

The new directive 2007/47EC amending the directives 93/42/EEC, 90/385/EEC and 98/8/EC was adopted on September 5, 2007.

MDD revised – a survey of the essential modifications

After a long period of consultation the revision of both the Medical Devices Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMD) was adopted by the European Parliament on March 29, 2007. The adoption by the Council is expected in the fall of 2007, after finalization of all legal text fine-tuning and translation into all member state languages. The publication in the Official Journal is then to follow. The revision of the directives needs transposition into each national law by the Member States within 15 months and should be legally enforced after another 15 months.

It can be concluded that in general there are no dramatic changes but many improvements by better and clearer wording. References are updated and missing definitions are completed. The AIMD remains a separate directive, but is aligned with the MDD.

However there are remarkable changes as well which, amongst others, will have an impact on the conformity assessment procedures for medical devices and on the relationship between manufacturers and the Notified Body.

For information and guidance the most important changes in the MDD are shown below.

Modifications to the MDD

Only important modifications which have some effect on the activities of medical device manu-

facturers or on Notified Bodies (NB) are mentioned; modifications which only improve existing wording or update references to other documents are neglected.

References to the articles and paragraphs of the existing MDD are printed in bold.

Intention of the legislator clarified

In the following articles and paragraphs the intention of the legislator has been emphasized and clarified without resulting in any changes in practice:

- Article 1, 2(a): Software as stand-alone medical device.
- Article 1, 2(k)-2(n): New definitions of "clinical data", "device subcategory", "generic device group", "single use device".
- Article 1, 5(c): Basis of demarcation from medicinal products.
- Annex II, 3.2b, Annex V, 3.2b: Monitoring of suppliers.
- Annex II, 3.3: Technical file review during the audit.
- Annex V, 4.2: Technical documentation as part of documents subject to the audit.

Internal procedures changed

In the following articles and paragraphs internal procedures of the European Commission (Commission Européenne) (CEC) have been changed without much relevance for the public:

- Article 6, Article 8(2), Article 9(3), Article 13.

Modifications in detail:

Definitions

- The Directive does not apply to products that include or that have been manufactured using material (cells, tissues, derivatives) of human origin except those covering combination products with human blood derivatives (**Article 1, 4(a), Article 1, 5(f)**).
- The vice-versa exclusion between MDD and Personal Protective Equipment Directive (PPE) is removed; where appropriate both directives may apply (remark: CE marking means compliance with all relevant directives; so one CE marking only in any case; if more than one NB has been involved, both NB numbers have to appear behind the CE marking) (**Article 1, 6**).

Essential Requirements (see also Annex I)

- Medical devices which are also under the Machinery Directive 2006/42/EC must additionally meet those essential requirements of the Machinery Directive which are more specific than the essential requirements of the MDD (**Article 3**).

Custom-made Devices

- Custom-made devices of class IIa, IIb and III: The statement to be drawn up by the manufacturer (Annex VIII, devices for special purposes) must be handed over to the patient (**Article 4, 2, 2nd indent**).

Conformity Assessment Procedures

- Validity of all EC certificates (except for Annex IV) is now limited to five years; no change versus actual practice (**Article 11, 11**).
- In the future CEC may allow alternatives to the delivery of instructions for use based on a regulatory procedure, without a legislative process (**Article 11, 14; new**).

Sterilization of Procedure Packs

- Conformity assessment for sterilizing companies is now directly limited to Annexes II and V (**Article 12, 3**).
- Reprocessing of medical devices: Announcement of activities of the CEC within 3 years (**Article 12a; new**)

Registration

- Competent Authorities (CA) may now request information from manufactures not only for medical devices of class IIb and III, but also for class IIa devices.
- Manufacturers shall designate a single authorized representative (per device). A gap has been closed; now an EU representative is necessary for non-EU manufacturers of devices of all classes, including systems and procedure packs and including custom-made devices (**Article 14, 2**).
- Registration of data in the European Database on Medical Devices (EUDAMED) is dropped for custom-made devices, but is additionally necessary for devices for clinical investigation. EUDAMED must be implemented not later than five years after adoption of the MDD amendment (**Article 14a**).

Clinical Investigation

- If clinical investigation is refused by a Member State, all other Member States have to be informed. For modifications and interruption of a clinical investigation called by a Member State, all other concerned Member States have to be informed. The sponsor of a clinical investigation has to inform the Competent Authorities concerned about the end of this investigation. In case of early termination a justification has to be given (**Article 15**).

Notified Bodies

- Obligation of NBs to inform CAs and other NBs slightly changed, but no change in practice (**Article 16, 5**).

Wrongly Affixed CE Marking

- Not only the “unduly affixing” of the CE marking, now also the “missing” of a CE marking is considered to be an offence (**Article 18**).

Confidentiality

- Confidentiality is no longer requested for: registration of persons responsible, information to users in case of an incident, information in and about certificates (**Article 20**).
- Cooperation of the CAs of member states and with the CEC is requested (**Article 20a; new**).

Annex I: Essential Requirements

I. General Requirements

- Reduction of use error due to ergonomic features and due to the environment in which the device is used becomes mandatory.
Design must consider technical knowledge, experience, education and training of the user and his medical and physical condition (design for lay, professional, disabled or other users) (**1**).
- Demonstration of conformity must include a clinical evaluation; emphasized, but no change in practice (**6a; new, formerly 14**).

