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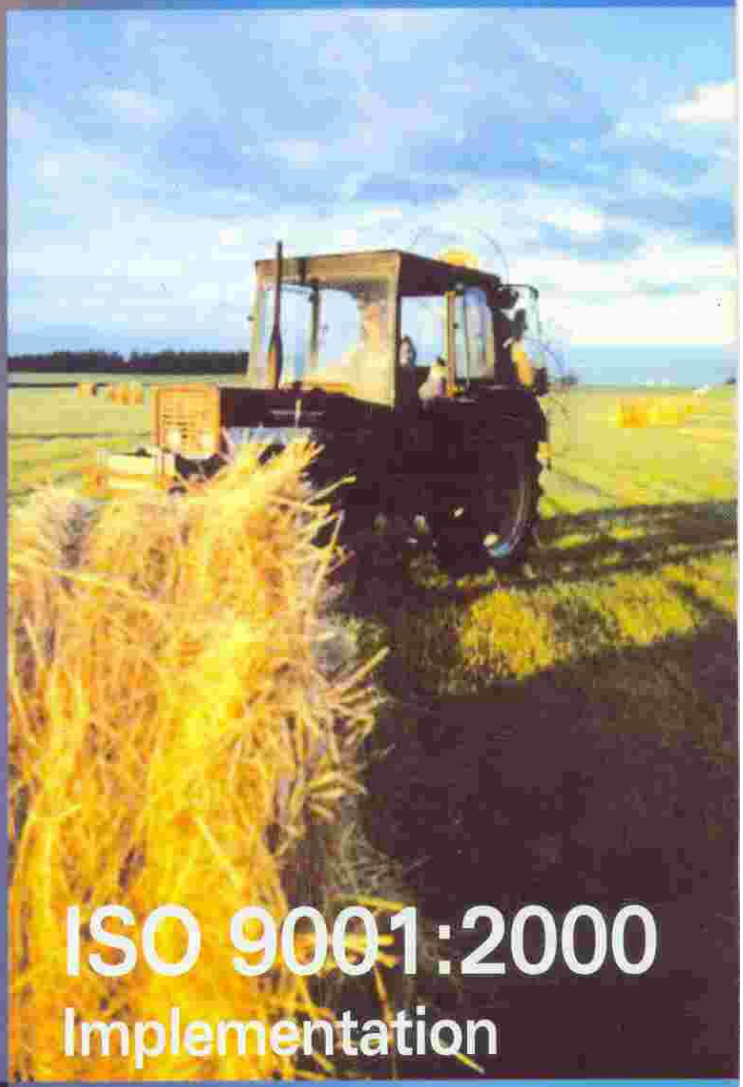
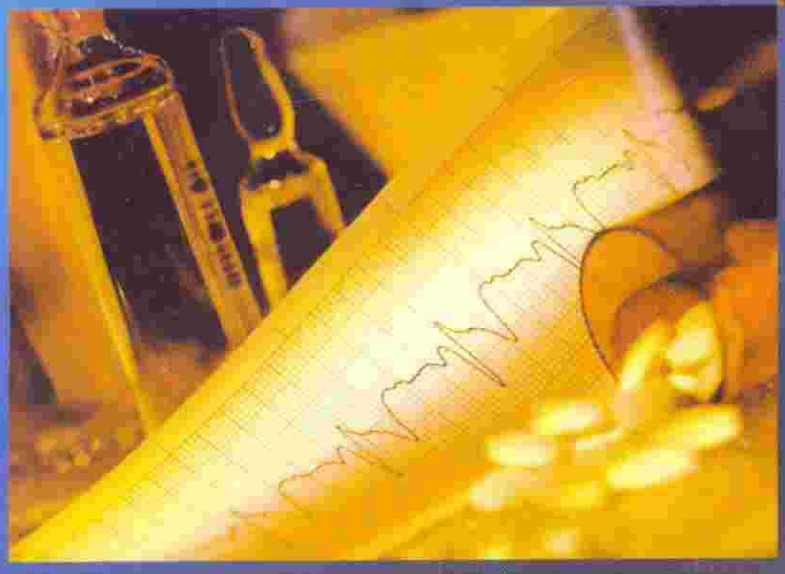
Making Management Reviews meaningful



ISO 9001:2000 Implementation



One More Day of Quality; through Health-care

CE Marking
-Need for the use of certified components

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About CE Mark

The CE Mark is a mandatory, European product safety requirement. The letters CE stand for the French phrase Conformité Européen, which in English, means, European Conformity.

About 21 categories of products require CE Mark to be affixed to be eligible to access the markets of unified Europe, comprising of 25 member countries and three European Economic Area (EEA) countries. The unified European market is bigger than the US market, population wise.

Products properly certified and bearing the CE Mark provide access not only to the recently enlarged, single Europe but also to many other quality and safety conscious markets

Importance of certified components in CE Marking of final products

Any product is an assembly or integration of components. It is not feasible for a manufacturer to produce all the required components, in-house. Therefore, companies usually use and depend on many critical components manufactured by others e.g. motors, heating elements, fuses, switches, etc.

Safety and reliability of the end product depends on the quality and performance of the individual components.

Therefore, it is important to choose quality and reliable components, but the question is, how to go about the process? What are the various aspects to look into, especially when one is interested in CE certification?

This article examines these questions and is intended to help manufacturers to make right choices.

Context:

Though various aspects discussed in this article apply to and used by manufacturers of any product, references are made to standards applicable to two important product categories, domestic appliances (EN 60335) and machinery (EN 60204).

Similarly, even though the title suggests a context of CE Marking, actually the concepts discussed here can equally be applied for procuring other marks too e.g. UL, CSA, VDE, etc.

Use Certified Components:

To ensure compliance, always use certified components. Components may be marked with CE, UL, CSA, VDE, etc. or conforming to International standards, especially to IEC Standards, for CE Marking.

CE Marked Components:

The first preference is CE Marked components, simply for the reason that the end product is to be CE Marked, and the best way to achieve this is to use CE Marked components.

However, a large number of components are not CE Marked, since CE Marking is generally applicable to final products, directly used by ultimate customers, rather than for

components. The exceptions to this general rule are components for which a safety assessment is feasible and are directly placed and available on the market e.g. motors.

One has to be careful with CE Marked Components. The European CE Marking regulations provide flexible conformity assessment options, especially electrical products falling under the low voltage directive, without the mandatory involvement of an independent third party. Under such circumstances it is possible that the CE Marking assessment may have been improperly made or the assessment is not stringent enough or in some extreme cases, downright suspect.

When intending to use CE Marked components, ask for the name of the Notified Body which is involved in certification. CE Marked products, with the involvement of a Notified Body in the certification process, mean more reliability. If a Notified Body is not involved in certification, ask for a copy of the manufacturer's declaration of conformity, and the test reports of an independent test laboratory which conducted the tests of applicable standards, mentioned in the declaration of conformity.

Where components cannot be CE Marked, they will have to conform to applicable IEC or other equivalent international standards.

UL Certified Components:

UL (Underwriters Laboratories) is a US based organization involved in evolving standards, which are popular and widely accepted in USA and Canada, and internationally. UL certification is a stringent process, with product testing and regular product surveillance. Certified products will carry UL's various, proprietary marks.

CSA Marked Components:

CSA is a Canadian Standard and Certification body. Like UL, CSA too writes standards and certifies products to it's own as well as international standards.

Components carrying VDE Mark: VDE is prominent, German organization, involved in writing standards, testing and certifying products. Certified products will carry various VDE marks.

Distinction between certified (marked) and conforming components

There is fine distinction between certified components and components conforming to applicable IEC or equivalent international standards. The distinction is that certified components will certainly meet the requirements whereas; non certified components may be conforming.

What is important is that the components must meet the requirements of applicable standards, i.e. they must be conforming, rather than being certified.

Therefore, in case the components are not marked or certified, the final product manufacturer can rely on a type test report from a reputed lab produced by the component vendor, to demonstrate the conformity of such components to applicable IEC and/ or equivalent international standards.

Throughout this article the term certified component is used with a meaning of either marked or conforming component, unless the context requires otherwise.

Is it mandatory to use certified components, in order to be able to get CE Mark?

Use of certified components not only make the final product safe and compliant to requirements but will also provide a great deal of self assurance in the final product.

Let us see what the standards' requirements are. Clause 4.2 of IEC 60204-1, dealing with electrical equipment of machinery says "Electrical components and devices shall be suitable for their intended use and shall conform to relevant IEC standards where such exist".

Clause 24.1 of EN 60335-1says, "Components shall comply with the safety requirements specified in the relevant IEC standards as far as they reasonably apply".

From the above it is clear that, for CE Marking, wherever IEC standards exist or wherever they reasonably apply (to components) only conforming comp'onents shall be used.

The words, "...as far as they reasonably apply" should be interpreted as the safety criticality of the component. For example, an electrical heating appliance is provided with rubber supports/ legs. The function is to provide stability to the equipment. In this case if the legs are adequate in terms of strength and providing mechanical stability to the equipment. One need not look for marks or conformity to standards. On the other hand the thermal cutout, provided as a protective device, performs a safety critical function and therefore must conform to IEC 730.

It is not just sufficient that the components are certified- they need to be suitable!

Even when components are certified, they may not be suitable, i.e. there is a mismatch. This mismatch may be for different reason but let us examine a couple of common mismatches:

Improper Application: A switch disconnecting device conforming to IEC 60947-3, utilization category AC-23B (general switch) is a permitted supply disconnecting device as per EN 60204, clause 5.3.2. The final product to be CE marked has a certified main switch of utilization category AC-23A (suitable switching motors). In this example, though a certified component is used, it is not suitable for

the application and therefore requirement of the standard is not met.

Incorrect Rating: Equipment has a rated current of 3A and rated voltage of 220V a.c. The equipment has a certified HRC fuse link of 415V, 20A. Here, though the component is certified, there is a rating mismatch and the equipment does not meet the requirements.

Use of certified components does not automatically make the end product eligible for CE Mark

During discussions with clients regarding certification of their products, I frequently face the question, "All our components are certified, does it not mean our product is CE compliant?" The answer is quite simple and a definite no. The end product is not a mere sum of its components. It has got an independent function, with associated risks. The end product is governed by standards with their unique requirements.

Of course, if all the components are suitable and certified, it makes the task of CE Marking of the end product that much simpler and faster, but certainly does not mean that the end product automatically becomes eligible for CE Marking.

This position is reiterated by the Note to Clause 24.1 of EN 60335-1, which says, "Compliance with the IEC standard for the relevant component does not necessarily ensure compliance (of the end product) with the requirements of this standard".

Sourcing certified components

Sourcing certified components is a difficult task; certainly in India. Some of the important reasons for this difficulty are:

- Lack of readily accessible information.
- Most of the Indian components are not certified, at least presently (consequently loosing business to competitors from developed countries).
- Sourcing from overseas companies is complex, time consuming and expensive.
- Small volume/ value of purchase make no sense for large/ overseas component manufacturers.
- Small/ medium size of the end product manufacturers, place them in a disadvantageous position in demanding for information/ documentation.

Let us examine the information gap in a little more detail.

CE Marked products:

The CE Mark is not owned by any single entity, unlike others, e.g. UL, CSA, VDE, etc. Therefore, there is no centralized database of CE Marked products. In the absence of such a centralized database, it is very difficult to source CE Marked components.

There are a few private efforts, for example CE Directory (www.cedirectory.com), but it cannot be comprehensive since they charge for listing of certified products.

UL has a readily accessible online directory of certified companies and products at http://database.ul.com. However, the directory provides only the name and address of the manufacturer but no telephone, e-mail and website addresses, which is handicap.

I could not find such directories on the websites of CSA and VDE.

As a consulting company, clients look up to us, for help in sourcing certified components. In order to service our valuable clients, we at Ace are compiling and continuously updating our database of certified components; but the task is enormous.

Change the basic Approach:

Under normal conditions, any manager entrusted with the task of sourcing good components, naturally starts with short-listing of standard companies, understanding their product range and selection of suitable components, out of this range, required for the end product.

When it comes to CE Marking or other product certifications, the process is better reversed, though the final outcome is more or less the same.

Start with understanding the conformity requirements specified by the standard. For example, EN 60335-1 requires use of automatic controls (e.g. thermostat) conforming to IEC 730. Determine the correct specifications/ ratings for the application. Next, identify the brands/ companies making components conforming to the requirements of the standard. Communicate with those companies for their catalogues and specifications. Select the part number that is suitable for the application.

Identifying and sourcing certified components is a lengthy, tedious and time consuming process that has to be pursued with patience and persistence but in the end it is both a learning and rewarding experience.

Summary

- Successful CE Marking of a product necessarily require the use of certified components.
- One should be sure that that they are properly certified. Certification documents should be collected from the vendor to establish proper certification.
- It is not just enough that components are certified but they should be suitable and of correct ratings.
- Use of certified components does not automatically lead to conformity of final product.
- Sourcing certified components is tedious and time consuming process.