation
Medical device	Medical purpose; principal action is not pharmacological, immunological or metabolic.
Medicine	Separate pharmaceutical authorisation framework and evidence.
IVD	Examination of human specimens to provide medical information.
Software	Assess medical function and its effect on decisions.
Borderline	Justify coating, medicinal component, accessory or cosmetic claim.

For a combination product, assess principal action together with design and clinical claims. An antibacterial coating does not automatically make an article a medicine merely because a substance is present; qualification requires a defensible rationale. A general appointment-management app differs from software supporting diagnosis. For medicines, plan pharmaceutical quality, clinical evidence and applicable GMP requirements separately. This handbook explains the boundary rather than the complete pharmaceutical authorisation procedure.

In practice

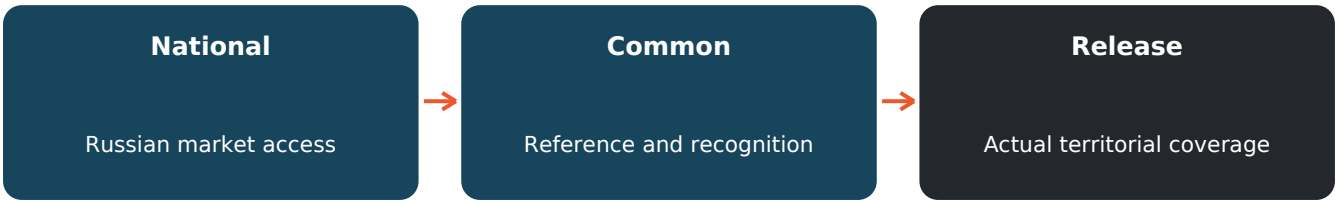
Resolve borderline cases before importing samples or ordering tests. Late reclassification can change the entire evidence programme.

Sources: [3], [4], [16]

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National or EAEU registration?

Market strategy determines the most suitable regulatory route.



Product-specific assessment · schematic explanation

Assessment area	Project implementation
National Russia	Russian market access under national registration rules.
EAEU route	Reference state, selected recognition states and common product dossier.
Existing dossier	Check transferability, currency and missing evidence.
Market coverage	Check territorial scope against the actual decision.
Ongoing effort	Allow for changes, translations, authority contacts and support.

Russian national registration does not become approval in all five states merely because Russia belongs to the Union. Deliberately select the reference state and recognition countries under the common route. Multiple destinations may support an EAEU strategy; an existing national file may matter for a Russia-only project. Compare evidence gaps, planned changes, suitable testing organisations and transition conditions. Choosing solely on an assumed shorter processing time can complicate future expansion.

In practice

State the route and covered countries expressly in the quotation; “valid in the EAEU” without territorial detail is insufficient.

Sources: [3], [7], [8]

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Legal framework: October 2026

Read baseline decisions together with their amendments.

Assessment area	Project implementation
No. 46/2016	Common registration and expert assessment of medical devices.
No. 27/2016	General safety and performance requirements; labelling.
No. 173/2015	Risk classification; include amendment No. 18/2025.
No. 106/2017	Risk-based quality management; amendment No. 43/2026.
Russia No. 1684	National registration rules of 30 November 2024, as amended.

The AC Inorms regulations archive supports orientation on technical regulations. Medical devices also require their own registration framework. For the EAEU route, Decision No. 46 should be read particularly with amendment No. 50 of 8 July 2025. Decision No. 43 of 27 April 2026 amended QMS requirements and took effect on 18 June 2026. Inspection guidance No. 6 of 7 April 2026 is a recommendation: it supports implementation but is not a registration authorisation itself.

In practice

Keep a legal-status sheet identifying each decision, amendment, application date and dossier consequence.

Sources: [2]-[6], [8], [9]

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Transition through the end of 2027

Distinguish filing deadlines, certificate status and change deadlines.

Assessment area	Project implementation
Applications	National or common registration applications possible through 31 December 2027.
Basis	Protocol of 29 December 2025; consult the official EEC announcement.
Legal effect	Distinguish provisional application from formal entry into force.
Existing products	Check validity and change duties separately against the actual file.
Project planning	Schedule complete filing, samples and testing well in advance.

The EEC announced that the protocol signed on 29 December 2025 extends the choice between national and common applications through 31 December 2027. It provides for provisional application ten days after signature; formal entry into force follows the last required notification. This does not establish a blanket claim that every existing national document expires on 1 January 2028. A deadline for updating representative details is likewise not the filing deadline. For an existing product, assess document status, transition provisions and changes together.

In practice

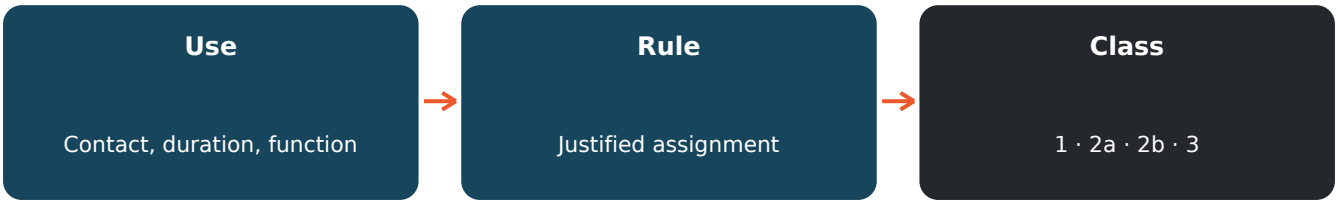
Recheck official status before contracting and set an internal filing buffer ahead of the legal deadline.

Sources: [7], [8]

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Risk classes 1, 2a, 2b and 3

The rule rationale matters more than a generic product description.



Product-specific assessment · schematic explanation

Assessment area	Project implementation
Class 1	Low potential risk; document the actual classification rule.
Class 2a	Medium potential risk; assess use and contact characteristics.
Class 2b	Increased potential risk; examine active functions and consequences.
Class 3	High potential risk; critical use and evidence needs.
Factors	Invasiveness, duration, body site, energy and diagnostic decision.

Derive classification from intended use. A microscope, scale or contact-lens product must not be assigned a class solely by its name. Document the applicable rule, assessed functions and reasons for excluding other rules. Accessories and software may require their own assessment. Where several rules apply, follow the prescribed classification logic. An EU MDR class is useful background but does not automatically replace an EAEU rationale.

In practice

Approve classification before placing binding orders for testing scope, inspection needs and clinical strategy.

Sources: [5]

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In vitro diagnostics: separate rules

The significance of the result determines diagnostic risk.

