

EUROPEAN COMMISSION

DG ENTERPRISE

Directorate G

Unit 4 - Pressure Equipment, Medical Devices, Metrology

MEDICAL DEVICES : Guidance document

MEDDEV 2.1/2 rev 2
26 April 1994

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
--

FIELD OF APPLICATION OF DIRECTIVE 90/385/EEC

--- () ---

INTRODUCTION

These guidelines should be read in conjunction with the Directive 90/385/EEC relating to active implantable medical devices and the Directive 93/42/EEC relating to medical devices. They provide a practical support for the uniform application of these Directives. The guidelines deal with specific issues in the context of the aforementioned Directives. They are therefore of complementary nature to the general vade-mecum relating to the application of New Approach Directives.

LIST OF CONTENTS

I. FIELD OF APPLICATION - DEFINITIONS

1. Directive 93/42/EE on medical devices^(*)
2. Directive 90/385/EEC on active implantable medical devices
3. Interface with other directives^(*):
 - medical devices/medicinal products
 - medical devices/electromagnetic compatibility
 - medical devices/personal protective equipment

II. CLASSIFICATION OF MEDICAL DEVICES COVERED BY DIRECTIVE 93/42/EEC^(*):

III. CONFORMITY ASSESSMENT PROCEDURES^(*):

1. CE-marking
2. Application
 - Annex 5
 - Annex 2
 - . Quality systems
 - . Examination of the design dossier
 - Annex 3
3. Conduct of audits
4. Format of decisions, design examination certificate
5. Technical Dossier

IV. CUSTOM MADE DEVICES^(*):

V. DEVICES INTENDED FOR CLINICAL INVESTIGATIONS^(*):

VI. MEDICAL DEVICE VIGILANCE^(*):

VII. USE OF LANGUAGES^(*):

VIII. TRANSITIONAL PERIOD^(*):

^(*) These parts of the guidelines will be circulated as separate working documents

I. FIELD OF APPLICATION

I. 2. DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES

The Directive 90/385/EEC covers the placing on the market and putting into service of "active implantable medical devices".

2.1. *Active implantable medical device*

A product falls within the field of application of the Directive if it complies with the definition given in this Directive. That means, it must be a "medical device" as defined which is, at the same time, both "active" and "implantable".

- 2.1.1 The "device" definition within the meaning of Directive 90/385/EEC relates to a product intended by the manufacturer for a medical purpose "whether used alone or in combination, together with any accessories or software for its proper functioning". The medical purpose may be achieved either by a "stand alone device" or as a result of several devices acting each in combination with the other as part of a system. Where the medical purpose is achieved by a system, each element of the system may be regarded as a medical device. The device definition may consequently apply to the system as such or to interchangeable parts intended to form a system together with other devices, therefore for the purposes of the Directive on Active Implantable Medical Devices each part belonging to such system is covered by the Directive regardless of whether such part on its own is "active", "active implantable" or not.

Examples of AIMDs :

- a) - *implantable pulse generator for pacing including the electrode*
 - *implantable pulse generator without electrode*
 - *electrode*
- b) - *implantable drug administration device with or without catheter*
 - *catheter for implantable drug administration device*

- 2.1.2. For the purpose of the Directive 90/385/EEC a medical device is active if it "relies for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity. This includes, for instance, devices activated by means of pressure unless this effect is achieved by energy resulting from the body of the patient. The definition implies that the function of the device involves using the source of power to perform useful work. The mere transmission of heat, light, pressure or vibration does not mean that a device is active.

Examples :

- *a hydrocephalus pressure relief allowing release of cerebro-spinal fluid when a spring is overcome is not "active". Even where the setting of the spring can be adjusted by electro-magnetic means, it remains non-active as the medical function of the device is to relieve pressure, not to be adjusted,*

- *a drug delivery device in which the drug is driven from a reservoir by means of a stored energy source (spring, fluid, gas, etc...) is "active"*
- *an intravascular catheter containing a fibre-optic bundle connected to an external light source may be used to measure pressure or other characteristics of blood if some quality of the light can be changed by the blood characteristic and detected. Although the system as a whole depends on a power source to achieve its medical function (the measurement of a blood characteristic) the invasive element is not "active" as it does no more than transmit light*
- *a cochlear implant activated by an external power transmitter is regarded as "active" as the implanted component clearly depends on a power source for its function and its purpose is to convert the power it receives into electrical signals which trigger appropriate sensory channels in the brain, i.e. it performs useful work.*

2.1.3. An active medical device is defined as "implantable" if it is "totally or partly introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure".

The Directive has been conceived for active devices for which a potential high risk may be inherent due to the fact that they are totally or partly implanted into the body. Such devices may present hazards in particular with regard to impossibility of maintenance, calibration or control and problems relating to the ageing of materials, as mentioned in several essential requirements of Annex 1 to the Directive. The attribute "implantable" has therefore to be interpreted bearing in mind those hazards typical for implantable devices.

For the aforementioned reasons, an external drug infusion pump, although for long-term or permanent use, which is connected to a catheter "partially introduced" into the body is not considered as an active implantable device.

One of the essential characteristics of an implantable device is its relatively long-term use. Distinction is to be made between an intended use of a device which is permanent or long-term in the order of several months compared to a temporary use during a given medical intervention. An external pacemaker, including its electrode, used for an interim process is thus not considered as "remaining after the procedure". The same applies to the use of an intra-aortic balloon pump. For the purpose of the Directive 90/385/EEC, the term "procedure" is to be interpreted as a process of diagnosis, monitoring or treatment which may last for some days, generally in hospital, and not necessarily exclusively relating to an operation carried out in the theatre in the course of which the device is placed in the body.

2.2. "Accessories" to an active implantable medical device are by definition "active implantable medical devices" and therefore covered by the Directive 90/385/EEC. This does not presuppose that the attributes "active" and "implantable" must be necessarily met by a product called "accessory". It is sufficient that a product in its intended purpose is ancillary to the purpose of an active implantable medical device in such a way that it enables the device to be used in accordance with the intended device purpose or that it enhances the purpose of a device as intended by the device manufacturer. Following this a programmer or an external transmitter intended for activating or controlling the implantable part of the device is covered by the definition of "active implantable medical device".

2.3. exemplative list of active implantable medical devices. The subsequent list contains examples of types of devices which are normally covered by Directive 90/385/EEC :

1. implantable cardiac pacemakers
2. implantable defibrillators
3. leads, electrodes, adaptors for 1. and 2.
4. implantable nerve stimulators
5. bladder stimulators
6. sphincter stimulators
7. diaphragm stimulators
8. cochlear implants
9. implantable active drug administration device

10. catheters, sensors for 9.
11. implantable active monitoring devices
12. programmers, software, transmitters.



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE