

Unit 4: European Union

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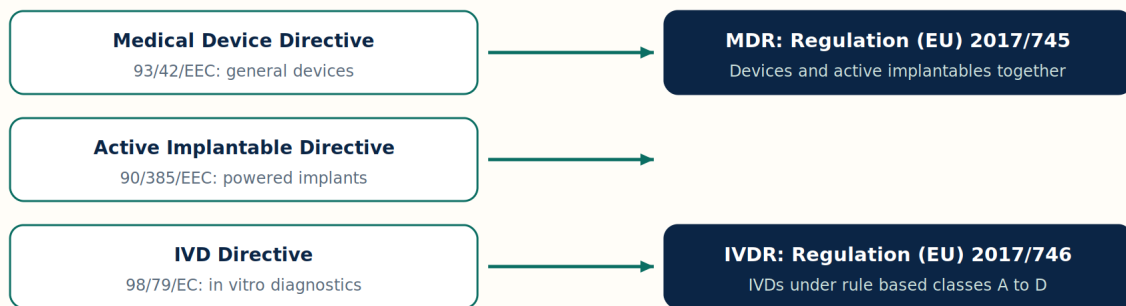
4.1 Introduction: the European approach

The European system inverts the American architecture, and this unit cannot be understood without holding the inversion clearly. Where the United States puts a federal agency between the manufacturer and the market, Europe built a **New Approach** system: legislation states the essential requirements, harmonised standards supply the technical detail, and the assessment of conformity is performed by **notified bodies**, independent organisations designated and supervised by the member states, with the manufacturer's reward a **CE mark** that opens every member state market at once. The syllabus prints the framework in its directive form: the **Medical Device Directive 93/42/EEC** for general devices, the **Active Implantable Medical Device Directive 90/385/EEC** for powered implants, and the **In Vitro Diagnostic Directive 98/79/EC** for IVDs, and the sections that follow teach that framework exactly as printed. The current position is then stated where it belongs, in section 4.2 and carried through the unit: the two regulations of 2017, the **MDR (Regulation (EU) 2017/745)** for devices and active implantables together, and the **IVDR (Regulation (EU) 2017/746)** for IVDs, have replaced the directives, keeping the architecture, classification tiers and CE logic while tightening clinical evidence, notified body oversight, traceability and post market duties.

4.2 The three directives and their successors

The **Medical Device Directive** covered the general run of devices, from syringes to scanners, defining the medical device in the mode of action language of Unit 1, stating the essential requirements in its first annex, classifying devices by rules in its ninth annex, and setting the conformity assessment routes of section 4.4. The **Active Implantable Medical Device Directive** covered the small, highest risk family of powered implants, pacemakers and implantable defibrillators and drug pumps, imposing the fullest conformity route on all of them without class gradation, because a powered device inside the body that cannot be inspected concentrates risk. The **In Vitro Diagnostic Directive** covered IVDs with its own proportionate scheme of section 4.6, in which most tests were self declared and only the highest risk lists attracted notified bodies. The succession matters to practice and must be stated correctly: the directives are repealed, the MDR has applied since 2021 and the IVDR since 2022, each with staged transition for legacy devices holding directive certificates; the MDR absorbed the active implantables into the single device regulation; both regulations are directly applicable law in every member state rather than texts awaiting national transposition; and the classification rules, vigilance duties and UDI system of the regulations are materially stricter than the directives they replaced. The examination strategy follows the branch pattern of MRA103T: answer the printed syllabus in the directive framework, and show that you know the regulation now in force.

From directives to regulations: the EU succession



Architecture, tiers and CE logic carried across; evidence and oversight tightened

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Figure: The succession of section 4.2: the Medical Device Directive and the Active Implantable Directive together replaced by the MDR 2017/745, and the IVD Directive replaced by the IVDR 2017/746, the architecture, tiers and CE logic carried across and the evidence, oversight and vigilance duties tightened (Unit 4, section 4.2).

4.3 Classification in the European system

European classification is performed by the manufacturer, applying the classification **rules** to the device's intended purpose, and defended to the notified body, a discipline opposite to the American assignment of classes by regulation to listed device types. The MDD rules, eighteen in number, sort devices by the logic of Unit 1: non invasive devices in the lowest classes unless they channel or store blood or modify composition; invasive devices graded by duration, transient, short term and long term, and by the sensitivity of the site, the teeth and lower orifices below the body interior, the central circulatory and nervous systems at the top; active devices graded by the energy they exchange, diagnostic energy below therapeutic energy, and the administration of medicines or radiation highest; with special rules for contraception, disinfection, recording of diagnostic images and devices incorporating a medicinal substance. The output is the four tier ladder: **Class I** low risk, **Class IIa** medium, **Class IIb** medium to high, **Class III** high, with Class I subdivided for sterile devices and devices with a measuring function, which alone in their class need a notified body, for the sterile or measuring aspect. The MDR keeps the four tiers and the rule machinery, extends it to twenty two rules, and moves several families upward, software and devices in contact with the central systems among them, so legacy classifications cannot simply be carried across. IVDs kept their own scheme under the IVDD, and the IVDR replaced it with a rule based A to D classification aligned with the GHTF model, the two states of the IVD scheme being compared in section 4.6.

