



# **ITC**

**Amendment to the  
Medical Device Directive  
(92/42/EEC)**



## Directive 2007/47/EC amending MDD and AIMD - Overview

Amendment to the Medical Device Directive (92/42/EEC),  
the Active Implantable Medical Device Directive (90/385/EEC),  
and the Biocidal Products Directive (98/8/EC)

Dated **5 September 2007**

### Structure:

- Whereas section  
rational for the changes implemented with this directive
- 6 Articles
- 2 Annexes



## Directive 2007/47/EC amending MDD and AIMD - Overview

- **Article 1**  
amends Active Implantable Medical Device Directive
- **Article 2**  
amends Medical Device Directive (47 changes)
- **Article 3**  
amends Biocidal Products Directive (1 change)
- **Article 4**  
establishes the transition periods
- **Article 5**  
establishes the date when this directive enters into force
- **Article 6**  
addresses this directive to the Member States of the EU



## Directive 2007/47/EC amending MDD and AIMD - Overview

- **Annex I**  
amends Annex 1 to 7 of the Active Implantable Medical Device Directive
- **Annex II**  
amends Annex I to X of the Medical Device Directive  
(91 changes in total – additions, replacements, deletions)



## Directive 2007/47/EC amending MDD and AIMD - Overview

### Main Areas of Change:

- Definition of Medical Device (software)
- Clinical Evaluation
- Combination Devices (medicinal products & human blood derivatives)
- Classification rules
- Essential Requirements (use errors, labeling)
- Increased transparency to the public – European Database
- Updates AIMDD for coherency with MDD
- Updates Biocide Directive to remove IVDs from its scope



## Directive 2007/47/EC amending MDD and AIMD - Overview

Redesign or Restart or Clarification of the MDD?

Manufacturers which applied the old version of the Directive correctly, are already in compliance with most of the new requirements?

True or False?



## Directive 2007/47/EC amending MDD and AIMD - Overview

### ■ Article 4

1. Member States shall adopt and publish by **21 December 2008** the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those measures.

They shall apply those measures from **21 March 2010**.

**The provisions of this Directive will become  
mandatory for manufacturers on  
March 21<sup>st</sup>, 2010**



## Directive 2007/47/EC amending MDD and AIMD - References to other directives

- Directive **2001/83/EC** replaced 65/65/EEC and 89/381/EEC  
Article 1 of 2001/83/EC defines medicinal products  
(MDD essential requirements – 7.4)
- Directive **67/548/EEC** – Annex I defines substances which are carcinogenic, mutagenic, or toxic to reproduction  
(MDD essential requirements – 7.5)
- Personal Protective Directive **89/686/EEC** has to be applied in addition to the MDD for devices, which are used in accordance with the provisions of both directives



## Directive 2007/47/EC amending MDD and AIMD - References to other directives

- Directive **2006/42/EC** – Machinery Directive  
MDD – Article 3 – Essential Requirements.  
Medical Devices which are also considered Machinery also have to meet the essential health and safety requirements of the machinery directive.  
*e.g. X-ray systems, CT, Robotic Equipment*
- Directive **2004/108/EC** – EMC  
replaced Directive 89/336/EEC, otherwise no change:  
neither the old or the new directive apply to devices covered by the medical device directive



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

- Requirements have been clarified and expanded
- Clinical evaluation is required for **all** risk classes (I, IIa, IIb, and III)
- Clinical evaluation must be actively updated with data from post-market surveillance
- Communication and exchange of information regarding clinical investigations – increased transparency



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Article 1 – Definitions

#### Added:

"(k) "clinical data" means the safety and/or performance information that is generated from the use of a device.

#### **Clinical data are sourced from:**

- clinical investigation(s) of the device concerned; or
- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
- published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Article 15 – Clinical investigations

- Clinical Study Notification to Competent Authorities per section 2.2 of Annex VIII
- Favorable opinion on the program of investigation in question from the relevant ethics committee has to be based on the clinical investigation plan
- Member States (Competent Authorities) have to inform other Member States and the Commission about cases where they
  - refused clinical investigations
  - called for a significant modification
  - called for a temporary interruption



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Article 15 – Clinical Investigation – cont.

