Route to CE Safety

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What is CE marking?

- Manufacturers Declaration
- Compliance to applicable New Approach Directives
- NOT a quality or performance mark
- CE mark demonstrates compliance to essential requirements of all applicable New Approach Directives

Directives that you may use

http://ec.europa.eu/growth/single-market/ce-marking/manufacturers/directives/index_en.htm

- Low Voltage

- EMC

- Safety of Toys

- Construction products
- RTTE/RED
- Personal protective equipment

- Machinery

- Medical devices

CE Marking Process

Step 1 - Identify the relevant Directive

Download the relevant Directive free from European Union Website

Verify the essential requirements, as described in the directive

CE marking only applies to products within the scope of these Directives.
It should not be applied to products if they are outside the scope of the Directives.

CE Marking Process

Step 2 - Identify the conformity assessment procedure

Depending on the product and the Directive the route to conformity may differ.

- self-declaration by the Manufacturer, Business or Person placing the product onto the European market for the first time
- product testing, inspection
- quality system assessment from an Notified Body
- or a combination of these.

CE Marking Process

Step 3 - Identify applicable Harmonised European Standards

Whenever possible or appropriate, you should follow identified Harmonised standards

Demonstrating compliance via Harmonised Standards is the simplest route to CE marking

Harmonised standards are updated regularly and can be found on the Official Journal

CE Marking Process

Step 4 – Create & Maintain Technical Documentation

A Technical file should be created support your compliance with the requirements of your chosen Directive.

Include

- General product description
- Test reports
- Technical information, drawings, diagrams, BOM

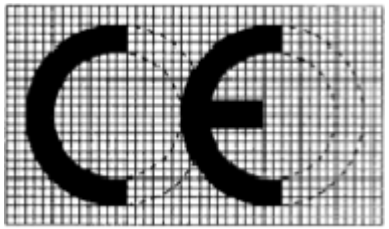
Maintaining a Technical file is essential and a requirement

CE Marking Process

Step 5 - Prepare the Declaration of Conformity

The declaration of conformity along with Technical Documentation should always be available for authorities that may request this.

Affix your CE mark where necessary



What happens when it goes wrong?

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RAPEX

EU rapid alert system to prevent or restrict the marketing of products posing a serious risk.

UK Example

Report 45

13/11/15

Category: Electrical appliances and equipment
Product: Egg incubator
Brand: HDD
Name: Egg incubator
Type/number of model: Unknown
Batch number/Barcode: Unknown
OECD Portal Category: 78000000 - Electrical Supplies
Description: Mini electrical 7 egg incubator. Product packaged in a cardboard box.
Country of origin: China

Electric shock
The **cable** is not protected against pulling and could detach leaving the live wires of the cable exposed. The electrical insulation is inadequate and the fuse rating is too high. These defects could lead to the user getting an electric shock from accessible parts of the product.
The product does not comply with the requirements of the Low Voltage Directive and the relevant European standard EN 60335.

Compulsory measures: Withdrawal of the product from the market

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RAPEX

- http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/how_does_it_work/index_en.htm
- How to, and when to use

- http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.listNotifications
- Weekly search

- http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.search
- Keyword, advanced search

Questions

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How can TUV Rheinland make the process easier

LVD example

- Importing and own-branding an SDA, AV or IT product
- You have your name on the product so you are responsible for the CE marking

Option 1

Do nothing

Under the LVD you are able to self declare on this product,

You need to create a technical file and include a risk assessment which shows how you have come to your decisions that the product meets the requirements of the directive.

If it goes wrong, you have no test reports or third party data to support your technical file and declaration of conformity and you may be prosecuted and fined (possible imprisonment)

Option 2

Documentation review


CERTIFICATE

- If the manufacturer has supplied test reports

- We recommend at minimum a documentation review
  - To include checking standards used, correct version and dates
  - Checking the test lab has the correct accreditation
  - Checking the reports/certificate is not a fake

  - if anything is missing or incorrect we can re-test the product

Option 3

Basic safety assessment

- Even if you have test reports from the manufacturer you cant be 100% certain the product is still the same as when it was originally tested.

- We can carry out a basic safety examination of the sample, looking at critical safety criteria Inc:
  - Markings/instructions/general observations
  - Plug/fuse/cable
  - Access to live parts
  - Electric strength

Option 4

Full testing

If the manufacturer cant supply in date or correct test reports we can carry out full safety testing using the appropriate standard.

We can offer

Safety testing with certification if required – CB/NRTL/PSE etc

EMC – including wireless/Bluetooth

RoHS and other chemical tests

Questions

Lab Demonstration

Over to Engineers

- Some basic safety tests similar to the basic safety assessment

Lab Demonstration

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