
MEDICAL DEVICES : Guidance document

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GUIDELINES RELATING TO THE APPLICATION OF :

THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES

THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

Definition of "medical devices"

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I. FIELD OF APPLICATION - DEFINITIONS

1. Directive 93/42/EEC on medical devices

1.1 Definition of "medical devices"

a) devices - accessory

The definition of the term "medical device" together with the definition of "accessory" is determinant for the delimitation of the field of application of Directive 93/42/EEC. A slight difference exists between the definition in article 1(2) (a) of Directive 93/42/EEC and in article 1(2) of Directive 90/385/EEC.

Following the latter directive, accessories are by definition medical devices, whilst following Directive 93/42/EEC, a distinction is made between "devices" and "accessories". Therefore within the meaning of Directive 93/42/EEC, accessories are products in their own right and, although being treated as devices (article 1(1)) do not follow, as a general rule, the classification of related devices in conjunction with which they are used.

Accessories are therefore following Directive 93/42/EEC to be classified in their own right.

b) medical purpose

Medical devices are defined as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer. The manufacturer determines through the label, the instruction for use and the promotional material related to a given device its specific medical purpose. As the directive aims essentially at the protection of patients and users, the medical purpose relates in general to finished products regardless of whether they are intended to be used alone or in combination. This means that the protection ensured by the directive becomes valid for products having a stage of manufacture, where they are supplied to the final user.

Following this concept, raw materials, components or intermediate products are as such normally not medical devices. Such raw materials may need to present properties or characteristics which are determinant for the safety and quality of finished devices. It is therefore the responsibility of the manufacturer of finished devices to select and control by adequate means his raw materials or intermediate products (see Annex I, section 7.1; Annex II, section 3.2; Annex V, section 3.2 of Directive 93/42/EEC)

Spare parts supplied for replacement of existing components of a device, the conformity of which has already been established, are not medical devices. If spare parts, however, change significantly the characteristics or performances of a device with regard to its already established conformity, such spare parts are to be considered as devices in their own right.

c) customizing

The concept of "finished device" does not imply that a device when reaching the final user is already in a state ready for use. Prior to use further preparatory processing, preparation, configuration, installation, assembling, adaptation or fitting to the needs of the user or patient may be required. Examples :

- sterilisation of medical devices supplied non-sterile
- assembling of systems
- configuration of electronic equipment
- preparation of a dental filling
- fitting of contact lenses
- adaptation of prosthesis to the needs of the patient.

The aforementioned activities are normally not manufacturers activities if they are carried out by the final user as part of the use or preparation for use. In this context a distinction needs to be made between a typical professional activity performed by a healthcare professional and processing and assembling activities done by a specialist for such processing. In the latter case relevant activities may become proper manufacturing or assembling activities relevant within the meaning of articles 11 and 12.

A particular consideration in this context needs to be given for the manufacture of custom-made devices. Custom-made devices (such as dental appliances, prosthesis, hearing-aid inserts) are in most cases one-off devices and the Directive subjects their manufacture to the procedure of article 11(6) in conjunction with Annex VIII. In these cases intermediate products specifically intended for this kind of custom-made devices may be considered also as medical devices. This applies essentially to dental alloys, dental ceramics, modular components for prosthesis, if the intended purpose of such products is specifically related to medical devices.

d) medical - toiletry purpose

The definition of "medical device" should be understood to include products intended to be used principally for a medical use. Therefore products intended to have a toiletry or cosmetic purpose are not medical devices even though they may be used for prevention of a disease. Examples for products for which a medical purpose can normally not be established :

- tooth brushes, dental sticks, dental floss;
- baby diapers, hygiene tampons;
- contact lenses without corrective function intended to provide another colour to the eyes,
- bleaching products for teeth [needs to be further discussed with regard to products intended specifically for application by dentists]
- instruments for tattooing.

Examples for products, where depending on the circumstances, a medical purpose can be established :

- incontinence products.

e) aids for handicapped persons

In the case of equipment intended for alleviation of or compensation for a handicap, there must be a direct link between the corrective function and the person concerned. Therefore the following equipment are not medical devices :

- acoustic signals at traffic lights,
- special water taps, toilet equipment for handicapped

f) software

The following distinction can be made : software influencing the proper functioning of a device and software used in combination with non-medical equipment.

Software related to the functioning of a medical device may be part of a device or a device in its own right if it is placed on the market separately from the related device.

In the case of software intended for use with multipurpose informatic equipment a distinction has to be made between software providing for a proper diagnostic or therapeutic tool and software for handling general patient-related data. Only in the first case may a medical purpose be determined. Examples for medical devices :

- calculation of anatomical sites of the body,
- image enhancing software intended for diagnostic purpose.
- software for programming a medical device

There is no medical purpose in the case of software used for administration of general patient data

g) multipurpose products

Products with a multiple purpose which may be used occasionally in a medical environment are normally not medical devices, unless a specific medical intended purpose is assigned to them. Examples :

- multipurpose PC, printer, scanner, ...
- magnetoscope, screen.

1.2 Definition of "accessory"

The question whether a product is a "device" or a "accessory" has not practical consequence. Following article 1(1) of Directive 93/42/EEC, "accessories shall be treated as medical devices in their own right". Therefore the main question is whether a product with a rather remote link to a medical use can still be considered as "accessory" (article 1(2)b) and as a matter of consequence is covered by the directive.

The definition of "accessory" requires that the accessory is specifically intended by the manufacturer of the accessory to be used together with a device. The intended use of the accessory must be such as to enable a device to be used in accordance with its intended use. Therefore a product can only become an accessory to a medical device if the manufacturer of such a product establishes an intended use in conjunction with one or several medical devices.

Examples for accessories depending on defined circumstances of device-related use :

- sterilizers for use in a medical environment,
- pouches for packaging re-sterilised medical devices,
- specific battery chargers for battery driven electromedical devices,
- contact lens care products, disinfectants specifically intended for invasive medical devices
- special water treatment device for use in conjunction with dialyzing machines,
- gas cylinders / pressure release devices for use in conjunction with anaesthesia machines.

1.3 Definition of "manufacturer"

Users in-house manufacturing

The Directive defines a manufacturer as the natural or legal person responsible for defined manufacturing activities related to a device with a view to its being placed on the market under the manufacturers own name. The reason for this link with the placing on the market is that the directives aims to subject to its protection requirements the transaction of a device from the sphere of a manufacturer towards the public. The directive does not provide any specific provisions for the case where a device is manufactured by the user (for example, a hospital) without being transferred to another person. The decision to which extent such in-house manufacturing activities by hospitals are subjected to legal requirements, belongs therefore to the national legislator. This relates however exclusively to such in-house manufacturing activities where a device remains within the users, but not to cases where, for example, a hospital produces orthopaedic devices for use with patients.

