

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Recommendation  NB-MED/2.1/Rec3</b></p>
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<b>Title:</b>	<b>Accessories and other parts for Active Implantable Medical Devices</b>
<b>Chapter:</b>	<b>2.1 Scope, field of application, explanation of terms</b>

<b>Text:</b>	<b>„Accessories and other parts for Active Implantable Medical Devices“</b>
<b>Key words:</b>	<b>accessories, spare parts, labelling</b>

## 1 Introduction and purpose

With the application of the provisions of the Active Implantable Medical Device Directive (AIMD) an issue became apparent with regard to the requirements of the Conformity Assessment and labelling of the minor accessories and spare parts, used with the active implantable medical devices.

For example it is clear how the AIMD needs to be applied to:

- The minor accessories, such as screw-drivers, stylets, screwsets etc. and
- Other parts (Spare parts) such as power supply cords, printing paper etc.

However it is clear that the requirements of Annexes 2-5 are too heavy and overdone.

The purpose of this position paper is to present a proposal on the application of the AIMD Directive to the minor accessories and spare parts. This proposal is addressed to the CEC, Member States, Notified Bodies and other interested parties for endorsement and application, in order to bring clarity to all concerned and uniformity of treatment, so that application and compliance by the industry will be able to proceed as smoothly as possible.

*A rationale and history sheet is not available.*

<b>Reference to Directives:</b>	<b>Article/ Annex:</b>	<b>Reference to standards:</b>
AIMD	Article: 2a	
MDD		
IVD		

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3		2	21.06.96	25.09.96			1/7

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p style="text-align: center;"><b>Recommendation NB-MED/2.1/Rec3</b></p>
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## 2 Definitions

### a. Accessory

"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.

### b. Spare parts

"Spare parts" means a sub-assy or component used in the composition of a medical device or system and which is not in itself a medical device with an intrinsic function intended for the final user and which may also be supplied for replacement of existing components of a medical device.

Note: Spare parts for use with active implantable medical devices are not subject to the provisions of the AIMD Directive.

## 3 General Principles

With the operation of the AIMD Directive, manufacturers are discovering that the global wording of the AIMD Directive in respect to accessories may give rise to inappropriately stringent conformity assessment procedures for those articles.

This in distinctness with regard to accessories has been improved in the MDD, in which an accessory is defined as an article, whilst not being a device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of this device intended by the manufacturer of this device (Accessories).

From this definition it can be recognised that the manufacturer indicates which specific articles are the accessories to be used with the medical device(s) so that the device and accessory combination achieves the performance as a medical device as intended by the manufacturer.

However it is known that for the proper operation of the device other parts, which are not in itself a medical device with an intrinsic function for the final user, are needed.

These articles may also be supplied for replacement of existing components of a medical device (Spare parts).

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Recommendation  NB-MED/2.1/Rec3</b></p>
<p><b>Title:</b></p>	<p style="text-align: center;"><b>Accessories and other parts for Active Implantable Medical Devices</b></p>	

#### 4 Discussion

In MEDDEV 5/93 Rev. 2, clause 2.2 the definition of an accessory covered by the Directive 90/385/EEC has been elucidated.

However this clarification focuses mainly on the parts specifically intended for the use in an AIMD system, e.g. the programmer of implantable part(s) of an AIMD.

All these parts of the AIMD system can be regarded as a medical device and are covered by the AIMD Directive.

Examples of elements of the AIMD system are:

- Implantable Pulse Generators (IPG's)/Drug Pumps
- Implantable leads/catheters
- Implantable lead adapters
- Programmers and software
- Implantable receivers
- Transmitters

They must bear the CE marking in accordance with requirements of the AIMD Directive (90/385/EEC).

However in addition to the above AIMD elements, other minor accessories may also be used, which may remain in the patient or may be used during a given medical procedure.

These articles

- May have an intended use which is permanent or long term (e.g. IPG pouch, lead anchors) or temporary (e.g. screwdrivers, tunnelling rods, lead introducers etc.).
- Are provided sterile (for implantable or invasive use) and non-sterile (e.g. programmer head or its cable).
- Are placed on the market as a spare part of an AIMD product or as a separate product (e.g. power supply cord, printing paper) for proper function of the device as indicated in the manual of the manufacturer.

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Recommendation  NB-MED/2.1/Rec3</b></p>
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For "Minor accessories" was indicated that a practical solution within the scope of the AIMD should be regarded. In this respect the Conformity Assessment procedure should be agreed with the Notified Body. This procedure shall be appropriate to the complexity of the product.