Assessment area	Project implementation
Product boundary	Identify reagent, calibrator, control, instrument and software.
Purpose	Define analyte, specimen, population, user and clinical claim.
Risk logic	Assess error consequences for individuals and public health.
Performance	Plan analytical and clinical performance data matching claims.
Self-test	Additionally assess lay use, result comprehension and warnings.

IVDs follow the specific rules within the EAEU classification framework. Do not transfer EU IVDR letters A to D into an EAEU application without assessment. A test selecting treatment, screening or detecting a transmissible infection has a different risk context from a general laboratory aid. Explain how positive, negative and inconclusive results are used. Include controls, calibrators and instrument interfaces in the system description; compatible combinations need demonstrated performance.

In practice

Before starting studies, document specimen matrix, comparator method and evaluation criteria.

Sources: [5], [10]

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Manufacturer, representative and applicant

Secure responsibilities and access to records contractually.

Assessment area	Project implementation
Manufacturer	Maintain product responsibility, design records and manufacturing status.
Representative	Eligible local representation, authorisation and authority communication.
Applicant	Coordinate filing, fees, responses and dossier completeness.
Importer	Check supplied identity, customs records and distribution conditions.
Assessment bodies	Eligible scope, independence and responsibility for reports.

A foreign manufacturer needs an eligible authorised representative for the selected route. Verify required location, legal form and evidence under that route. A distributor is not automatically a suitable regulatory representative. The contract should address dossier access, complaints, changes, authority requests and potential replacement. Distinguish registration holder, manufacturer and production sites. The consultant supports the project; the competent authority retains responsibility for the registration decision.

In practice

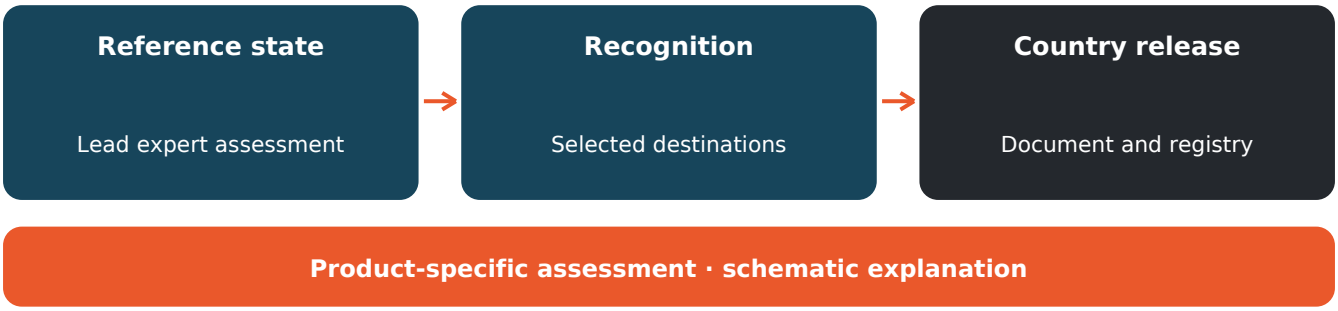
Changing representatives requires a controlled transfer of the dossier, authorisation, reporting and registry particulars.

Sources: [3], [8]

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Reference and recognition states

A common procedure with deliberately selected territorial coverage.



Assessment area	Project implementation
Reference state	Lead expert assessment and registration handling.
Recognition state	Assessment and recognition in a selected destination.
Five members	Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan.
Selection	Coordinate market strategy, language, evidence and authority capacity.
Expansion	Plan later addition of countries under the applicable procedure.

The reference state leads the common assessment; recognition states are defined in the project. A positive reference-state outcome alone does not settle shipment release in every other country. Verify actual territorial coverage using the registration document and common register. National language, import or operator requirements may also apply. Decide during dossier planning which countries belong to the initial application and which will follow later. Expansion can require further translations, fees and coordination.

In practice

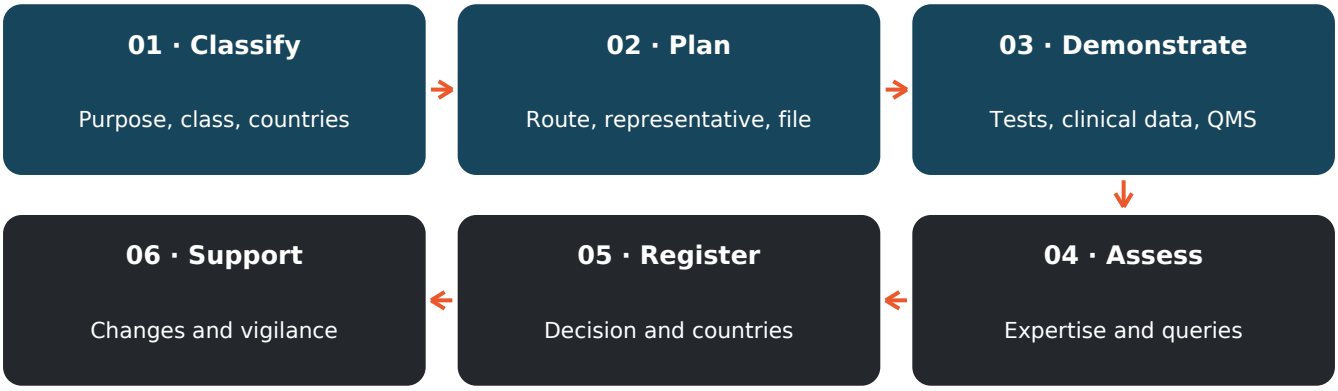
Maintain a separate release row for each destination with recognition status and market-ready labelling.

Sources: [3], [11]

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From project start to market release

Technical tests and regulatory expert assessment are different steps.



Assessment area	Project implementation
Preparation	Approve qualification, route, representative and variant structure.
Dossier	Review records, translate and close evidence gaps.
Evidence	Coordinate technical, biological and clinical programmes.
Assessment	Handle regulatory expertise, queries and country coordination.
Release	Check decision, registry, labelling and supplied identity.

A laboratory report records results within a test assignment. Regulatory expert assessment instead examines the complete product dossier against the applicable registration framework. Do not treat these documents as interchangeable. Parallel work is possible when product version and protocols are stable; uncertain intended purpose or model boundaries can invalidate testing. Set milestones with entry criteria: testing after sample approval, filing after dossier review, and shipment after legal and technical release.

In practice

Manage queries in one log: question, response, revised document, owner and deadline.

Sources: [3], [10]

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The registration dossier

A consistent file connects identity, risk and performance evidence.



