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The CE Mark Mystery: What It Really Means in a Diagnostic Laboratory

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Have you ever looked around a diagnostic laboratory and wondered what all those CE marks actually mean?

A CE mark can appear on an analyzer, a centrifuge, a Bluetooth-enabled reader, an IVD reagent, a battery, or even a complex automated platform. At first glance, the symbol always looks the same. Legally, however, it may stand for very different things.

For one product, the CE mark may indicate conformity with the In Vitro Diagnostic Medical Devices Regulation. For another, it may be based on electrical safety and electromagnetic compatibility requirements. A connected instrument may additionally fall under radio equipment legislation. A battery may have its own regulatory obligations. Packaging, chemicals and end-of-life disposal may be subject to further EU legislation without requiring any CE mark at all.

This creates a common misunderstanding:

A CE mark does not tell you, by itself, which legislation has been applied.

It also does not automatically mean that a product is suitable for diagnostic use.

A research-use-only sequencer may carry a CE mark under electrical, electromagnetic and environmental legislation while remaining outside the IVDR. A general laboratory instrument may be CE-marked but have no medical intended purpose. An IVD analyzer may carry the same CE symbol, although its conformity has been assessed under a fundamentally different regulatory framework.

The laboratory therefore needs to look beyond the logo.

The relevant questions are:

- What is the manufacturer's intended purpose?
- Which EU legislation applies to the product?
- Does the CE mark relate to IVDR conformity, general product legislation, or several frameworks at once?
- Which additional obligations apply even though they do not require CE marking?
- What changes when the laboratory uses a GLU or RUO product in a diagnostic workflow?

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These distinctions are particularly important in modern laboratories, where diagnostic systems often combine IVD products, RUO instruments, general laboratory equipment, software, reagents, radio modules, batteries and packaging into one operational workflow.

This article provides a practical overview of the main EU regulatory frameworks that may apply to products used in diagnostic laboratories. It explains which legislation requires CE marking, which obligations apply in parallel without CE marking, and why two products carrying the same CE symbol may have very different regulatory meanings.

Because in the laboratory, the real question is not simply:

“Does this product have a CE mark?”

The more important question is:

“What exactly is this CE mark based on—and does that match the way we intend to use the product?”

Consolidated EU regulatory matrix for products used in diagnostic laboratories

Legend

Symbol	Meaning
●	Normally applicable
△	Potentially applicable; requires product-specific assessment
—	Normally not applicable
I	Requirement is integrated into another applicable CE-marking regime
C	Applies at component level, rather than as a CE regime for the complete instrument

The decisive criteria are the **manufacturer’s intended purpose**, product design, voltage, radio functionality, target users and whether the product is placed on the market as a separate product.

A. CE-marking legislation

Product type	IVDR 2017/746	LVD 2014/35/EU	EMC 2014/30/EU	RED 2014/53/EU	RoHS 2011/65/EU	Battery Regulation 2023/1542	Machinery legislation
General electrical laboratory instrument — GLU	—	●[1]	●	—	●	—	△
GLU instrument with Bluetooth/Wi-Fi	—	I[2]	I[2]	●	●	—	△
RUO electrical instrument, e.g. research sequencer	—[3]	●[1]	●	—	●	—	△
RUO instrument with Bluetooth/Wi-Fi	—[3]	I[2]	I[2]	●	●	—	△
IVD instrument without radio transmission	●	—[4]	I[5]	—	●	—	△[6]
IVD instrument with Bluetooth/Wi-Fi	●	I[2]	I[2]	●	●	—	△[6]
Battery-powered GLU instrument without radio	—	△[1]	●	—	●	C[7]	△
Battery-powered RUO instrument without radio	—[3]	△[1]	●	—	●	C[7]	△
Battery-powered IVD instrument without radio	●	—[4]	I[5]	—	●	C[7]	△[6]
Battery-powered IVD with Bluetooth/Wi-Fi	●	I[2]	I[2]	●	●	C[7]	△[6]
Standalone IVD software	●	—	—	—	—	—	—
General laboratory software	—	—	—	—	—	—	—
IVD reagent, calibrator or control	●	—	—	—	—	—	—
RUO reagent	—[3]	—	—	—	—	—	—
General laboratory chemical reagent	—	—	—	—	—	—	—
Electrical IVD cartridge or disposable	●	—[4]	I[5]	△	△	C[7]	—
Separate battery placed on the market	—	—	—	—	△	●	—
Ordinary packaging	—	—	—	—	—	—	—

The IVDR covers IVD reagents, instruments, software, systems, calibrators, controls and related accessories where they have an IVD intended purpose. (Eur-Lex)

Footnotes

1. LVD voltage scope

The LVD generally applies to equipment designed for use within:

- **50–1,000 V AC**, or
- **75–1,500 V DC**.

A low-voltage battery-powered instrument may therefore fall outside the LVD, although its separately supplied mains adapter may itself be subject to the LVD.

