

Understanding the Requirements of the Medical Devices Directive

Manufacturers must educate themselves on what is truly necessary in order to comply with this directive.

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BACKGROUND

Today, the U.S. is the world leader in medical technology, with thirteen of the world's twenty largest medical technology firms operating from the U.S. Of great importance to these firms is the European Union's Medical Devices Directive (MDD), which will become law at midnight, June 14, 1998 and affect sales of all medical equipment sold in any of the fifteen member nations of the European Union. Without a CE Mark signifying compliance with the MDD, manufacturers will not be able to do business within the EU after that date. This could have a major impact on U.S. medical manufacturers who currently export 45% of total exports to Western Europe.¹

Although June 15, 1998 is less than two years away, there are still many U.S. manufacturers who are not aware of this comprehensive directive. Among those who *are* familiar with the directive, many are still unclear about the actual MDD requirements.

A surprising number of people believe that since they are ISO 9000 registered, they meet all the Directives. This is clearly not the case. In fact, in terms of medical devices, they couldn't be farther from the truth because ISO 9000 in itself is simply not sufficient.

There is no statutory requirement to have any standardized system in the MDD; the requirement is that the system shall be *documented* and *implemented* and shall *control* the manu-

facturing and/or design process to the satisfaction of the auditing body. However, the directive does say that a quality system implemented in line with the harmonized standards (meaning ENs) published for the purpose shall be presumed to comply with the requirements of the directive.

There is such a standard or series of standards in EN 46000, which is based on EN 29000 (or ISO 9000), but which has been specifically modified to cover medical devices. This is the standard to which Notified Bodies will be auditing because it covers their specific medical requirements. Neither ISO 9000, EN 29000 or U.S.

Good Manufacturing Practices (GMPs) have these additions and so are not adequate as they stand. Likewise, EN 46001 and EN 46002 are not "stand-alone" standards and must be used in conjunction with EN 29001 or EN 29002.

COMPLIANCE WITH THE DIRECTIVE: STEP 1

In order to meet the Medical Devices Directive, a manufacturer must first determine the classification of its product. There are four main categories for medical devices:

- Class I
- Class IIa
- Class IIb
- Class III

The Classification system is discussed in Annex IX, Section III of the Medical Devices Directive, 93/42/EEC. Manufacturers should bear in mind that it is the "intended purpose" of the device and not the particular technical characteristics that determines the class of the product. Class I represents the lowest risk products, generally those which do not make contact with the patient. Class III, on the other hand, imposes the greatest risk to safety, and thus requires more stringent conformity requirements (Table 1).

CLASS I	General unpowered (non-active) devices which do not penetrate the body or non-surgically invasive devices for transient use (less than 60 minutes). Some low-risk, powered (active) devices for patient support or examination.
CLASS IIa	Generally nonhazardous, active therapeutic and diagnostic devices. Low-risk, surgically invasive devices for transient use or short-term use (up to 30 days).
CLASS IIb	Generally potentially hazardous active therapeutic and diagnostic devices (e.g., X-ray sources). Higher risk surgically invasive devices for transient or short-term use. Surgically invasive devices for long-term (more than 30 days) or implantable (non-active) use.
CLASS III	All devices which make contact with the heart, central circulatory system or central nervous system. All long-term invasive or implantable devices which have a biological effect on the body or are absorbed into it.

Table 1. Classification of Medical Devices.

CONFORMITY ASSESSMENT REQUIREMENTS, STEP 2

Having classified a product, a manufacturer can look at Article 11 of the Medical Devices Directive to determine which route to follow. There is a requirement to assess both the product and the manufacturer's ability to produce consistently compliant products. Therefore, there is heavy emphasis on quality assurance.

CLASS I PRODUCTS

These follow the EC Declaration of Conformity procedure laid out in Annex VII. This is basically self-certification, where the manufacturer declares that the product meets the essential requirements. There is a presumption of compliance where harmonized standards are met. No Notified Body involvement is required except in the case of sterile products and measuring devices.

CLASS IIA PRODUCTS

Here the manufacturer's declaration must be supported by a Notified Body Conformity Assessment. This may, at the manufacturer's discretion, consist of an audit of the production QA system as laid out in Annex V or an audit of final inspection and test as laid out in Annex VI, or an examination and test of product samples as specified in Annex IV.

Alternatively, the manufacturer may elect to follow the full QA procedure laid down in Annex II (with the exception of Clause 4 which is not applicable) which involves an audit of the QA system by a Notified Body.

CLASS IIB PRODUCTS

For these, the declaration must be supported by an EC Type Examination by a Notified Body, as laid down in Annex III, together with either an audit of final inspection and test as laid out in Annex VI or an audit of the production QA system laid out in Annex V or an examination and test of product samples laid out in Annex IV.

Alternatively, the manufacturer may elect to follow the full QA procedure laid down in Annex II

(with the exception of Clause 4 which is not applicable) which involves an audit of the QA system by a Notified Body.

CLASS III PRODUCTS

The choice is between an EC Type Examination by a Notified Body as laid down in Annex III, together with either an audit of the production QA system laid out in Annex V or an examination and test of product samples laid out in Annex IV.

Alternatively, the manufacturer may elect to follow the QA procedure laid down in Annex II which involves an audit by a Notified Body. Clause 4 is applicable and requires a design dossier to be prepared for the product. This dossier is subject to examination by a Notified Body.

CONCLUSION

Attaining compliance can take as long as two years. Therefore, although the Medical Devices Directive does not become mandatory until June 15, 1998, it is important for manufacturers to begin looking at their compliance choices. For now, manufacturers have two options for claiming compliance. They can either comply with the MDD and place the CE marking on their product, or they can continue to comply with national regulations on a country-by-country basis. However, it is vital that manufacturers educate themselves on what is truly necessary in order to comply with this directive.

REFERENCES

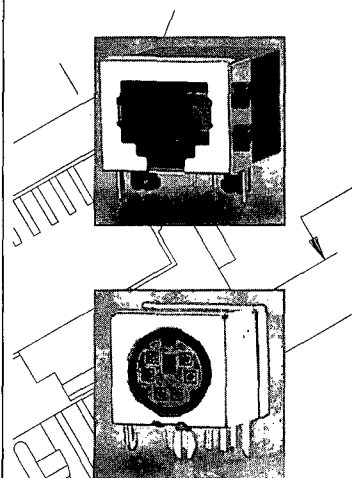
1. Victor Clements, Director of Interference Technology International.
2. "The U.S. Global Trade Outlook 1995-2000," U.S. Department of Commerce.

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