Assessment area	Project implementation
Administrative	Application, authorisation, manufacturer, sites and product list.
Technical	Description, drawings, specifications, manufacturing and controls.
Safety	Risk management and justified safety evidence.
Performance	Clinical or clinical-laboratory evidence and test reports.
Use	Labels, packaging, instructions and service information.

A dossier index identifies each document by number, language, revision, approval date and covered models. Existing EU records can provide a basis but must match the selected route substantively and formally. A report covering another material, site or software version does not establish evidence for the submitted configuration. Link translations to approved originals. Avoid conflicting manufacturer addresses, inconsistent model names and unexplained technical changes between the application and reports.

In practice

Before filing, independently check consistency across application, model list, reports, label and IFU.

Sources: [3], [4], [8]

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Intended purpose and product family

The requested scope must be technically and clinically supportable.

Assessment area	Project implementation
Indication	Specify condition, medical task and expected benefit.
Population	Consider age, condition, contraindications and contact.
User	Professional, patient or lay user; define necessary training.
Variants	Justify similarities, differences and evidence bridging.
Accessories	Assess compatibility, separate purpose and dossier inclusion.

A shared brand alone does not establish a product family. Materials, operating principle, clinical claims and manufacturing may limit a common scope. Justify which variant represents the most demanding test configuration. For sets, explain whether components may be used separately and which combinations are approved. “Research use only” must not conflict with medical sales claims. New indications may require new clinical evidence and a regulatory change.

In practice

A variant matrix with explicit differences is more informative than a large catalogue without explanation.

Sources: [3]-[5]

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Technical documentation

The description must explain the device actually manufactured.

Assessment area	Project implementation
Design	Operating principle, assemblies, interfaces and drawings.
Specification	Performance values, tolerances, operating limits and essential performance.
Materials	Patient contact, suppliers, composition and changes.
Manufacturing	Sites, critical processes and final checks.
Service	Maintenance, repair, spare parts and return to safe operation.

For Russia, consider current manufacturer technical and operational documentation requirements, including Order No. 181n/2025 published in the authority catalogue. Technical records must provide traceable information; marketing literature is insufficient. Specify required characteristics of safety-critical components. Document which activities users may perform and which require trained service. Configuration lists connect hardware, accessories and software so the registered version can be identified later.

In practice

Testing organisations, translators and regulatory dossiers should receive the same approved document version.

Sources: [8]

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Risk management

Consider hazards across the complete product lifecycle.

Assessment area	Project implementation
Analysis	Describe hazard, foreseeable sequence of events and harm.
Evaluation	Assess probability and severity using approved criteria.
Control	Justify design, protective measures and information.
Evidence	Verify effectiveness of controls and residual risks.
Feedback	Feed complaints, incidents and changes back into the file.

A generic risk sheet without product relevance does not answer registration questions. Address normal use, misuse, transport, storage, maintenance and disposal. Active equipment includes energy delivery, alarms and power failure; software includes incorrect results, data loss and foreseeable use errors. ISO 14971 can support the structure but does not replace assessment of applicable EAEU requirements. Each significant safety requirement should be traceable through risk, control and evidence.

In practice

Residual risks must agree with clinical benefit and instructions; warnings alone do not resolve a design problem.

Sources: [4], [6]

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Standards and evidence matrix

Select standards deliberately by product, edition and regulatory route.

Assessment area	Project implementation
Requirement	Identify the applicable safety or performance requirement.
Standard	Document technical scope and edition used.
Testing	Define method, sample, acceptance criterion and organisation.
Deviation	Justify gaps and inapplicable clauses.
Report	Link results to model, revision and risk control.

Typical standards families cover electrical safety, EMC, biocompatibility, sterilisation, software and usability. Examples such as IEC 60601, ISO 10993, IEC 62304 or ISO 11607 provide orientation; confirm applicability and accepted editions in the actual project. International reports are valuable, but acceptance depends on route, organisation status and product scope. Use the official EAEU standards recommendation as additional orientation. A standards list without links to product requirements conceals significant evidence gaps.

In practice

Assess existing CE records systematically: directly usable, requiring supplementation or requiring new evidence.

Sources: [4], [8], [10]

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Electrical and mechanical safety

Demonstrate essential performance under fault conditions too.

Assessment area	Project implementation
Electrical	Protection against electric shock, insulation, leakage currents and supply.
Mechanical	Stability, movement, pressure, sharp edges and loading.
Thermal	Surfaces, temperature rise, fire and contacted body areas.
System	Include accessories, connected equipment and interfaces.
Faults	Assess failure, alarm behaviour and safe recovery.

Testing must represent intended use: hospital, practice, mobile use or home environment. A power-supply certificate does not establish safety of the complete medical system. Patient connections, external ports and accessories affect setup. Define essential performance and acceptable fault responses in advance. Passing a partial test does not justify a blanket claim for the entire device. Reports must identify configuration, connected components and tested operating states.

In practice

Justify the most demanding representative configuration rather than merely choosing the most readily available sample.

Sources: [4], [10]

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EMC and usability

Disturbances and user interaction form part of medical safety.

Assessment area	Project implementation
Emissions	Test emissions appropriate to the intended environment.
Immunity	Relevant electromagnetic influences and functional behaviour.
Performance	Define essential-performance acceptance criteria before testing.
Usability	Analyse tasks, user groups and foreseeable use error.
Warnings	Assess alarms, displays, comprehension and response pathways.

Medical equipment must do more than remain powered during a disturbance; assess its relevant performance against defined criteria. Include cables, wireless modules and connected sensors in the configuration. Usability concerns safety-critical tasks such as dose setting, connection, result interpretation or alarm response. Check translated interfaces against instructions. Clinically significant use error may require additional controls and reassessment of user information.

In practice

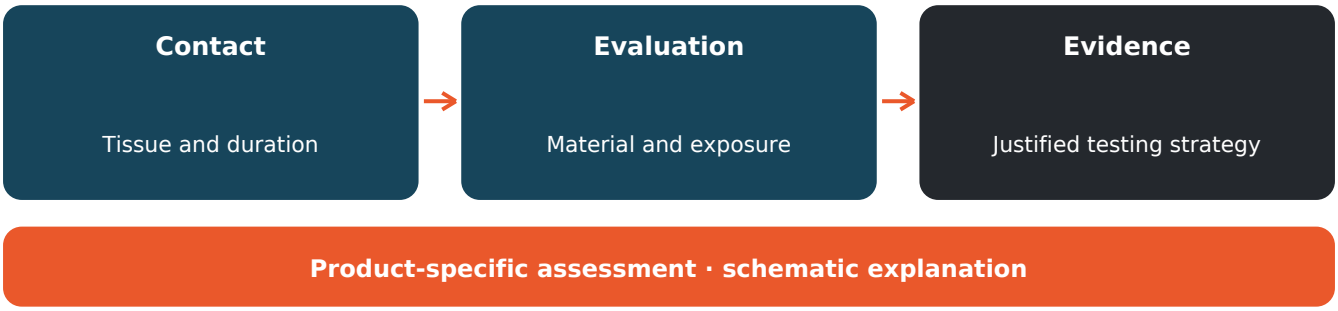
Derive the EMC protocol and usability plan from the same risk-management file.

