Accessing the EU market with connected products

UL Solutions

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Placing your products on the EU market: Definitions to know

CE marking

The CE mark, which stands for the Conformité Européenne, is a European mark that indicates the manufacturer has ensured the product meets all EU standards for safety, health and environmental protection.

For products with EU specifications, manufacturers must affix CE marking. That includes electrical and electronic equipment.

Electrical equipment:
- RoHS Directive (2011/65/EU)
- EMC Directive (2014/30/EU)
- Low Voltage Directive (2014/35/EU)

Electronic equipment:
- RoHS Directive (2011/65/EU)
- EMC Directive (2014/30/EU)
- Radio Equipment Directive (2014/53/EU)
- Low Voltage Directive (2014/35/EU)

CE marking is required to sell most products in the European Economic Area (EEA), but it's also commonly found on goods outside the EEA to show they meet the same standards.

To qualify, product manufacturers must complete the following steps:
- Determine whether a Notified Body is needed to assess the product
- Comply with all EU requirements
- Complete the technical file documenting conformity
- Draft and sign an EU Declaration of Conformity (DoC)

Technical file

The technical file provides essential reference that should be kept up-to-date and readily accessible. It should demonstrate that your product meets all applicable requirements and include accurate data relating to its design, operation and testing.

EU Declaration of Conformity (DoC)

Manufacturers or authorized representatives are required to take full responsibility for their products by signing a Declaration of Conformity (DoC). It must also be translated into the local languages of each EU country you want to sell your products in, and importers must keep copies on file for up to 10 years.

DoC checklist:
- The date this document is issued
- Name and signature of the manufacturer or authorized representative and business address
- A statement accepting full responsibility for the product
- Product identification such as a serial number, model or type, and a system to keep track of it
- An index of legislation, harmonized standards and other means used to prove compliance with EU requirements
- If a Notified Body is employed, include their name and contact information along with the type examination certificate (TEC).

FAQ

The following are some of the most frequently asked questions related to Notified Bodies (NB) and market surveillance in Europe for connected products.

Q: What is a Notified Body?

A: A Notified Body is an organization designated by an EU country or through a mutual recognition agreement that certifies whether products meet European Union regulations and industry standards. EU countries notify conformity assessment bodies within their jurisdictions, which are insured and cover their own professional activities unless the national legislation of the notifying country assures liability.

Find the official list of EU-recognized UL Solutions Notified Bodies here: **Europa.eu/youreurope**

Q: What can Notified Bodies do?

A: Notified Bodies streamline the certification process and enable manufacturers to sell their products in EU markets with confidence. They perform conformity assessment services on your behalf to help meet the technical requirements and quality standards necessary to place your products on the EU market.

Manufacturers may choose any legally designated Notified Body to conduct their conformity assessment services. According to Decision 768/2008/EC, NBs can:

- Carryout conformity assessments based in EU or non-EU territories
- Provide non-discriminatory, transparent, neutral, independent and impartial services
- Ensure that services are performed by qualified personnel according to applicable laws and standards
- Deliver assessments in a way that preserves the confidentiality of the information collected
- Provide information to your notifying authority, the market surveillance authorities and other NBs

Q: What is EU market surveillance?

A: Market surveillance helps ensure that products sold in the European Union conform to applicable laws and regulations, including the latest health and safety requirements. By fostering a level playing field for economic operators, market surveillance also helps maintain consumer confidence in European products.

EU-wide cooperation occurs through informal groups called Administrative Cooperation groups (AdCos), such as AdCo RED, representing electromagnetic compatibility and the Radio Equipment Directive (RED). Member states appoint AdCos to represent the national authorities responsible for a particular sector and they're able to:

- Cover a full range of actions, including oversight of the market and enforce corrective measures and penalties when necessary. This involves close contact with manufacturers, importers, distributors, online platforms, retail shops, consumers and consumer organizations
- Work with brick-and-mortar shops and online markets to collect or assemble samples and send them to specialized laboratories for analysis to monitor product safety and issue alerts
- Cooperate closely with customs to prevent unsafe or non-compliant products from entering the EU market

Q: How is market surveillance performed?

A: Each country's market surveillance authority is able to initiate actions outside of the coordinated surveillance initiatives conducted by the Administrative Cooperation group. However, local authorities are still responsible for conducting investigations in the product sectors in which they occur.

AdCo members meet several times a year at the EU level to share information and coordinate action plans for each sector. The Commission then releases the results of these initiatives to all EU member states, authorities and citizens.

Q: Who is my national market surveillance authority?

A: See the list of national market surveillance authorities by **Country** or by **Sector**

Q: What has RED AdCo done so far?

A: Over the last ten years, many AdCo-coordinated action initiatives have addressed electromagnetic compatibility (EMC) and radio products. The European Commission has published these results and removed non-compliant EMC and radio products from circulation.
A product can be barred from entering the market for even a minor nonconformity, costing manufacturers and importers money and time as well as damaging consumer opinion and brand value. **Learn more** about market surveillance activity and find the 2019 AdCo RED Report on the 10th RED Market Surveillance Campaign on IoT.

Q: What are the critical points when compiling the technical file?

- A: Manufacturers must meet the latest safety and EMC and radio compliance obligations and apply all applicable European Norm (EN) standards published in the latest edition of the Official Journal of the European Union (OJEU) before their products can circulate in the EU market.
- Some EN standards are not available or harmonized, are in draft form or only partially cover a product. When standards are not listed in sthe RED OJEU, manufacturers are required to work with a Notified Body.
- A Notified Body can help ensure product compliance even where harmonized standards are available.
- Market surveillance exercises show that even when EN standards fully cover a product, many still present nonconformities that require corrective measures or be subject to complete market removal due to significant deviations from expected EN standards. Products that have undergone testing and achieved approval, sometimes still don't comply with field tests or display unexpected behavior.

2020 non-compliance rates from RED AdCo

- 56.18% of products checked exhibited some form of non-compliance
- 51.65% of the products checked were found non-compliant with overall formal requirements

Q: How does involving a Notified Body help manufacturers addresses regulatory requirements and minimize risk?

A: You're probably already aware that withdrawing products from the market can result in substantial financial losses, but did you know that NBs can provide you with a group of experts with in-depth knowledge of your products?
Engaging a Notified Body to check your technical files before a market surveillance exercise can help identify and reduce the number of non-compliance issues, allowing you to avoid considerable costs and delays in bringing your product to market. A Notified Body is also required to review your technical file and issue a type evaluation certificate (TEC) before your product is allowed to access the global market. Three main reasons for manufacturers to engage a Notified Body are:

- When not using harmonized standards in the Official Journal of the European Union
- To ensure the technical file correctly reflects the latest thinking, not just regarding standards but also Technical Guidance Notes (TGN)
- To acquire the TEC for global market access

How UL Solutions can help

We work extensively with manufacturers of all sizes around the world. UL Solutions International Italia S.r.l. is accredited by ACCREDIA as an EU Notified Body for the EMC Directive (2014/30/EU) and RED (2014/53/EU) and provides a local presence for manufacturers with a Notified Body for RED and EMC-Directives.
Engaging an independent third party like UL Solutions to review your technical file, particularly the test report, provides credibility to your product and demonstrating that all documentation and specified requirements have been met.

Learn more at

EU Notified Body definition
NANDO database
RED guide
Radio Equipment Directive
EMC Directive
List of national (MSAs) Market Surveillance Authorities

Contact UL.com/sales-inquiries for your compliance needs

UL.com/Solutions

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