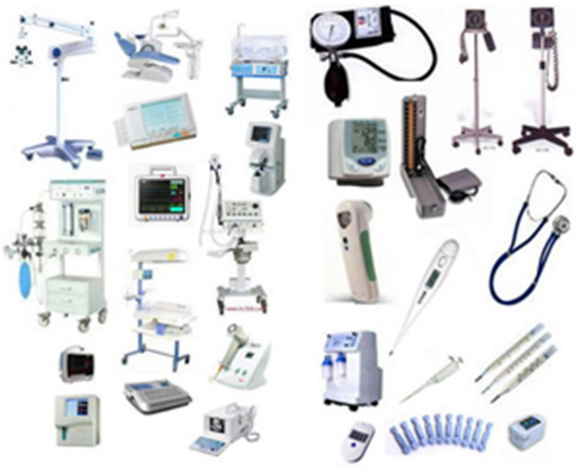
Medical Devices Directive 93/42/EEC

The Medical Devices Directive aims to ensure the free movement of goods within the Community, while providing patients, users and third parties with a high level of protection and attaining the levels of performance attributed to the medical devices by the manufacturer.

The Medical Devices Directive defines which products fall within its field of application, it provides the essential requirements that medical devices and accessories covered by it must comply with, and it outlines the conformity assessment procedure the manufacturer must apply in order to ensure compliance with the essential requirements.



WHICH PRODUCTS ARE COVERED BY THE MEDICAL DEVICES DIRECTIVE?

This Directive applies to medical devices and their accessories. For the purposes of this Directive, accessories are treated as medical devices in their own right.

For the purposes of this Directive, the following definitions apply:

'Medical device' means 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,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

'Accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

'In vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body,

solely or principally for the purpose of providing information:

— concerning a physiological or pathological state, or
— concerning a congenital abnormality, or
— to determine the safety and compatibility with potential recipients, or
— to monitor therapeutic measures.
Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles' are those devices, whether

vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived
– from the human body for the purpose of in vitro diagnostic examination.
Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

'Custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices;

'Device intended for clinical investigation' means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of Annex X in an adequate human clinical environment. For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

WHICH PRODUCTS ARE NOT COVERED BY THE MEDICAL DEVICES DIRECTIVE?

This Directive does not apply to:

(a) in vitro diagnostic devices;

(b) active implantable devices covered by Directive 90/385/EEC;

(c) medicinal products covered by Directive 65/65/EEC, including medicinal products derived from blood as covered by Directive 89/381/EEC;

(d) cosmetic products covered by Directive 76/768/EEC

(e) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices referred to in paragraph 4a;

(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;

(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

HOW TO COMPLY WITH THE MEDICAL DEVICES DIRECTIVE:

Before proceeding with the assessment procedure, it is important to establish whether the manufacturer, can assess the product by itself or whether there is a need to involve a Notified Body. In order to do that, the manufacturer must first determine under the Class (I,IIa, IIb or III) under which the medical devices falls.

The involvement of a Notified Body is not necessary for medical devices of Class I unless they have a measuring function or are placed on the market in a sterile condition. For all medical devices belonging to class III, and for medical devices belonging to class IIa and IIb on a representative basis, the design of the medical device and its compliance with the Essential Requirements must be examined by a Notified Body. The Notified Body issues then, a certificate that indicates, by referring to one of the Annexes II to VI of the MDD, what has been verified.

In the case of devices falling within Class I (low risk), other than devices which are custom-made or intended for clinical investigations, the manufacturer performs the conformity assessment and documents the assessment in his own right. In this case, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.

In the case of devices falling within Class IIa (medium risk), other than devices which are custom-made or intended for clinical investigations, the manufacturer performs the conformity assessment and documents the assessment in his own right. And, in order to affix the CE marking, shall follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either:

(a) the procedure relating to the EC verification set out in Annex IV; or

(b) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance); or

(c) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

Instead of applying these procedures, the manufacturer may also follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance)

In the case of devices falling within Class IIb (medium risk), other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable; or

(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to the EC verification set out in Annex IV; or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance); or

(iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

In the case of devices falling within Class III (high risk), other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or

(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to the EC verification set out in Annex IV; or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).