Sources: [4], [10]

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Biological safety

Material, contact type and duration determine assessment strategy.



Product-specific assessment · schematic explanation

Assessment area	Project implementation
Contact	Identify all direct and indirect patient contact.
Materials	Composition, additives, process residues and suppliers.
Evaluation	Existing data, chemical characterisation and testing needs.
Samples	Finished processed product including relevant sterilisation.
Change	Reassess new materials, processes and contact characteristics.

Biocompatibility is not one universal test. Strategy depends on contacted tissue, exposure duration and product chemistry. Use existing evidence only with a traceable bridging rationale. A raw-polymer data sheet does not necessarily cover a sterilised finished product with adhesives and colorants. Avoid both unjustified gaps and unnecessary duplicate testing. Connect biological evaluation to risk management and intended clinical applications; assess acceptance of evidence under the selected route.

In practice

A component contact matrix helps prevent overlooked indirect exposure or process residues.

Sources: [4], [10]

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Sterility, cleaning and shelf life

Claimed safety must persist through the end of shelf life.

Assessment area	Project implementation
Sterilisation	Document process, validation, routine control and release.
Packaging	Assess sterile barrier, sealing and transport stress.
Reuse	Validate cleaning, disinfection and sterilisation where applicable.
Shelf life	Demonstrate performance and packaging under justified storage conditions.
Instructions	Clearly state cycles, limits, checks and rejection criteria.

For sterile products, manufacturing environment and process control form part of safety. Sterilisation evidence alone does not establish package integrity after transport or ageing. For reusable products, reprocessed states must match technical and biological assessment. Shelf-life claims need traceable data; accelerated ageing requires a justified method and, where appropriate, supporting real-time evidence. Assess packaging or supplier changes before switching production.

In practice

Label, IFU, validation and release records must describe the same sterility and reuse logic.

Sources: [4], [6], [10]

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Clinical evidence and effectiveness

Suitable data must substantiate medical claims.

Assessment area	Project implementation
Claims	Define benefit, indication, endpoints and target population.
Data base	Assess own studies, literature and justified bridging.
Study needs	Resolve missing data and route-specific requirements.
Conduct	Suitable institutions, ethics, protocol and participant protection.
Conclusion	Connect performance, safety and residual risks to product scope.

A CE certificate is not a clinical evaluation. Check international clinical data for product identity, indication and acceptance under the selected route. Clinical assessment does not always mean an identical new human study; confirm scope and permissible evidence forms under the actual legal framework. Protocols need defined endpoints and analysis rules. Evidence for earlier software or another population cannot be bridged without justification. Include negative findings and relevant uncertainty in the evaluation.

In practice

Approve clinical claims only when the same evidence supports the dossier, advertising and IFU.

Sources: [3], [4], [10]

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Analytical and clinical IVD performance

Assess the complete test system under realistic conditions.

Assessment area	Project implementation
Analytical	Assess precision, trueness, detection limit and range as appropriate.
Interference	Interferents, cross-reactivity, matrix and specimen handling.
Clinical	Relevant population, reference method and diagnostic claim.
Stability	Assess transport, storage, opened-use and on-board stability.
System	Connect reagent, instrument, software, controls and calibration.

Performance assessment follows intended use. Sensitivity and specificity are not the same as analytical detection limit. Define handling of invalid and borderline results. Quantitative systems require documented units, measuring range and traceability strategy; qualitative tests require defined decision rules. Specimen types and storage conditions must match manufacturer information. For self-tests, additionally assess whether lay users can safely collect, perform and interpret the test.

In practice

A new instrument platform or revised interpretation software can affect the entire performance bridge.

Sources: [4], [5], [10]

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Software, AI and cybersecurity

Version and medical function form part of the registered identity.



Assessment area	Project implementation
Qualification	Standalone software, embedded function or general IT?
Lifecycle	Maintain requirements, architecture, tests, defects and releases.
Data	Control inputs, interfaces, integrity and access.
AI	Demonstrate dataset, population, limits and reproducible performance.
Updates	Assess medical effect and change route before deployment.

Software can itself be a medical device when intended purpose and functionality satisfy the definition. A version number without traceable release records is insufficient. Document clinically relevant algorithms, configuration, test coverage and known limitations. Link cyber risks to patient safety, for example when altered data triggers an incorrect decision. AI performance claims must fit the intended population. The Russian authority catalogue contains specific guidance on changes to AI medical-device software; automatic model changes must not enter the registered configuration without assessment.

In practice

Document a regulatory decision for every update, including security corrections.

Sources: [4], [8]

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Quality management for medical devices

A certificate supports the dossier; actual processes remain decisive.

Assessment area	Project implementation
Risk basis	Determine requirements by class and product configuration.
Design	Maintain traceability of changes, verification and validation.
Suppliers	Control critical parts, outsourced processes and release criteria.
Production	Document process validation, traceability and final inspection.
Correction	Complaints, root-cause analysis and action effectiveness.

EAEU Decision No. 106/2017 establishes risk-based requirements for implementing, maintaining and assessing the QMS. Amendment No. 43/2026 forms part of current legal status. ISO 13485 can provide a suitable system framework but is not an automatic registration decision or universal substitute for required inspections. Certificate scope must support submitted products and relevant sites. Contract manufacturing still requires traceable supplier control and product responsibility; a supplier certificate alone does not complete the manufacturer dossier.