II. Requirements Regarding Design and Construction

Chemical, Physical and Biological Properties

- Where appropriate, the results of biophysical and modeling research have to be demonstrated as well as the validity of the data.
- Quality, safety and usefulness of the drug component of a combination product are to be assessed using procedures defined in Annex I of the Drug Directive (2001/83/EC). The Competent Authority has to assess the quality and safety of the drug component of the combination product. The clinical benefit of the final product as assessed by the Notified Body is to be taken into consideration. The Notified Body shall evaluate the quality and safety of the medical device component. It shall come to a preliminary conclusion regarding a clinical risk/benefit assessment of the final product before consulting the Competent Authority.
The Competent Authority will inform the Notified Body in case new information regarding the risk/benefit profile of the drug component of a combination device becomes available (**7.4**).
- Consideration of risks from leaking substances is emphasized, especially from carcinogenic mutagenic reprotoxic substances (CMR). Devices containing phthalates must be labeled accordingly; if intended for the use with children or pregnant or nursing women, the use of such substances must be justified in the instructions for use (IFU), residual risks and precautionary measures must be described (**7.5**).

Active medical devices

- Software must be validated according to the state of the art (**12.1a; new**).

Information supplied by the manufacturer

- The manufacturer's indication that a device is for "single use" must be consistent across the Community (13.3f; new).
- For devices declared as "for single use" information on known risks in the case of re-use must be indicated in the IFU; if no IFU is needed, this information must be given to the user on request (13.6h).
- Not only medicinal substances (as up to now), but also human blood derivatives contained in a device must be indicated in the IFU (13.6o).
- The date of issue or the latest revision of the IFU must be indicated (13.6q; new).

For all Annexes II-VII, Conformity Assessment Procedures

- The retention period for documents for implantable devices has been extended to 15 years (from five years) (6.1, 7.3, 7, 5.1, 5.1, 2).

For Annexes II, V, VI, Quality Systems:

- Post-marketing surveillance now includes post-market clinical follow-up; it can only be omitted in duly justified cases (3.1, each Annex).
Declaration of Conformity (DoC) must clearly identify the product(s) it relates to (2, each Annex).
- Technical file review is emphasized for devices of class IIa (at least one representative sample per device subcategory) and class IIb (at least one representative sample per generic device group). Criteria for the selection of samples are given; sampling must be justified and documented by the NB. During surveillance audits technical file review is also necessary (7.2–7.5; 6.2–6.4; 6.2–6.4; new).

Annex II: Full Quality Assurance System

- Consultation process for drug/device and blood derivatives/device combination products: The assessment by the EMEA or Competent Authority is to be finalized within 210 days (4.3).
- Inspection of post-market clinical follow-up activities is part of the surveillance audit (5.2).

Annex III: EC Type Examination

- Consultation process for drug/device and blood derivatives/device combination products: The assessment by the EMEA or Competent Authority is to be finalized within 210 days (5).

Annex IV: EC Verification

- Post-market clinical follow-up is the obligation of the manufacturer (3).
- Details for sampling system have been removed, reference to harmonized standards for sampling (6.3).

For Annexes V, VI: Production/Product Quality Assurance System

- Technical documentation is part of the information which has to be provided to the NB for audit by the manufacturer; no change in practice (4.2).

Annex VII: Self-Declaration of Conformity

- The technical file must include the intended use of the device; no change in practice. The technical file must include sterilization validation reports; no change in practice. Clinical evaluation always has to be included (not only "where appropriate") (3).
- For class 1 sterile/measuring devices Annex II may also be used, not just V (IV, VI) (5).

Annex VIII: Devices for Special Purposes

- In addition to the clinical investigational plan, the investigator's brochure, the confirmation of the insurance, and the informed consent must be contained in the statement of the manufacturer.

For custom-made devices incidents have to be reported (5).

In case of implantable devices the necessary information has to be kept for 15 years instead of five years (4).

A statement must be provided if human blood derivatives and/or Transmissible spongiform Encephalopathy (TSE) relevant tissue is integrated or utilized for manufacturing. For this materials tests and risk management measures have to be provided on request (2.2).

Annex IX: Classification

- Software is considered to be an active medical device (this statement is contained already in a MEDDEV document; no practical change) (I, 1.4).
- The definition of the "central circulatory system" has been corrected and modified: All parts of the aorta are now belonging to the central circulatory system (I, 1.7).
- A definition of the "duration of use" for the case of interrupted use or subsequent use of identical devices is given (I, 2.6; new).

Rule 5

- A gap has been closed: Invasive devices with respect to body orifices intended for connection to an active medical device of class I which have not been classified at all before, are now included in classification (III, 2.5).

Rule 6

- "To control" has been added to "diagnose, monitor or correct" (III, 2.2, 1st indent).
- A new indent (now 3rd indent) has been added:
"– intended specifically for use in direct contact with the central nervous system, in which they are in class III" (this case has only been in rules 7 and 8 before; this is a real change of the classification rules) (III, 2.2).

Rule 7

- "To control" has been added to "diagnose, monitor or correct" (III, 2.3, 1st indent).

Rule 15

- "... unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb." This is a real change of the classification rules (III, 4.3, 2nd paragraph added).

Rule 16

- Rule 16 has been extended to cover all devices for recording of X-ray diagnostic images, not just non-active devices; this is a real change of the classification rules (III, 4.4).

Annex X: Clinical Evaluation

- Evaluation of clinical data must follow a defined and methodologically sound procedure (1.1); for implantables and class III devices, clinical investigations are the preferred method (1.1a); clinical evaluation and documentation must be actively updated with data from post-market surveillance (1.1c).

In this Med-Info used abbreviations

| | | | |
|------------|--|------------|---|
| CA | Competent Authorities | MDD | Medical Device Directive |
| CEC | European Commission (Commission Européenne) | NB | Notified Body |
| CMR | Carcinogenic mutagenic reprotoxic substances | PPE | Personal Protective Equipment Directive |
| DoC | Declaration of Conformity | TSE | Transmissible spongiform Encephalopathy |
| IFU | Instructions for use | | |

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