4.4 Conformity assessment and notified bodies

Conformity assessment is the European route system: the manufacturer demonstrates conformity with the essential requirements by a route proportioned to the class, draws up a **declaration of conformity**, and affixes the **CE mark**. The routes combine two kinds of examination in different proportions: examination of the **quality system**, by audit of the manufacturer's ISO 13485 based system in its full or production limited forms (the directive annexes II, V and VI), and examination of the **product**, by type examination of a representative device (annex III) or by verification of each product or batch. Class I devices, sterile and measuring aspects aside, are self declared on the manufacturer's own responsibility. Class IIa devices engage a notified body on the quality system or the type. Classes IIb and III engage the notified body fully, with design dossier examination for Class III, in which the authority reviews the design documentation itself before certification. The **notified body** is the system's load bearing institution: a conformity assessment body designated by its member state against competence criteria, notified to the Commission and the other states, listed with the scope of device types it may certify, and itself audited and supervised, a supervision

the MDR made markedly harder after the failures discussed in Unit 1. Its certificate, not a state approval, is the manufacturer's passport, and its withdrawal closes the European market to the device. Beside the bodies stand the **competent authorities** of the member states, who run vigilance, market surveillance and the safeguard clause by which a CE marked device can still be stopped where it endangers health.

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The CE certification process
Classify the device by the rules (manufacturer, intended purpose)
|
Select the conformity route for the class
|
Compile the technical documentation: essential requirements
checklist, risk file, clinical evaluation
|
Notified body audit of the quality system and, by class,
type or design examination
|
Declaration of conformity drawn up by the manufacturer
|
CE mark affixed: the whole European market opens
|
Post market surveillance and vigilance under the member states
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4.5 The CE certification process, step by step

Read as a workflow, the process of section 4.4 runs in eight movements, and the syllabus names the process itself, so it is set out in sequence. First, **determine the framework**: confirm the product is a medical device under the definition, and fix its intended purpose in writing, since purpose drives everything. Second, **classify** by the rules and record the reasoning. Third, **identify the applicable requirements and standards**: the essential requirements, and the harmonised standards whose application confers presumption of conformity. Fourth, **compile the technical documentation**: device description, design and manufacturing information, the essential requirements checklist, risk management file under ISO 14971, verification and validation evidence, and the **clinical evaluation**, the structured appraisal of the clinical literature and any investigation data that supports safety and performance, which every class owes in some depth. Fifth, **run the quality system**: the ISO 13485 system of Unit 2, under which design, production and vigilance operate. Sixth, **submit to the notified body** where the class requires one: application, documentation review, quality system audit, and for the higher classes design or type examination, answering its questions until certification. Seventh, **declare and mark**: the manufacturer draws up the declaration of conformity and affixes the CE mark, with the notified body's number beside it where a body took part. Eighth, **register and watch**: registration of the manufacturer and device with the competent authority, and the post market surveillance, vigilance reporting and periodic updating of the clinical evaluation for the product's life. The MDR adds the European database registration and the UDI assignment to the closing movements. What the student should see is that CE marking is a manufacturer declaration resting on audited systems and reviewed documents, a different species of market licence from FDA clearance or approval.

Conformity assessment: the route rises with the class

Class I	Self declaration by the manufacturer	Body only: sterile or measuring aspect
Class IIa	Quality system or type examination	Notified body engaged on one limb
Class IIb	Full quality system or type plus verification	Notified body on both limbs
Class III	Full quality system plus design examination	The design dossier itself is reviewed
Active implantable	Fullest route for the whole family	No class gradation: the risk is concentrated

The certificate, not a state approval, is the passport; the CE mark follows the declaration

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Figure: The conformity assessment ladder of section 4.4: self declaration for Class I, notified body engagement rising through IIa and IIb, and full quality system audit with design dossier examination for Class III, with the active implantable family held at the fullest route throughout (Unit 4, section 4.4).

4.6 IVDs in the European Union: basics, classification and approval

Under the **IVD Directive**, classification was by lists rather than rules, and its proportionality was extreme in the direction of trust: the great majority of IVDs, the **general** category, were placed on the market by the manufacturer's own declaration of conformity. Notified bodies entered only for the named high risk territories: **List A**, the highest, covering tests for blood grouping and for transfusion transmitted infection markers such as HIV and the hepatitis viruses, which required design examination and batch verification; **List B**, covering a further schedule of significant tests, among them certain infectious disease, tumour marker, genetic and blood grouping reagents, which required type examination or a full quality system; and **self testing** devices, designed for lay users, which required notified body examination of the design for usability by non professionals. Performance evaluation, the demonstration that the test achieves its analytical and diagnostic performance in the hands of intended users, was the IVD's clinical evidence, and common technical specifications set binding performance floors for the List A and B territories. The **IVDR** replaced the lists with the rule based, GHTF aligned classification the model of Unit 1 predicts: **Class A** low individual risk (general laboratory products, instruments and specimen receptacles), **Class B** moderate (most self assessed routine assays, for example many pregnancy and fertility and cholesterol tests falling here by rule), **Class C** high individual or moderate public health risk (tests whose error carries serious consequence, including many infectious disease and cancer related assays), and **Class D** the highest, tests for transfusion and transplantation safety and life threatening transmissible agents. The practical consequence is the largest single change in the IVDR: notified body involvement, once the exception, now covers the great majority of IVDs, and the transition has been staged by class precisely because the notified body capacity had to grow to meet it.

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