In practice

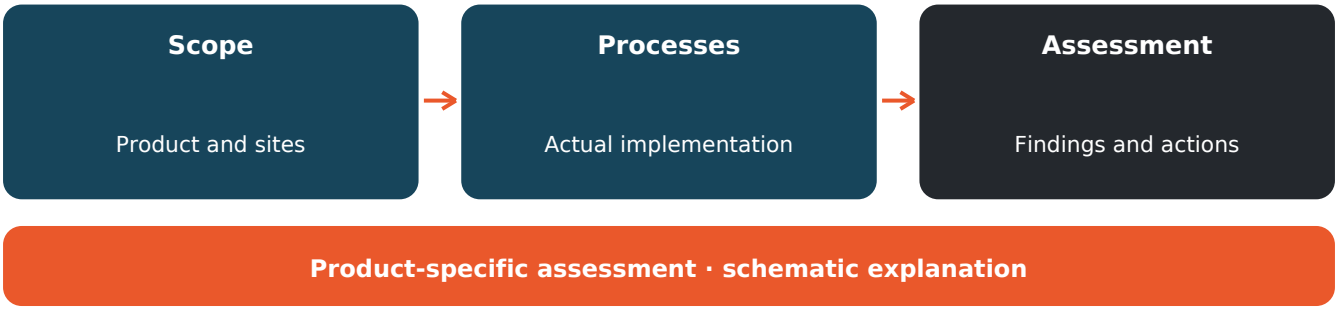
Match product list, QMS scope and site matrix before planning inspection.

Sources: [6], [9]

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Preparing for production inspection

Inspection scope and conduct are determined on a risk basis.



Assessment area	Project implementation
Plan	Define products, sites, processes and required competence.
Records	Provide QMS, production, validation and release records.
Implementation	Compare actual operations with documented procedures.
Findings	Track deviations, causes, actions and effectiveness.
Currency	Reassess inspection status after site or process changes.

Required assessment depends on class, sterility, product scope and current procedural rules. Agree which sites and outsourced processes are covered beforehand. EAEU Recommendation No. 6/2026 provides methodological guidance on production inspections; read it alongside binding QMS rules. Presentations alone do not replace production and quality evidence. Effective closure of findings requires traceable corrections and cause assessment, not merely a new procedure.

Amendment No. 43/2026 clarifies representation and inspection of outsourced processes, among other matters. For periodic inspection, apply no later than 90 working days before the previous inspection report expires; organisation and conduct together must not exceed 90 working days from contract conclusion. Outsourced sterilisation may qualify for simplified assessment using valid inspection and process records under specific conditions. Verify those conditions case by case.

In practice

Conduct an internal readiness audit and record review early enough to close significant gaps before the official visit.

Sources: [6], [9], [15]

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Test samples and import logistics

Samples must be representative, identifiable and lawfully imported.

Assessment area	Project implementation
Selection	Agree variants, demanding configuration and quantities with testers.
Identity	Record model, serial number, batch, software and manufacturing version.
Import	Resolve purpose, records and import authorisation where required.
Transport	Consider temperature, humidity, sterile barrier and dangerous goods.
Disposition	Agree consumption, retention, return or disposal.

Importing registration-test samples differs from a commercial shipment. The Russian authority provides dedicated information and procedures. Ship only after confirmation of the permitted import route and laboratory acceptance. IVD reagents may need controlled temperature; electrical devices need suitable accessories and safe operating instructions. Destructive tests and clinical programmes affect sample quantities. An incorrect configuration can trigger repeat testing and significantly extend schedules.

In practice

A sample list with photographs and documented handover connects import, testing organisation and dossier.

Sources: [8], [10]

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Medical measuring functions and metrology

Not every device with a display requires the same additional approval.

Assessment area	Project implementation
Measuring function	Describe quantity, unit, range and medical decision.
Russian list	Check the current list of relevant medical measuring devices.
Type evidence	Plan required metrological type assessment separately.
Individual unit	Assess verification and operating duties for actual units.
Documentation	Connect measurement performance to clinical claims and IFU.

The Russian authority catalogue lists Order No. 257n of 29 April 2025 on medical measuring devices and their assessment. The actual list entry and use are decisive; a numerical display alone does not settle qualification. Medical-device registration does not universally replace required metrological assessment. Calibration, legal verification and type approval answer different questions. Plan these records with the operator and actual intended use, including service and periodic checks.

In practice

Maintain medical-device status and metrology status in separate release fields.

Sources: [8]

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Additional EAC and import requirements

Derive each additional requirement from its actual scope.

Assessment area	Project implementation
Technical TRs	Check product definitions and exclusions in the actual regulation.
Accessories	Distinguish separate power supplies, wireless modules or general products.
Import	Check customs code, description, documents and restrictions.
Operator	Resolve installation, training, service and permitted use.
Trade	Assess current export controls and supply conditions for the project.

Electrical construction does not automatically establish TR CU 004/2011 or a blanket combination with TR CU 020/2011. Medical devices may be expressly excluded from a technical scope; separately marketed accessories can receive different treatment. Likewise, sanitary SGR registration is not a synonym for a medical registration certificate. Assess every obligation against product description and legal basis. Medical use does not provide a blanket exemption from trade or import restrictions; the actual goods, recipient and route matter.

In practice

Always document an additional EAC obligation with regulation, product scope and evidence type.

Sources: [2], [3], [8]

PRACTICAL GUIDE

Label and product identification

Labelling forms part of assessed product information.

Assessment area	Project implementation
Identity	Product name, model, manufacturer and required representative details.
Traceability	Batch or serial number, manufacturing and expiry particulars.
Safety	Sterility, single use, storage and relevant warnings.
Language	Required language by destination and understandable symbols.
Approval	Match artwork to IFU, registration and product list.

A label must identify the supplied configuration unambiguously. For small devices, assess permitted placement rules rather than deleting information arbitrarily. Link symbols to user information; a QR code does not automatically replace mandatory particulars. Assess print quality, durability and legibility under intended conditions. Changes to manufacturer or representative particulars need controlled regulatory and artwork approval. IVD reagent, control and kit-component labels must agree with overall scope.

In practice

Version artwork by language and release it to production only after documented approval.

Sources: [4], [12]

PRACTICAL GUIDE

The special EAEU medical-device mark

Distinguish the medical mark from the general EAC mark.



Official medical-device mark · No. 26/2016, annex, figure 1

Assessment area	Project implementation
Legal basis	EEC Council Decision No. 26 of 12 February 2016.
Application	Check conditions for the commonly registered product scope.
Artwork	Use official form and proportions; do not invent EAC-MED artwork.
Placement	Check prescribed device, packaging and document levels.
National route	Do not infer entitlement from Russian national registration alone.

The AC Inorms sector page uses the expression “EAC MED”. Operational labelling must follow the officially established special circulation mark for medical devices. The official mark contains EAC and MED within a prescribed frame; an ordinary EAC mark with freely added text is not a substitute. Minimum width B is 6 mm; height and width have a ratio of 30 to 28. Use the original annex to Decision No. 26 as the artwork reference and check minimum dimensions, contrast, legibility and placement against the effective rule. Do not interpret a national Russian document as entitlement to use the common mark without assessment.

