European Medical Devices Industry Group, EMIG

COCIR, EDMA, EUCOMED, EUROM VI, EUROMCONTACT, FIDE

EMIG Statement on „Own Brand Labelling„

With the implementation of the European Medical Devices Directives and the increasing presence on the market of CE marked medical devices, it is becoming more and more important, in the interest of users, regulators and health authorities, to have a clear understanding of who has the legal responsibility for the products which are being placed on the market and put into service.
To this purpose the European Medical Devices Industry Group (EMIG) which represents all of the European medical devices manufacturers is releasing the following statement.

The growing global dimension of the medical device market is increasing the complexity of the supply chain that delivers the products to the final users. In this situation it may be possible to have several company names/addresses which appear on the same device. While there are no regulatory limits to the number of names/addresses that may appear on the products, there is a legal obligation to have on the label and instructions for use the name and address of the „manufacturer„. Here the word „manufacturer„ has the meaning given by the Medical Devices Directives (93/42/EEC), i.e. the person who has (a) assumed overall responsibility for the design and manufacture of the device (whether or not he delegates part or all of that responsibility to a third party) and (b) places that device on the market under his own name. If the manufacturer of the device is located outside the European Economic Area, there is also a requirement to print the name/ address of the Authorised European Representative [1]) or importer on the label or the outer packaging or the instructions for use.

It is the EMIG position that any labelling configuration is acceptable (regardless of what logo, colours, names and addresses appear on the products) provided that the legal obligations are fulfilled, namely:

- that the manufacturers name and address is given on the label and any instructions for use
- and that, if the manufacturer is located outside the European Economic Area, the name and address of the authorised representative or importer is also given on the label and any instructions for use
- and that if more than one name appears it is made clear in what capacity each name appears and particularly that the person who has legal responsibility as manufacturer (as defined in MDD) and as Authorised Representative or importer (where appropriate) is clearly identified.

EMIG advocates the introduction of harmonised symbols to designate a) the legally responsible „manufacturer„ and b) where relevant, the „authorised representative„. Such symbols simplify product labelling and help to contain associated manufacturing costs. It will also facilitate understanding by the end-user. The Commission should mandate CEN Technical Committee (CEN TC 257) to develop appropriate symbols for inclusion in the relevant CEN Standard.

EMIG suggests that until such time as the Standards for symbols are in place, the CEC and Competent Authorities should adopt a pragmatic approach to this issue.

This EMIG position is supported by a legal opinion (Attachment A) and by some examples of product labelling which could help the reader in better understanding the above position (Attachment B).

EMIG January 1998

---

[1]) „Authorised Representative“ means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community in substitution of the manufacturer with regard to the latter’s obligation under the Medical Devices Directives.