CE MARKING MEDICAL DIRECTIVES

GENERAL

As part of the New Approach to technical harmonization in the European Union, directives have also been established for medical devices. These directives specify conditions to be met before permission is granted to apply the CE Mark and cover all medical devices and accessories.
A medical device is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

A medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

Three Directives have been drawn up.

ACTIVE IMPLANTABLE MEDICAL DEVICES (90/385/EEC)

This directive covers all medical devices, that rely on a power supply and are left in the human body.

MEDICAL DEVICES (93/42/EEC)

The Medical Device Directive covers most other medical devices (active and non-active) and their accessories that are not covered by the first or the third directive.

IN VITRO DIAGNOSTIC MEDICAL DEVICES (98/79/EC)

This directive covers any medical device instrument, apparatus or system which is intended to be used in-vitro for the examination of substances derived from the human body.

CLASSIFICATION OF MEDICAL DEVICES

A classification system has been developed for the Medical Device Directive, dividing the related devices into four classes based on the risk factor involved and the intended use to be made of the product. This classification is based on the following principles:

- The duration of contact between the device and the patient
- The degree and manner of the device penetrating the human body
- The degree of the device's impact on the human anatomy.

CLASSIFICATION RULES

Based on the above-mentioned principles, 18 classification rules have been developed; Annex IX to the Directive contains a list of these rules.
Rules 1 through 4 apply to devices that do not penetrate the human body (non-invasive devices), whereas rules 5 through 8 apply to devices that do penetrate the human body (invasive devices).
A distinction is made between the manner of penetration (through a natural or an artificially created orifice) and the duration of contact between the device and the patient.
For powered devices (active devices) supplementary rules 9 through 12 are also applicable. A distinction is made between therapeutic and diagnostic devices, devices administering or removing medicines, devices administering or exchanging energy to the human body from it, and other devices.
Rules 13 through 18 are special rules for specifically defined devices used for special applications.

CLASSIFICATION

According to the classification rules given in Annex IX to the directive, devices are classified as follows:

- Class I for low-risk devices.
  This includes hospital beds, incontinence diapers, ordinary band-aids, external splints, spectacle glasses, examination gloves, reusable surgical tools, non-invasive electrodes etc.
- Class IIa for medium-risk devices.
  This includes catheters, ultrasound equipment, blood filtration equipment, standard contact lenses, surgical gloves, dental fillings, hearing aids etc.
- Class IIb for medium-risk devices.
  This includes haemodialysis equipment, standard intra-ocular lenses, drug administration devices, anaesthetic apparatus, contact lens fluids, blood bags, X-ray equipment etc.
- Class III for high-risk devices
  This includes cardiac valves, neurological catheters, implants with a biologically active coating etc.

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ESSENTIAL REQUIREMENTS

Each medical device must, regardless of its classification, comply with the essential requirements specified in Annex I of the directive. The essential requirements consist of general requirements and a number of more specific requirements.

THE GENERAL REQUIREMENTS

The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, the safety and health of users or, where applicable, other persons. Any risks which may be associated with their use must be deemed acceptable risks when weighed against the benefits to the patients and be compatible with a high level of protection of health and safety.
The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- Eliminate or reduce risks as far as possible (inherently safe design and construction)
- Where appropriate, take adequate protection measures including alarms, if necessary, in relation to risks that cannot be eliminated
- Inform users of the residual risks due to any shortcomings of the protection measures adopted.

The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

The characteristics and performances referred to in Sections, 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.
The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage, taking account of the instructions and information provided by the manufacturer.
Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

SPECIFIC REQUIREMENTS

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Devices with a measuring function
- Protection against radiation
- Medical devices connected to or equipped with an energy source
- Information supplied by the manufacturer
- Clinical data

PRODUCT QUALITY ASSURANCE

Generally speaking, the manufacturer's quality system should ensure that the design and/or manufacture of a medical device is in compliance with the requirements of the directive. If the relevant harmonized standards are implemented in the quality system, it is presumed to conform to the directive.
A selection can be made of several quality assurance methods, depending on the classification of the products and the corresponding conformity procedure in accordance with the directive. The manufacturer can apply a `full quality assurance system' or a `product quality assurance system' if this is applicable to the products concerned. The different options are listed in Annex I to this brochure.

POST-MARKET SURVEILLANCE

The manufacturer's responsibility for product quality continues after utilization of the product has started. The directive therefore stipulates that the manufacturer shall implement and maintain a systematic procedure based on which the experiences gained with products during their utilization can be evaluated, so as to be able to make improvements to these products where necessary.

VIGILANCE SYSTEM

The manufacturer shall notify the competent authorities of any incidents involving products in use that have or could have seriously compromised the patient's or user's health.

CONFORMITY ASSESSMENT PROCEDURES

Before being permitted to apply a CE marking, the manufacturer must demonstrate that his product satisfies the essential requirements of the directive and that he has an operational vigilance system for it. Moreover, one of the procedures specified in the directive is to be observed. The selection of a procedure depends among others on the classification of the product.

For products to be placed on the market in sterile condition, the notified body will conduct an audit of the sterilization process, regardless of the product classification, in order to verify whether the implemented quality system ensures conformity of the sterilization process to the relevant harmonized standards.

CLASS I PRODUCTS:

In principle Module A applies unless the product needs a sterile condition or has a measuring function (in which case Modules Aa apply).

CLASS IIA AND IIB PRODUCTS:

In principle Module H applies, or, as an alternative, the Modules B and D, B and E or B and F apply. With Class IIa products an EU-Type Examination certificate (Module B) need not be issued.

CLASS III PRODUCTS:

In principle Module H applies, or, as an alternative, the Modules B and D or B and F apply.
Attached (p.t.o.) are block-diagrams, generally indicating the procedures.

SGS METHOD OF OPERATION

The philosophy of the SGS Medical Certification System is based on the principle that the manufacturer's interests are best served if, within the provisions of the directive, he has maximum freedom to develop new products or modify existing ones.
Based on this principle SGS Medical has developed a certification system that considerably simplifies the certification procedures by means of clustering. In the long term this approach, which is based on control of the manufacturer's implemented quality system, saves time and money by preventing the unnecessary issue of new CE certificates and/or modification of existing certificates.
SGS is a notified body (0649) for the 93/42/EEC directive.