In practice

The illustration is explanatory. For printing, use the complete official annex and its dimensional rules.

Sources: [1], [12]

PRACTICAL GUIDE

Instructions for use and translation

Understandable information must match the registered purpose.

Assessment area	Project implementation
Use	Explain indication, users, preparation, operation and results.
Limits	Contraindications, limitations and foreseeable risks.
Care	Cleaning, maintenance, functional checks and disposal.
Language	Review specialist translation, terminology and destination duties.
Revision	Approve original, translation and software interface together.

The IFU requires specialist translation and technical review. A linguistically correct term can be medically wrong if a result, alarm or procedure is understood differently. Review units, decimal notation and figure labels as well as prose. For self-tests and home use, information must match intended user competence. Russian documents are not automatically sufficient for every other EAEU market; confirm national language duties by destination. Apply revised safety information consistently across labels, training and sales records.

In practice

Use a controlled glossary for model names, clinical terms, warning levels and units.

Sources: [4], [8]

PRACTICAL GUIDE

Packaging, storage and digital marking

Product information and logistics conditions must agree.

Assessment area	Project implementation
Protection	Shock, humidity, temperature and sterile barrier where relevant.
Levels	Distinguish unit, kit, sale pack and transport packaging.
Shelf life	Apply expiry particulars and approved storage conditions.
Digital	Check current product-specific Russian digital marking duties.
Release	Align labelling, registry identity and customs description.

Medical registration and digital goods marking are different duties. Certain Russian product categories may be subject to separate identification and traceability rules; a generic DataMatrix code is not registration evidence. Check covered category, implementation dates, exclusions and responsibilities using the current authority marking section. Stability data must support temperature instructions. Repacking or translated labels must preserve traceability to approved goods; a damaged sterile barrier is not merely a cosmetic deviation.

In practice

Importer and manufacturer should agree who maintains codes, packaging data and traceability in practice.

Sources: [4], [8]

PRACTICAL GUIDE

Filing and regulatory expert assessment

Completeness and defensible responses support assessment.

Assessment area	Project implementation
Receipt	Check formal requirements, fees and dossier structure.
Expert assessment	Quality, safety and effectiveness against the complete dossier.
Queries	Technical response with document references and version control.
Supplementation	Target additional data or testing to specific gaps.
Decision	Check official scope, conditions and product identity.

Filing does not guarantee completion, and a positive laboratory result is not state registration. Manufacturer, representative and technical owners should handle queries together. If scope changes during assessment, examine consequences for reports, clinical data and fees. Responses should explain where requirements are met rather than resubmitting large documents without references. Track deadlines under the actual procedure; distinguish manufacturer waiting time from authority processing time in the schedule.

In practice

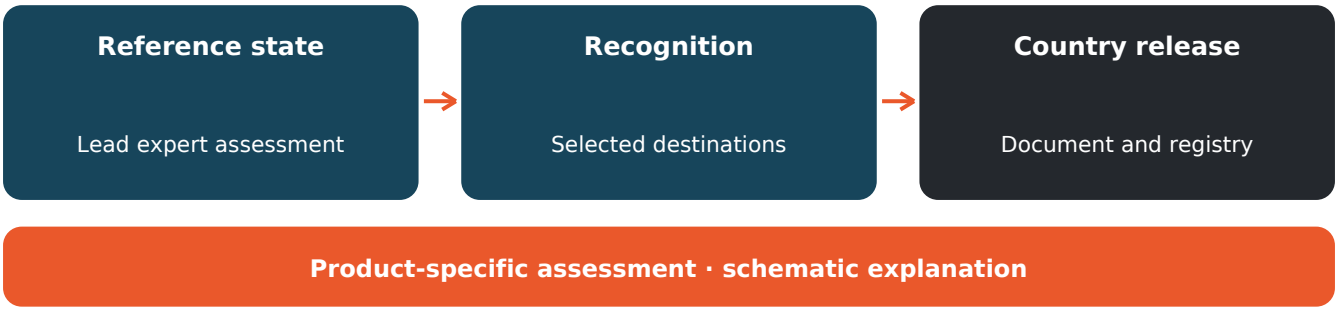
Before each response, assess effects on every affected dossier document.

Sources: [3], [8]

PRACTICAL GUIDE

Recognition and market coverage

Establish country release using official records.



Assessment area	Project implementation
Common dossier	Connect reference assessment and recognition process.
Country	Document selected recognition state and status.
Records	Required translations and country-specific information.
Supply	Only approved models and registered configurations.
Expansion	Add countries using the prescribed procedure.

The common framework facilitates coordination but does not replace checking the actual outcome. A certificate from an EAEU state can have different territorial reach depending on national or common issue and recognised countries. Check document type, number, models and states together. Before distribution in a new market, establish whether recognition, expansion or another permitted route is required. Marketing must not claim broader approval than the documented status.

In practice

Regularly reconcile distribution lists with regulatory country release.

Sources: [3], [11]

PRACTICAL GUIDE

Registry checks and document identity

Match official entries to the goods actually supplied.



Assessment area	Project implementation
Russia	Check the Roszdravnadzor national medical-device register.
EAEU	Use the common registry within the medical-device portal.
Identity	Check manufacturer, product, models and attachments.
Status	Countries, conditions, changes and possible restrictions.
Archive	Record comparison date and checked source in project records.

A registry result with a similar trade name is insufficient. Compare full model lists, variants, manufacturer and production site where relevant. Certificate annexes can materially define permitted scope. A distributor’s registration number does not authorise supply of a different product using the same name. The EAEU portal provides further information on testing organisations and authorities alongside product registers. Document a hold on shipment release where records conflict until the issue is resolved.

In practice

Repeat registry checks immediately before first shipment and after relevant changes.

Sources: [8], [11]

PRACTICAL GUIDE

Validity and actual shipment release

A valid document is only one part of product release.

Assessment area	Project implementation
Document	Check status, territorial coverage and conditions.
Product	Registered models, materials, software and configuration.
Information	Approved labels, IFU and required languages.
Import	Permitted supply, required records and customs identity.
Support	Representative, service, complaints and traceability available.

Read the registration certificate against its actual status rather than a generic validity assumption. An unchanged number does not prove coverage of new software or a new manufacturing site. Even a document without fixed expiry remains tied to registered scope and applicable duties. Assess transition rules separately. For serial supply, confirm the batch matches the approved configuration; installation and training can be additional conditions for safe use.

In practice

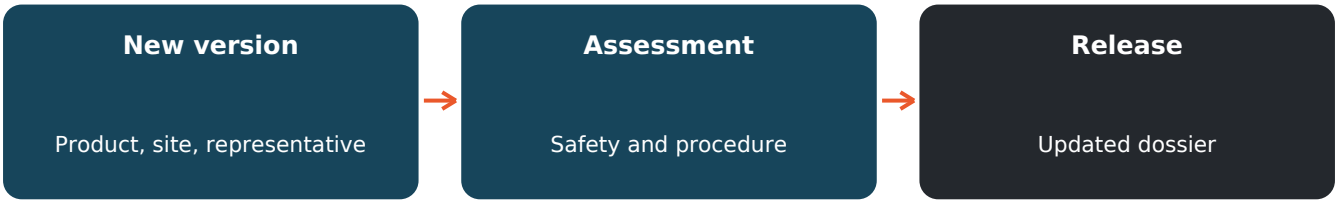
Release only when document, goods, information and import route agree.

Sources: [3], [7], [8]

PRACTICAL GUIDE

Changes and representative particulars

Complete regulatory assessment before supplying the changed version.



Product-specific assessment · schematic explanation

Assessment area	Project implementation
Product	Changed purpose, material, design, software or accessories?
Manufacturing	New site, supplier or critical process involved?
Administrative	Changed manufacturer, representative, name or address?
Procedure	Determine change route with or without further expertise.
Evidence	Update registry, label, IFU and assessment file together.

A technical change requires documented impact assessment. Examine safety, performance, clinical claims and continued applicability of reports. Roszdravnadzor’s 2026 notice addresses Russian Government amendment No. 974 of 3 August 2026: the deadline for updating certain authorised-representative particulars was extended to 1 September 2027. This specific deadline is not a general extension for every product change or registration filing. Its actual scope and the existing dossier remain decisive.

In practice

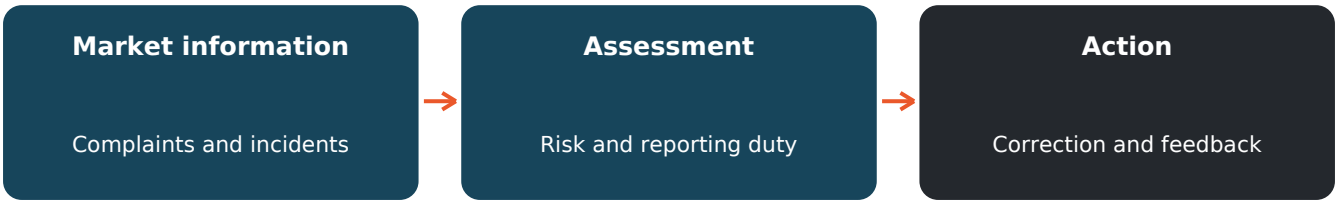
Keep changes on release hold until the required regulatory step is complete.

Sources: [3], [8], [13]

PRACTICAL GUIDE

Vigilance and post-market support

Registration establishes an ongoing responsibility process.



Product-specific assessment · schematic explanation

Assessment area	Project implementation
Collection	Collect complaints, malfunctions and adverse events.
Assessment	Assess harm, recurrence risk and reporting duties.
Reporting	Identify competent authority, deadline and representative by route.
Actions	Coordinate safety notices, corrections or recall.
Learning	Update risk file, clinical evaluation and quality actions.

A complaint process connects distribution, service, manufacturer and representative. An event may be safety-relevant even without confirmed patient harm. Document the decision, rationale and required reporting; derive deadlines from the current applicable procedure. Define affected models, batches or software versions for safety corrections. The authority provides information on adverse events, clinical monitoring and safety notices. Market monitoring is therefore part of product lifecycle rather than merely a later customer-service activity.

In practice

Establish an available escalation chain and current recipient records before first supply.

Sources: [8], [14]

PRACTICAL GUIDE

Costs and a realistic schedule

Effort follows product complexity and evidence gaps.

Assessment area	Project implementation
Scope	Resolve purpose, class, models, countries and route first.
Cost blocks	Dossier, translation, testing, clinical work, inspection and fees.
Additional effort	Samples, import, travel, retesting and queries.
Time	Plan manufacturer work, studies and authority processing separately.
Ongoing costs	Changes, support, surveillance and country expansion.

The AC Inorms sector page gives an indicative overall duration of approximately ten to twelve months. This is not a universal statutory duration or guaranteed completion. Studies, sample availability, QMS gaps and additional countries can change the schedule. A sound quotation states included work, assumptions, excluded fees and rules for additional testing. Product name alone cannot determine a fixed price. A documented gap assessment with owners and realistic milestones provides the strongest planning basis.

In practice

File after dossier approval; a deadline buffer cannot substitute for missing evidence.

Sources: [1], [3], [8]

PRACTICAL GUIDE

Case study: active diagnostic equipment

A fictional example shows how work packages connect.

Assessment area	Project implementation
Starting point	EU manufacturer, two models, patient sensors and diagnostic software.
Objective	Russia and Kazakhstan; assess the common route.
Classification	Justify purpose and rule rather than copying the CE class.
Gaps	Review configuration, clinical claims, EMC and translation.
Release	Connect country status, registration, IFU and software version.

First establish which sensors and software functions belong to the submitted configuration. Compare existing safety reports to that combination and supplement missing scenarios selectively. Clinical evidence must support both models' diagnostic claims. Manufacturer and representative agree change and vigilance processes. Choose testers by eligible scope rather than price alone. After the decision, verify actual registered countries and models. A subsequent new analysis function receives its own impact assessment before deployment.

In practice

This example is not a classification or approval commitment for any actual device.

Sources: [3]-[6], [8]

PRACTICAL GUIDE

Frequently asked questions and common mistakes

Concise answers to recurring project questions.

Are CE or ISO 13485 sufficient?

No. Both can support the dossier but do not automatically replace required Russian or common registration. Check scope, currency and accepted evidence forms.

Does a Russian certificate cover all five states?

Not universally. National and common registration have different reach. Check document type, recognition states and registry status together.

Does every medical device need an EAC certificate?

No. Registration is the central medical authorisation. Justify additional TR requirements using product scope and exclusions rather than a generic list.

Can a new variant be supplied immediately?

Only if approved scope actually covers it and required changes are complete. A similar model name or shared brand is insufficient.

Most frequent mistakes

Unclear intended purpose, unreviewed class transfer, unsuitable representative, unrepresentative samples, obsolete translations and excessive territorial claims. Structured dossier review before testing can identify most of these errors.