For a consistent approach, the medical device/system, the accessories and other components can be divided in the following categories. Each category will have its own assessment procedure and labelling/CE marking requirements.

The categories are:

1. Medical device/system:

The medical product or accessories of the medical system, which is ancillary to the intended purpose of the active implantable medical device. Such IPG's leads, adapters and programmers.

2. Minor Accessories subject to AIMD Directive

Minor accessories, which will be used with the product/system and are

- Intended to remain implanted after the procedure such as IPG pouch, set screws etc.

or

- Used with the product/system during the implanting procedure or follow-up.

Such as stylets, ECG cables, magnets etc.

3. Spare parts

Products covered by the AIMD Directive will be subject to any of the applicable provisions of this Directive. However it is clear that for a number of minor accessories/parts of the AIMD system, the provisions of the Directive will become too burdensome heavy and overdone.

5 Guidance (See attached labelling requirements overview)

In order to bring more clarity to the application of the provisions of the Directive the following guidelines are prepared.

	<b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b>	<b>Recommendation  NB-MED/2.1/Rec3</b>
<b>Title:</b>	<b>Accessories and other parts for Active Implantable Medical Devices</b>	

## 1. Active Implantable Medical Devices

All active implantable medical devices and accessories/parts of the medical system must be certified for CE marking under the provisions of Article 9 of the AIMD Directive.

## 2. Minor Accessories

### a. Conformity Assessment Requirements

A minor accessory marketed as an active implantable medical device in its own right is subject to the provisions of the AIMD Directive for the CE marking, whether sold in combination with or separately from the active implantable medical device.

All certified minor accessories may be placed on the market in combination (same package) with an active implantable medical device as a system or as separate products or sets/kits.

The Conformity Assessment of accessories can be:

- Included in the assessment of the complete AIMD system, or
- Assessed separately with a specific Conformity Assessment procedure as agreed with the Notified Body.

If assessed separately, the specific Conformity Assessment procedure could be either:

1. EC Declaration of Conformity according Annex 2 of the AIMD Directive (90/385/EEC), whereby the design dossier will be provided in a condensed way (e.g. in a matrix).

or

2. EC Declaration of Conformity according Annex 5 of the AIMD Directive (90/385/EEC) whereby for the Annex 3 assessment the above condensed design dossier will be provided to the Notified Body. If appropriate the Notified Body may request a test sample or more technical details. The

	<b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b>	<b>Recommendation  NB-MED/2.1/Rec3</b>
<b>Title:</b>	<b>Accessories and other parts for Active Implantable Medical Devices</b>	

relevant technical documentation shall be kept available by the manufacturer.

Note: The technical documentation to be kept available should at least provide the following information:

- Product name
- Model/Part number
- Intended use
- Materials in contact with the body and/or body fluids
- Implantable (Y/N)
- Sterile (if applicable)
- Manufacturing place
- Test data and whether appropriate clinical data.

#### b. Labelling requirements

1. Assessed as a part of the AIMD system assessment, and the intended use of it has been described in the manual of the active implantable medical device for which it is intended.

In this case the label of the minor accessory packaging should make reference to the manual(s) of the product(s) for which certification for the CE marking has been received.

e.g.! See instructions for use of the CE marked medical device(s) (e.g. IPG's of this manufacturer)

No manuals but adequate labels with the CE marking are required for these accessories, also if placed on the market as separate products or set/kits.

2. If the accessory is not described in the manual of the AIMD, it has to be assessed separately with one of the above conformity procedures.

In this case the CE marking shall be provided in accordance to the provisions of the AIMD Directive. If the application of the accessory(ies) cannot be recognised from the label a manual shall be provided.

#### c. Illustrative list of minor accessories

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Recommendation NB-MED/2.1/Rec3</b></p>
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The subsequent list contains a number of examples of products which could be considered as minor accessories:

- Implantable:

IPG pouch/set screw kits/lead anchors/lead/medical adhesive/oil etc.

- Invasive:

Tunnelling rods & tubes, lead introducers etc.

- External (Sterile or non-sterile):

Programmer head/head/cable/patient and ECG cables/AC-DC adapters/screwdrivers etc.

### 3. Spare parts

These spare parts are not covered by the AIMD Directive (90/385/EEC) and need not to be assessed as such and bear the CE marking.

Note: They may be covered by another EEC Directive or local requirements.

#### Illustrative list of spare parts

The subsequent list contains a number of examples of parts/components, which could be used with active implantable medical devices and are considered as Spare Parts.

- Power supply cords/extension cables/printer paper/touch pen etc.
- Programmer boards/replacement parts etc.
- Software which handles data related to healthcare such as patient records.