



European  
Commission



# Implementation Model for *in vitro* Diagnostic Medical Devices Regulation Step by Step Guide

MEDICAL DEVICES CHANGE OF LEGISLATION  
**What you need to know!**



## STEP

## INTENTION / ACTION

1

### Pre-assessment

Brief management to ensure a clear understanding of the importance and business implications of the IVDR

Consider organisational challenges: management awareness, staffing capability and availability, budget implications

Assess impact on products, internal resources, organisation and budget

Check new classification rules (IVDR Classes A–D) and confirm conformity assessment routes for existing and future products. Check the requirement for involving the Notified Bodies

Review the changes needed to existing technical documentation (Technical Files)

Review and upgrade quality management system (QMS) (point 3 below)

2

### Gap analysis and actions resulting from this

Check the adequacy of available clinical evidence and risk management and identify any gaps (Article 56)

Review product labelling (Annex I Chapter III)

Ensure post-market surveillance (PMS) arrangements are adequate (Chapter VII Section 1)

Prepare a post-market performance follow-up plan (PMPF, Annex XIII Part B)

Get ready for the new vigilance requirements (Chapter VII Section 2)

Ensure the respect of traceability obligations (Chapter III)

3

### Quality Management System (QMS)

Review adequacy of QMS to meet standards and processes for IVDs under the new Regulation

Build new regulatory requirements into the QMS

Identify/hire the person responsible for regulatory compliance within your organisation (Article 15) and be sure it is adequately qualified and trained

<b>4</b>	<b>Legal entities</b>	Clarify how the company is affected: legal entities, obligation of economic operators, organisational structures and resources
		Consider organisational challenges: management awareness, staffing capability and availability, budget implications
		Ensure product liability insurance is adequate
<b>5</b>	<b>Portfolio</b>	Do a cost/benefit analysis for your product portfolio; bear in mind costs related to the new risk classification system and the need of involving a Notified Body and costs for post-market surveillance and gaps in the technical documentation, and plan your transition to the IVDR accordingly
		Review supply chain provisions, and clarify roles and responsibilities of business partners (authorised representatives, importers, distributors)
<b>6</b>	<b>Master implementation plan</b>	Build a roadmap for implementation, including definition of sub-projects, resource requirements and a steering group, and ensure overall responsibility for IVDR implementation has been established
		Give special consideration to certificate expiry dates, bearing in mind the transitional period, transitional provisions and availability of your Notified Bodies
<b>7</b>	<b>Notified Bodies</b>	Contact the selected Notified Bodies and determine their capacity and availability to service the implementation plan
<b>8</b>	<b>Regulatory training</b>	Empower and train staff through IVDR implementation and transition workshops
<b>9</b>	<b>Execute master implementation plan</b>	Implement the various sub-projects (performance evaluation, technical documentation, relations with other economic operators, Unique Device Identification, labelling, post-market surveillance, vigilance, and reporting IT systems)
		Ensure a cross-functional project management team is in place to cover all aspects of implementation
		Ensure overall and individual responsibilities for IVDR implementation have been established
<b>10</b>	<b>Review efficiency and effectiveness</b>	Implement regular meetings on project status and progress, discrepancy and gap analyses, risks, next steps and requirements
		Hold regular progress reviews against the IVDR implementation plan and include these in the management review process
<b>11</b>	<b>Notified Body submission</b>	Discuss submission dates to avoid delays in the approval process
<b>12</b>	<b>Ongoing monitoring</b>	Actively monitor the still-developing European regulatory environment and guidelines expected in the coming months (check DG GROW web pages on medical devices and subscribe to the newsletter)
		Establish a procedure for dealing with unannounced inspections from Notified Bodies
		Regularly review the IVDR implementation plan, identifying and addressing key areas of risk

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