Sources: [3]-[8]

PRACTICAL GUIDE

Project release checklist

Printable worksheet: status, owner and next action.

Checkpoint	Status / owner
Intended purpose and product boundary	_____
Risk class and rule rationale	_____
Destinations and registration route	_____
Representative, authorisation and contracts	_____
Models, accessories and production sites	_____
Dossier index and document revisions	_____
Technical and biological evidence	_____
Clinical / IVD performance evidence	_____
Software and QMS / inspection	_____
Sample import and test configuration	_____
Metrology and additional obligations	_____
Label, IFU and languages	_____
Registration and country status	_____
Change and vigilance processes	_____

Release rule

Mark each item complete, open or justifiably inapplicable. Open safety or registration matters prevent shipment release. Record date and approving person’s decision in project records.

Sources: [3]-[8]

PRACTICAL GUIDE

Enquiry form for AC Inorms

These details enable a focused initial assessment.

Item	Your information
Company / contact person	_____
Manufacturer / production sites	_____
Product / models / accessories	_____
Medical intended purpose	_____
Patients / users / environment	_____
Risk class / classification basis	_____
Sterility / body contact / duration	_____
Software / version / AI function	_____
Measuring function / unit / range	_____
Destinations / intended route	_____
Existing registrations / CE	_____
Reports / clinical data / QMS	_____
Sample availability / target date	_____

Attach product data sheet, model matrix, IFU, draft label, existing certificates with annexes, report list and software description where relevant. Provide confidential technical records using the agreed secure transfer method.

Contact

inbox@ac-inorms.com · +49 2161 9904970
The enquiry describes desired product and country scope; technical classification follows assessment.

PRACTICAL GUIDE

Product and evidence matrix

Use one worksheet per family and supplement by destination.

Characteristic	Model A	Model B
Purpose / indication	_____	_____
Class / rule	_____	_____
Hardware / materials	_____	_____
Software / version	_____	_____
Contact / duration	_____	_____
Sterile / reuse	_____	_____
Accessories / combination	_____	_____
Manufacturing site	_____	_____
Technical reports	_____	_____
Biological evaluation	_____	_____
Clinical / IVD performance	_____	_____
QMS / inspection	_____	_____
Labelling / IFU	_____	_____
Destination / recognition	_____	_____
Change status	_____	_____

Evaluation

Assess differences actively: which data cover both models, which variant is representative, and where is new evidence required? An empty cell means open status, not automatic exemption. Maintain rationales and report numbers in a supporting action log.

Sources: [3]-[6]

PRACTICAL GUIDE

Terminology and regulations archive

Use terms precisely and distinguish sources by purpose.

Term	Meaning
Registration certificate	Medical authorisation record; not general sanitary SGR.
Expert assessment	Regulatory evaluation of the complete dossier.
Reference state	Lead state in the common procedure.
Recognition state	Selected state recognising the common assessment.
IFU	Instructions covering purpose, limits and safe use.
IVD	Device examining human specimens in vitro.
QMS	Quality management system for relevant products and processes.
Vigilance	Collection, assessment and reporting of safety-relevant market information.

The AC Inorms regulations archive supports searches for technical regulations. Medical-device law is a separate framework; not every listed TR applies to a medical product. Record archive text, original legal act and applicable amendment separately.

Sources: [2]-[6], [8]

PRACTICAL GUIDE

Sources and references

Linked foundations for registration and project planning.

[1] AC Inorms: medical devices in Russia and the EAEU

Open original source

[2] AC Inorms: regulations archive

Open original source

[3] EAEU: registration, No. 46/2016; amendments in authority catalogue

Open original source

[4] EAEU: safety, performance and labelling, No. 27/2016

Open original source

[5] EAEU: risk classification, No. 173/2015; amendment No. 18/2025

Open original source

[6] EAEU: QMS, No. 106/2017

Open original source

[7] EEC: extension of applications through the end of 2027

Open original source

[8] Roszdravnadzor: medical devices and current legal acts

Open original source

Sources: [1]-[8]

PRACTICAL GUIDE

Further sources and image credits

Linked foundations for registration and project planning.

[9] EAEU: QMS amendment No. 43/2026

Open original source

[10] Roszdravnadzor: technical, biological and clinical procedures

Open original source

[11] EAEU: common medical-device portal and registry

Open original source

[12] EAEU: special medical-device mark, No. 26/2016

Open original source

[13] Roszdravnadzor: representative particulars, amendment No. 974/2026

Open original source

[14] Roszdravnadzor: medical-device safety monitoring

Open original source

[15] EAEU: methodological inspection guidance No. 6/2026

Open original source

[16] EEC: medical devices and medicines as separate regulatory fields

Open original source

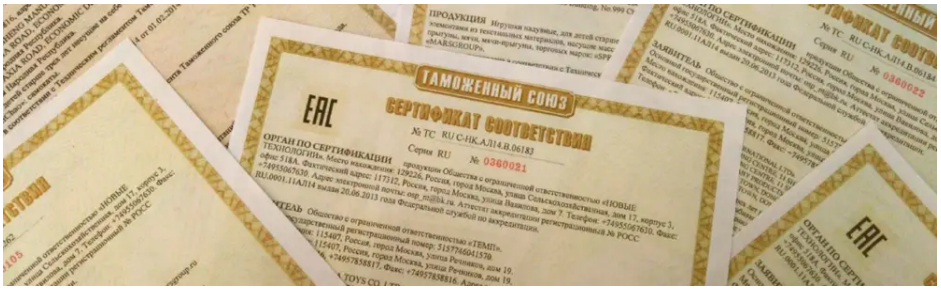
Image credits: medical-device cover photograph and closing EAC-documentation image from ac-inorms.com. Official medical-device mark: EAEU Decision No. 26/2016, annex, figure 1. Diagrams and worksheets are original explanatory material. Legal sources were reviewed as of 11 October 2026; official Russian texts and subsequent amendments govern the actual procedure.

Sources: [9]-[16]

PRACTICAL GUIDE

Your medical-device project with AC Inorms

From a precise product brief to a defensible regulatory strategy.



Documentation and market access · Image source: AC Inorms

AC Inorms supports qualification, route planning and coordination of required evidence. The basis is your actual product scope, intended medical purpose, variants and destinations. Together, identify open issues, suitable assessment organisations and a realistic workflow. Verify registration and territorial scope against the official outcome.

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Web: ac-inorms.com

For your first contact

Use the enquiry form on page 45. Send product description, model list, IFU, available reports and desired destinations. This enables a concrete gap analysis and a product-specific registration strategy.

Sources: [1], [2]