EUROPEAN COMMISSION
DG ENTERPRISE
Directorate G
Unit 4 - Pressure Equipment, Medical Devices, Metrology

MEDICAL DEVICES : Guidance document

MEDDEV 2. 1/4

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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

Demarcation with other Directives :

- **Directive 89/336/EEC relating to electromagnetic compatibility**
- **Directive 89/686/EEC relating to Personal Protective Equipment**

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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. Therefore they are of complementary nature to the general vade-mecum relating to the application of New Approach Directives.

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

1 see MEDDEV. 5/93 rev. 1

2 see MEDDEV. 10/93 rev. 1

I.3 INTERFACE WITH OTHER DIRECTIVES

3.1 MEDICAL DEVICES/MEDICINAL PRODUCTS

3.2 MEDICAL DEVICES/DIRECTIVE 89/336/EEC RELATING TO ELECTROMAGNETIC COMPATIBILITY

3.2.1 The Directive 90/385/EEC on active implantable medical devices (AIMD) and the Directive 93/42/EEC on medical devices (MDD) are "specific directives" with regard to Directive 89/336/EEC relating to electromagnetic compatibility [1.-] (see Article 1(5) AIMD, Article 1(7) MDD) The aforementioned medical devices directives cover all aspects related to electromagnetic compatibility (immunity and electromagnetic interference) of medical devices (see AIMD, Annex I, section 8; MDD, Annex I, sections 9.2, 11 and 12.5). Thus, in all cases when the medical devices directives are applied, whether during the transitional period for these directives or when the directives become mandatory, there is no need to apply the Directive 89/336/EEC with regard to EMC aspects.

3.2.2 There are rather complicated situations presented during the transitional period of the three Directives mentioned, caused by the different introduction dates for each Directive, and the different finishing dates of the appropriate transitional periods. This complication is caused by the fact that the medical devices directives, as with most other New Approach Directives, are only of optional application during their transitional periods.To clarify the choices open, during the transitional period, to a manufacturer in dealing with aspects relating to electromagnetic compatibility, the alternatives are illustrated as follows :

1.- Official Journal no. L 139 of 23 May 1989 as amended by :
- Directive 91/263/EEC of 29 April 1991 (L 128 of 23 May 1991, p. 1)
- Directive 92/31/EEC of 28 April 1992 (L 126 of 12 May 1992, p. 11)
- Directive 93/68/EEC of 22 July 1993 (L 220 of 30 August 1993).

ACTIVE IMPLANTABLE MEDICAL DEVICES

	National legislation covering active implantable medical devices		National legislation covering E M C	
1.1.1992-31.12.1992	Option A	Option B	Option C	Option D
	Not applicable	Pre-existing national legislation	Legislation transposing EMC Directive ⇨ CE marking, Dir. 89/336/EEC	Preexisting national legislation
1.1.1993-31.12.1994	National legislation transposing AIMD (including necessarily EMC aspects) ⇨CE marking , directive 90/385/EEC	Pre-existing national legislation	National legislation transposing EMC directive ⇨ CE marking, Directive 89/336/EEC	Pre-existing national legislation
from 1.1.1995	Exclusively national legislation transposing AIMD (including necessarily EMC aspects) ⇨CE marking, directive 90/385/EEC	Not applicable	Not applicable	Not applicable

MEDICAL DEVICES OTHER THAN ACTIVE IMPLANTABLE MEDICAL DEVICES AND IN VITRO DIAGNOSTIC

	National legislation concerning medical devices		National legislation covering E M C	
	Option A	Option B	Option C	Option D
1.1.1992-31.12.1994	Not applicable	Pre-existing national legislation	Legislation transposing EMC Directive⇨ CE marking, Dir. 89/336/EEC	Preexisting national legislation
1.1.1995-31.12.1995	National legislation transposing MDD (including necessarily EMC aspects) ⇨CE marking , directive 93/42/EEC	Pre-existing national legislation	Legislation transposing EMC directive⇨ CE marking, Directive 89/336/EEC	Preexisting national legislation
1.1.1996-13.6.1998	National legislation transposing MDD (including necessarily EMC aspects) ⇨CE marking , directive 93/42/EEC	Pre-existing national legislation	Legislation transposing EMC directive⇨ CE marking, Directive 89/336/EEC	Not applicable
from 14.6.1998	Exclusively national legislation transposing MDD (including necessarily EMC aspects) ⇨CE marking , directive 93/42/EEC	Not applicable	Not applicable	Not applicable

3.2.3. Labelling requirements

In order to establish clearly which directives have been effectively applied, attention shall by given to Article 4(5b) of Directive 90/385/EEC[3] and Article 4(5), second subparagraph of Directive 93/42/EEC relating to medical devices (MDD). Following these provisions, the manufacturer shall indicate in the instructions for use which directive(s) has (have) been applied. The particulars of the (or these) directive(s) as published in the Official Journal in conjunction with the relevant Directive, which has (have) been applied shall be given in the instructions for use accompanying the device. The relevant indication should relate to "Directive 90/385/EEC" in the case of application of AIMD, to "Directive 93/42/EEC" in the case of MDD and to "Directive 89/336/EEC" in the case of the EMC directive.

3.3. MEDICAL DEVICES DIRECTIVE - DIRECTIVE 89/686/EEC RELATING TO PERSONAL PROTECTIVE EQUIPMENT.

Following Article 1(6) of Directive 93/42/EEC, this Directive does not apply to personal protective equipment covered by Directive 89/686/EEC relating to personal protective equipment [4]. In deciding whether a product falls under Directive 93/42/EEC or under Directive 89/686/EEC, particular account shall be taken of the principle intended purpose of the product.

As a consequence of this clause a given product is either covered by Directive 89/686/EEC or by Directive 93/42/EEC. As a general rule, the principal intended purpose can be established as being the one of a medical device if the product is intended to be used in a medical context with the aim to provide protection of health and safety for the patient, regardless of whether the product aims simultaneously to protect also the user. Where a product is mainly intended to protect the person using it, irrespectively whether in a medical environment or not, it falls under Directive 89/686/EEC.

The labelling of the product is crucial for its classification under one or the other Directive.

Examples for medical devices
- surgical gloves, examination gloves
- face masks
- corrective glasses (including those intended at the same time for sun protection)
- surgeons gowns and hats

Examples for personal protective equipment
- protective gloves (for example, for use in a medical laboratory)
- clothing for protection against ionizing radiation
- sun glasses
- eye protection devices for professional use (for example, for welders, regardless of whether or not they contain corrective glasses adapted to the need of the user)
- gum shields for boxers.

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[3] It should be noted that Article 4 (5b) AIMD as amended by Directive 93/68/EEC (OJ no. L 220, 30.8.1993) becomes applicable 1 January 1995 (see article 14 of Directive 93/68/EEC).

[4] OJ Nr. L 399, 30.12.1989, p. 18 as last amended by Directive 93/95/EEC, OJ No. C 276, 29.10.1993