

Certification and Marking for Europe

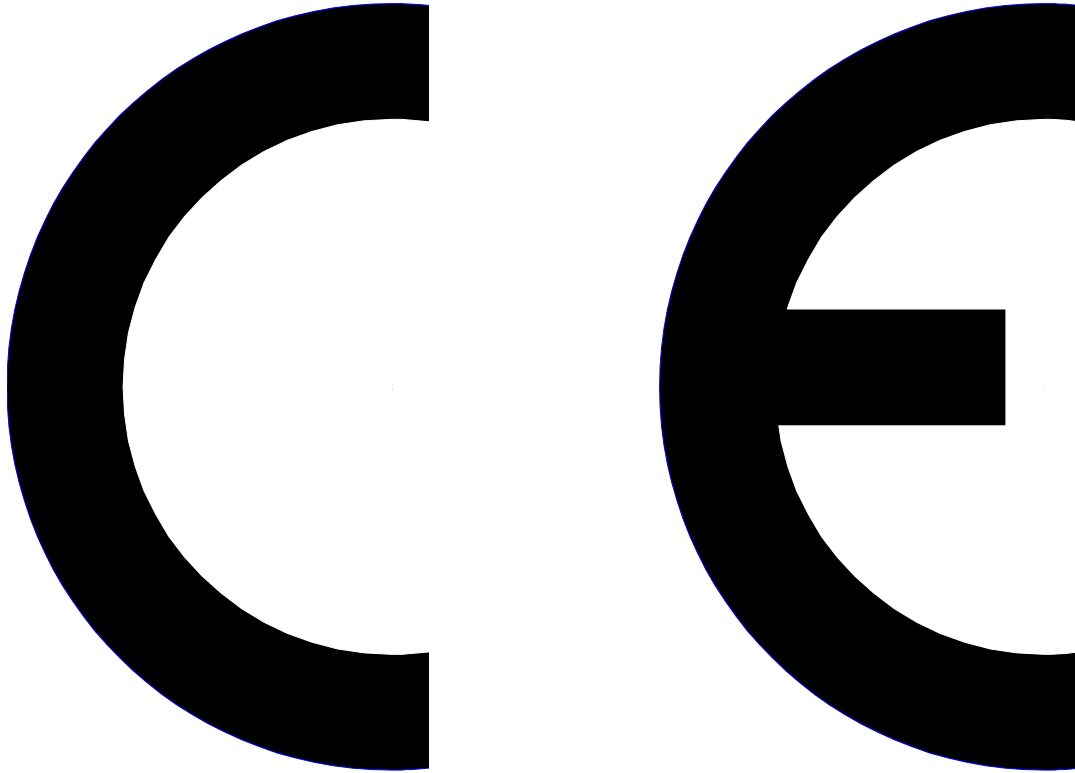
The Role of Market Surveillance

Jan Deconinck, M.Sc.

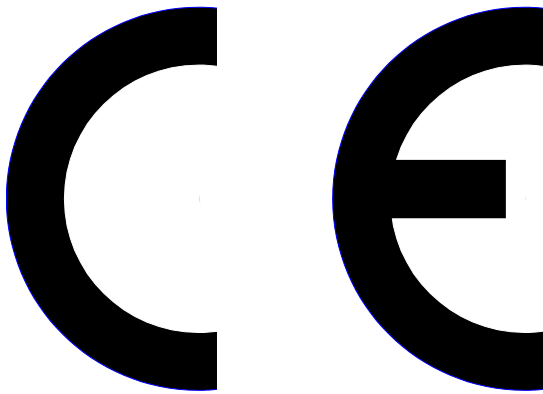
PROSAFE Chairman

1. Marks

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- It is prohibited to affix other markings or marks which might be confused with the CE marking, or to affix other markings which are liable to deceive third parties as to the meaning or form of the CE marking.

1. Marks



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A mark affixed alongside the CE - marking:



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A mark affixed alongside the CE - marking:

- signals conformity with requirements that differ from those behind the CE-marking



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Nature ? Type ? Degree ? of difference is NOT clear



1. Marks

Market Surveillance Experience:

- There are a large number of markings present of which the origin, the requirements and the validity is unclear (even doubtful)...***
- Marked products (of well-known marks) seem to be usually satisfactory...***
=> but NOT always !
 - counterfeiting, lack of quality control ?***

1. Marks

Market Surveillance Point of View:

- The directives establish **the essential safety requirements** which the products must satisfy. Products which do satisfy these requirements must be authorised by the various Member States on their respective markets.*
- Products which do not meet these requirements may not be placed on the market.*

1. Marks

Market Surveillance Point of View:

- Manufacturers may of course place on the market products which satisfy higher quality and safety levels ...***
- ... and use marks as a tool to make the consumer aware of this.***

1. Marks

Market Surveillance Point of View:

The presence of a mark (other than the CE-mark) will NOT influence the way market surveillance authorities will evaluate the product.

A "European Safety Mark"

- is not useful for market surveillance;***
- is probably not useful for enhancing consumer trust***

2. Certification

2. Certification

The CE marking can be obtained in a number of ways. The different possibilities vary according to the products and are described in the relevant directives.

SDoC

In most cases, the manufacturer can, firstly, provided he has followed the harmonized standards and is able to furnish proof of this by presenting a technical documentation, himself affix the CE marking without having an examination performed by a notified body.

Secondly, in case he did not take account of the harmonized standards (or if they do not exist, or only partially), he must obtain approval from a notified body which verifies whether the product satisfies the essential safety requirements.

Besides these two possibilities, there quite often exist intermediary possibilities or combinations of these possibilities.

2. Certification

higher risk => more stringent

Module A - Internal production control

Module B - EC type-examination

Module C - Conformity to type

Module D - Production quality assurance

Module E - Product quality assurance

Module F - Product verification

Module G - Unit verification

Module H - Full quality assurance

2. Certification

Market Surveillance Experience:

Certification can be useful:

- to create test reports to serve as part of the (obligatory) technical documentation***
- as part of the quality management system that is obligatory for certain modules.***

2. Certification

Market Surveillance Point of View:

- for SDoC: part of technical documentation

- for other modules:

***can be taken into account by notified
bodies (who take final responsibility).
useful:***

3. Conclusion

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Goal of Market Surveillance:

- **Safe Consumer Products (level playing field)**
- **Free Circulation of Products (internal market)**

3. Conclusion

Goal of Market Surveillance:

- Safe Consumer Products (level playing field)
- Free Circulation of Products (internal market)

Obligatory tools

CE Mark

Notified bodies

Voluntary tools

Other marks

Certification

LEGAL FRAMEWORK

LIMITED USE ?

3. Conclusion

All parts of the chain must take responsibility:

- **Manufacturer (producer)**
- **Distributor**
- **Standardisation bodies**
- **Testing laboratories (certification - notified bodies)**
- **Market surveillance**

Marks and Certification can be tools to achieve this (?)



DANGER!

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A dangerous toy. This toy is being made for the extreme priority the good looks. The little part which suffocates when the sharp part which gets hurt is swallowed is contained generously. Only the person who can take responsibility by itself is to play.