

EUROM VI "Medical Technology"

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Enhancing the health of the public European-wide and worldwide and facilitating innovation by harmonising the European and global regulatory environment

EUROM VI Medical Technology Statement

on the extension of the CE mark to include the term "Medical Device"

- The public expects the CE mark to be the universal symbol that clearly indicates that the product is safe and fulfills all relevant European requirements.
- Therefore the market should not be confused by a language specific extension of the CE mark, which is not readable and not understandable for the average user.
- EUROM VI is convinced that it would be best to stay with the widely recognised and accepted CE mark.
- **Extending the CE mark confers no benefit to patients, users or third parties.**

EUROM VI – Comments on the extension of the CE mark to include the term "Medical Device"

Preliminary remarks

Associated with the drafting of new regulations on medical devices (Annex IV – Section 1 – Introduction (new)), there has been a proposal to extend the CE mark to include the term "Medical Device".

EUROM VI Medical Technology is against this proposal because the desire to differentiate this mark from other CE marks would not achieve the aim of empowering the user by providing more information, but instead confuse users as to what the CE mark means, and lose the significant advantage of having a globally recognised, language-independent symbol.

Moreover, this approach clearly goes against the "New Approach" adopted for the generation of different CE marks.

Key points

We do not see any additional value in differentiating the CE mark for medical devices from the CE mark of other directives. The CE mark shows the compliance with all the essential requirements

For the reasons given below, the anticipated benefit of extending the CE mark to include the term "Medical Device" or a suitable symbol does not justify the time and effort involved in revising the product or the instructions for use – because the previous CE mark has already been in existence for 20 years without such an addition, and most instructions for use contain passages which explicitly refer to the Medical Devices Directive or indicate that the product in question is a medical device. To highlight the fact that medical devices are subject to more stringent requirements than, for instance, children's toys, more detailed information would be needed anyway.

EUROM VI Medical Technology therefore firmly rejects the proposal to extend the CE mark to include the term "Medical Device" or an equivalent universal symbol. The core elements of our criticism are the problems of:

- Language-specific labelling
- Labelling space
- Language-independent symbols
- Expenditure associated with changing product labels
- Inclusion into the instructions for use

In addition to these reasons, the purpose of the CE mark is to declare that all guidelines relevant to the product in question have been met. As many medical devices have to comply with e.g. the RoHS Directive with effect from July 22, 2014, it could also be argued this would have to be explicitly indicated, too. In the case of the CE mark, therefore, there seems to be little point in making reference solely to the Medical Devices Directive or the forthcoming EU regulations through the term "Medical Device".

Language-specific labelling

Medical devices manufacturers have good reason for trying to design product labels in as language-neutral a way as possible by using symbols which enable them to avoid country-specific labels and thereby minimise their spending on logistics. Used in conjunction with the CE mark, the term "Medical Device" is a language-specific text which under the national requirements of the 28 member states (as at July 2013) has to be translated into each of the official languages, with the consequence that we would need almost as many different labels per product as there are member states (not including affiliated EFTA states, Turkey and countries which also accept the CE mark, including many North African nations). This would lead to significantly higher inventory costs (tying up

capital and often leading to higher scrapping costs) and higher expenditure on logistics in production, warehousing and shipment in order to ensure that customers can be supplied with products bearing the correct (i.e. country-specific) label.

Moreover, changing product labels automatically triggers approval processes in several countries (including China). This means added expenditure of time and money for the medical technology companies operating in these export countries.

Labelling space

Maximum use is always made of the space available on product labels ("product identification") because, among other reasons, a number of other approval symbols have to be displayed next to the CE mark (also including, in future, an UDI barcode), hence the additional insertion of the term "Medical Device" in a legible font would, in many cases, lead to space problems; furthermore, there are also several multilingual countries (such as Finland, where both Finnish and Swedish are the official languages; or Switzerland (which, though not a member state, is classed as "affiliated" by way of a Mutual Recognition Agreement), which has German, French and Italian as its official languages) which would therefore require the term "Medical Device" in more than one language). Many directly identified products, particularly surgical instruments, do not provide sufficient space.

Language-independent symbols

A possible solution to this problem would be to declare "Medical Device" as an internationally harmonised, and therefore recognised, symbol or to create a small and, where possible, self-explanatory language-independent symbol. Harmonisation efforts such as these will usually involve the Commission mandating CEN or CENELEC to develop a harmonised standard. Last year, the previous EU "label standard", EN 980, was incorporated into the ISO 15223 international standard (which is now to be harmonised as EN ISO 15223, although unfortunately it was omitted from the last announcement in the OJ), with the result that a separate, new standard would now have to be created for such a language-independent symbol. There remains the problem of finding a universal symbol for medical device, because what symbol is self-explanatory for "Medical Device"?

Expenditure associated with changing product labels

Even the development of a small, language-independent symbol denoting "Medical Device" forces manufacturers to change all their product labels bearing the CE mark. The effort and expense involved (product labels are defined in technical drawings, so at least one drawing has to be revised per label!) is comparable to that involved in changing the legal form of a company (as the name of the manufacturer together with the registered legal form have to be displayed on the label, it can be assumed that the same expenditure will be incurred when making changes). Companies which have gone through the rigmarole of changing their legal form or name will know what that means!

In the case of directly marked products, e.g. surgical instruments (and there are many!), the initial outlay will be considerably higher: in addition to the identification mark drawings, the programs for the laser labelling of individual products would have to be revised and many of the product-specific clamping fixtures used for laser labelling would have to be redesigned or replaced; smaller companies which still use etching to identify their products would have to produce new etching templates in addition to revising their drawings.

In the case of some products where, for technical reasons, the CE mark is applied by the injection moulding or casting tool, it may also be necessary to make complete tool modifications which, in the case of injection moulding or casting tools, are very expensive and often very time-consuming.

Inclusion into the instructions for use

Even adding an identification marking to the instructions for use would involve a considerable amount of in-house revision work since all instructions for use (i.e. all language versions) would have to be adapted in the medium term, thereby altering the revision status of the instructions for use (i.e. drawing revision, modification of the parts list and master data etc. to ensure that the new revision status of the instructions for use is included). What places a particular burden on manufacturers is the commitment of considerable resources where it particularly hurts, namely in the area of development (including so-called Lifecycle Management).

Another drawback is that not all products come with their own instructions for use (except where necessary for informative or safety reasons, instructions for use do not have to be enclosed with class I and IIa products). In the case of products which do not come with instructions for use, new package inserts (in various languages for European countries) would have to be introduced just to indicate the "Medical Device" CE mark. This should be firmly rejected because it involves administrative overhead without providing any added value or enhancing product safety.

The instructions for use for medical devices are already amply informative without additional CE information with regard to the term "Medical Device" as this is usually implicit in the contents of the instructions for use and often referred to explicitly in the instructions for use themselves.

In conclusion, EUROM VI strongly believes that extending the CE mark would not be of any great benefit to users, patients or other stakeholders. To the contrary, the major expenditure that would be incurred by the medical technology industry would prevent investment into developing industry, providing employment, and creating innovative devices to advance healthcare.

EUROM VI Medical Technology
Secretary General

Nadine Benad

EUROM VI Medical Technology
Chairman Regulatory Affairs Committee

Dr. Peter Gebhardt

EUROM VI Medical Technology is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises.

The objectives of EUROM VI are:

- to represent European Medical Technology Industry;
- to promote cooperation between members but also with other European organisations;
- to encourage worldwide trade by being involved in harmonisation of legislation, standardisation, mutual recognition and certification procedures;
- to be a partner on works with the European Commission and Standardisation Bodies;
- to support European Industry views on international activities.