2. Radio equipment

For products within the RED:

- the RED contains the relevant electrical-safety requirements;
- the RED contains the applicable EMC essential requirements;
- separate conformity assessment under the LVD and EMC Directive is generally not performed for the radio equipment.

One CE mark can therefore represent, for example, **RED + RoHS**, or **IVDR + RED + RoHS**. (Eur-Lex)

3. RUO status

An RUO instrument or reagent is outside the IVDR only where it has a genuine **research-only intended purpose**. The label "RUO" alone is not decisive if the product claims, instructions or promotion establish a diagnostic medical intended purpose.

A research sequencer used by a laboratory in an in-house diagnostic workflow can remain an RUO instrument. The laboratory's complete workflow may nevertheless constitute an **in-house IVD** under Article 5(5).

4. IVD and LVD

Electrical equipment for medical purposes is excluded from the LVD. Electrical safety for the IVD is addressed under the IVDR General Safety and Performance Requirements rather than through a separate LVD declaration.

5. IVD and EMC

For an IVD without radio functionality, EMC must still be assessed and documented. However, the relevant EMC requirements are normally addressed within the **IVDR conformity assessment**, rather than by separately declaring conformity under the EMC Directive.

6. Machinery legislation

An automated analyser, robotic sample-processing platform, conveyor or similar system may also meet the definition of machinery.

Where machinery legislation applies, the machinery-related essential health and safety requirements must be assessed to the extent that they address risks not covered more specifically by the IVDR. Regulation (EU) 2023/1230 generally replaces the Machinery Directive from **20 January 2027**.

7. Incorporated batteries

The Battery Regulation applies to batteries whether they are:

- placed on the market separately; or
- incorporated into appliances or other products.

For a battery-powered analyser, the Battery Regulation normally regulates the **incorporated battery**, not the analyser as a complete product under an additional instrument-level CE regime. Batteries placed on the EU market are subject to the Battery Regulation's conformity assessment and CE-marking requirements. (Eur-Lex)

B. Parallel legislation and obligations

These frameworks may apply alongside the CE-marking legislation. Some do **not** require CE marking.

Product type	REACH	CLP	WEEE	Packaging / PPWR	GPSR	Battery obligations
General electrical laboratory instrument — GLU	△	△	●	●	— / △[8]	—
GLU instrument with Bluetooth/Wi-Fi	△	△	●	●	— / △[8]	—
RUO electrical instrument, e.g. sequencer	△	△	●	●	— / △[8]	—
RUO instrument with Bluetooth/Wi-Fi	△	△	●	●	— / △[8]	—
IVD instrument without radio transmission	△	△	● / △[9]	●	— / △[10]	—
IVD instrument with Bluetooth/Wi-Fi	△	△	● / △[9]	●	— / △[10]	—
Battery-powered GLU instrument	△	△	●	●	— / △[8]	●
Battery-powered RUO instrument	△	△	●	●	— / △[8]	●
Battery-powered IVD instrument	△	△	● / △[9]	●	— / △[10]	●
Standalone IVD software delivered electronically	—	—	—	—	— / △[10]	—
General laboratory software delivered electronically	—	—	—	—	— / △[8]	—
Software supplied on physical media	△	△	△	●	— / △	—
IVD reagent, calibrator or control	● / △	● / △	—	●	— / △[10]	—
RUO reagent	● / △	● / △	—	●	— / △[8]	—
General laboratory chemical reagent	● / △	● / △	—	●	— / △[8]	—
Electrical IVD cartridge or disposable	△	△	● / △[9]	●	— / △[10]	△
Separate battery	△	△	△	●	△	●
Ordinary packaging	△	△	—	●	— / △[11]	—

Footnotes

8. Professional GLU and RUO products: A sequencer, mass spectrometer, flow cytometer or other product designed exclusively for professional laboratory use will normally not be a GPSR consumer product.

GPSR relevance may arise where the product:

- is also marketed to consumers;
- is sold through general consumer channels;
- is reasonably likely to be used by consumers;
- has both professional and consumer variants.

9. WEEE and IVD equipment

WEEE applicability depends particularly on:

- whether the product is electrical or electronic equipment;
- whether it is expected to be infective at end of life;
- whether it can be appropriately decontaminated;
- national implementation.

10. GPSR and IVDs

For an IVD sold to consumers, such as a self-test, the IVDR remains the principal sector-specific legislation.

The GPSR may apply residually to risks or aspects not already covered by specific EU product-safety legislation. It does not replace or duplicate the IVDR requirements that specifically address the risk concerned. (Eur-Lex)

11. Packaging

Ordinary packaging is primarily regulated by packaging legislation. GPSR relevance would be exceptional, for example where the packaging is itself a consumer product or introduces an independent consumer-safety risk not adequately covered elsewhere.

