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STANDARDS & GUIDANCE BRIEF · EUROPEAN UNION · REGULATORY FRAMEWORK

CE Marking

CE marking and the EU declaration of conformity under the New Legislative Framework

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ISSUED BY	European Union (Regulation (EC) 765/2008 and Decision 768/2008/EC)	PREPARED BY	Conner Davidson
EDITION	Current	STATUS CHECKED	October 24, 2026
INDUSTRIES	General Manufacturing, Consumer Products & Toys, Medical Devices	ONLINE	qesisbest.com/standard-ce-marking.html

IN FORCE Each product law sets its own route to CE marking; the general rules come from Regulation (EC) 765/2008 and Decision 768/2008/EC.

What It Covers

The marking a manufacturer affixes to show that a product meets every applicable EU product law, and the technical file and declaration of conformity behind it.

Who It Applies To

Manufacturers of products covered by EU harmonization legislation such as machinery, toys, electrical equipment and medical devices, and importers who must check the manufacturer has done so.

Key Requirements

- Identify every EU law that applies to the product, not only the obvious one.
- Follow each law's conformity assessment route, using a notified body where required.
- Compile the technical documentation and sign the EU declaration of conformity.
- Affix the CE marking, and keep the file available to authorities for the required period.

What an Auditor Asks to See

- The technical file and declaration of conformity, and the list of laws and standards cited.

Where Systems Fall Short

- Declarations of conformity that cite superseded directives or standards.

How QES helps. Technical file audits that check every applicable law and the editions cited. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. EUR-Lex — Decision No 768/2008/EC (New Legislative Framework) — eur-lex.europa.eu/eli/dec/2008/768/oj; EUR-Lex — Regulation (EC) No 765/2008 — eur-lex.europa.eu/eli/reg/2008/765/oj.

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