C. Does each framework require CE marking?

Framework	CE marking?	Main purpose
IVDR	**Yes**	Safety, performance and regulatory conformity of IVDs
LVD	**Yes**	Electrical safety
EMC Directive	**Yes**	Electromagnetic emissions and immunity
RED	**Yes**	Radio safety, EMC and efficient use of radio spectrum
RoHS	**Yes**	Restriction of hazardous substances in electrical and electronic equipment
Battery Regulation	**Yes, for batteries**	Sustainability, safety, labelling, removability and lifecycle requirements for batteries
Machinery Directive / Machinery Regulation	**Yes**	Machinery-related health and safety requirements
REACH	**No**	Chemical registration, restrictions, authorisation and supply-chain communication
CLP	**No**	Chemical hazard classification, labelling and packaging
WEEE	**No**	Producer responsibility, collection, treatment, recycling and disposal of electrical equipment
Packaging and Packaging Waste Regulation	**No**	Packaging composition, sustainability, recyclability, labelling and producer responsibility
General Product Safety Regulation	**No**	General safety framework for consumer products

D. Key non-CE regimes

REACH and CLP

For chemical reagents, buffers, stains, solvents and mixtures:

- **IVDR** determines whether the product is an IVD and requires CE marking;
- **CLP** determines chemical hazard classification, pictograms, signal words and hazard statements;
- **REACH** governs matters such as restrictions, authorisation, registration, safety data sheets and supply-chain communication.

An IVD reagent may therefore carry both:

- an **IVDR CE mark**; and
- **CLP hazard pictograms**.

CLP and REACH obligations depend on the substance or mixture, concentration, quantity, economic-operator role and applicable exemptions.

WEEE

WEEE does not require CE marking. It may require:

- producer registration;
- reporting of equipment placed on the market;
- financing collection and treatment;
- take-back arrangements;
- provision of treatment information;
- the crossed-out wheeled-bin symbol.

Infective-device exclusion

Medical devices and IVDs expected to be **infective before end of life** may be outside the WEEE scope.

This exclusion does not apply automatically to every IVD:

- a reusable analyser that can be decontaminated will commonly remain within WEEE;
- an electrical disposable expected to remain infective may potentially be excluded;
- national implementation should be checked.

Packaging and PPWR

Packaging legislation applies to the packaging of:

- instruments;
- reagents;
- batteries;
- kits;
- cartridges;
- software supplied on physical media.

It does not create a CE mark.

Regulation (EU) 2025/40 (Packaging and Packaging Waste Regulation) generally starts applying from **12 August 2026**, with several requirements subject to later or transitional dates. As of **13 July 2026**, existing national packaging and producer-responsibility frameworks still require consideration during the transition.

General Product Safety Regulation

The GPSR does not require CE marking. It principally concerns products intended for consumers or products reasonably likely to be used by consumers.

E. Typical regulatory combinations

Product example	Legislation behind the CE mark	Additional non-CE obligations commonly relevant
230 V general laboratory centrifuge	LVD + EMC + RoHS; potentially machinery legislation	WEEE, REACH and packaging
GLU instrument with Wi-Fi	RED + RoHS; potentially machinery legislation	WEEE, REACH and packaging
RUO sequencer without radio transmission	LVD + EMC + RoHS; potentially machinery legislation	WEEE, REACH and packaging
RUO sequencer with Wi-Fi	RED + RoHS; potentially machinery legislation	WEEE, REACH and packaging
IVD analyser without radio transmission	IVDR + RoHS; potentially machinery legislation	WEEE, REACH and packaging
IVD analyser with Bluetooth/Wi-Fi	IVDR + RED + RoHS; potentially machinery legislation	WEEE, battery, REACH and packaging
Battery-powered IVD analyser without radio	IVDR + RoHS; potentially machinery legislation; battery CE at component level	WEEE, battery lifecycle and packaging obligations
Standalone IVD software	IVDR	Data protection, cybersecurity and software-specific obligations as applicable
General laboratory software	Normally no CE mark	Data protection, cybersecurity, contractual and general software obligations
IVD reagent	IVDR	REACH, CLP and packaging
RUO reagent	Normally no CE mark	REACH, CLP and packaging
General laboratory chemical reagent	Normally no CE mark	REACH, CLP and packaging
Separate battery	Battery Regulation; possibly other product-specific legislation	Waste-battery, producer-registration and packaging obligations
Consumer self-test	IVDR; potentially RED if connected	REACH, CLP, packaging, battery and residual GPSR obligations as applicable
Ordinary packaging	No CE mark	Packaging and producer-responsibility legislation

Takeaway

A product bears one physical CE mark, but that mark can represent conformity with several applicable CE-marking acts. REACH, CLP, WEEE, packaging legislation and the GPSR may apply in parallel without themselves creating an additional CE mark.

For example, an IVD analyser with Bluetooth and an incorporated battery may involve:

CE-marking frameworks

- IVDR
- RED
- RoHS
- potentially machinery legislation
- Battery Regulation conformity for the incorporated battery at component level

Parallel obligations

- WEEE
- REACH
- packaging legislation
- battery producer and end-of-life obligations
- potentially residual GPSR provisions for a consumer-facing product.