- Manufacturer or authorized representative **has to inform**
  - the Competent Authorities of the Member States concerned about the end of the clinical investigation
  - all Member States and the Commission about early termination of a clinical study on safety grounds, including a justification



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Annex I – Essential Requirements

#### Section I – General Requirements

##### Added:

**6a.** Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Annex VIII – Special Purpose Devices (e.g. for clinical investigation)

#### NEW:

Statement per this Annex has to include

- The investigator's brochure
- The confirmation of insurance of subjects
- The documents used to obtain consent
- A statement indicating if device contains tissues of animal origin

Technical documentation of product must include:

- Test data relating to human blood derivatives
- Risk management measures relating infection risks through animal tissue



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Annex X

Section 1 changed:

- Evaluation of the acceptability of the benefit / risk ratio
- The evaluation must follow a defined and methodologically sound procedure based on either
  1. Critical evaluation of scientific literature (need to demonstrate equivalence)
  2. Critical evaluation of results of all clinical investigations
  3. Combination of 1 and 2



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Annex X - Section 1 - Additions:

- **1.1a** In the case of implantable devices and devices in Class III clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.
- **1.1b** The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.
- **1.1c** The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

**MEDDEV 2.12/2 - Clinical Evaluation – Post Market Clinical Follow-up**



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Annex X - Section 1 - Additions:

- **1.1d** Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.



## Directive 2007/47/EC amending MDD and AIMD - Clinical Evaluation

### Annex X – Clinical Evaluation

Section 2 - change:

- **2.3.5.** All serious adverse events must be fully recorded and immediately notified to **ALL** competent authorities of the Member States in which the clinical investigation is being performed.



## Directive 2007/47/EC amending MDD and AIMD - Transparency

### Article 14 – Registration of persons responsible for placing devices on the market:

For all medical devices of classes IIa, IIb and III, Member States may request to be informed of all data allowing for identification of such devices together with the label and the instructions for use when such devices are put into service within their territory.

**NEW:** class **IIa** devices are covered under this rule.



## Directive 2007/47/EC amending MDD and AIMD - Transparency

Article 14 – Registration of persons responsible for placing  
devices on the market:

Section 2:

NEW: manufacturer designates a **single** authorized representative



## Directive 2007/47/EC amending MDD and AIMD - Transparency

### Article 14a – European Databank

Data to be stored in a European database accessible to the competent authorities now also has to include:

- **Data relating to the registration of authorized representatives**
- **Data relating to clinical investigations referred to in Article 15**

in addition to

- registration of manufacturers,
- data relating to certificates (issued, modified, supplemented, suspended, withdrawn or refused),
- data obtained in accordance with vigilance procedure.



## Directive 2007/47/EC amending MDD and AIMD - Transparency

### Article 14a – European Databank

#### Added

Provisions of article 14a shall be implemented no later than  
5<sup>th</sup> September 2012



## Directive 2007/47/EC amending MDD and AIMD - Transparency

### Article 20 – Confidentiality

added: Section 2

The following information shall not be treated as confidential:

- Information on the registration of person responsible for placing device on the market in accordance with article 14
- Information to users sent out by the manufacturer, authorized representative or distributor in relation to a measure according to article 10(3) (NOTE: Article 10 – Information on incidents)
- Information contained in certificates, issued, modified, supplemented, suspended or withdrawn.



## Directive 2007/47/EC amending MDD and AIMD - Transparency

### Article 20 – Confidentiality

added: Section 3

The Commission may, in accordance with the procedure referred to in article 7(2), determine the conditions under which other information may be made publicly available, and in particular **for class IIb and class III devices an obligation for manufacturers to prepare and make available a summary of the information and data related to the device.**



## Directive 2007/47/EC amending MDD and AIMD - Transparency

### New article: Article 20a – Cooperation

- Member States shall take appropriate measures to ensure that the competent authorities of the Member States cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.
- The Commission shall provide for the organization of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.
- Without prejudice to the provisions of this Directive, **cooperation may be part of initiatives developed at an international level.**



## Directive 2007/47/EC amending MDD and AIMD - Software

**Stand-alone software can be an active  
medical device  
and  
has to be validated**



## Directive 2007/47/EC amending MDD and AIMD - Software

Whereas:

- (6) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. **Software for general purposes when used in a healthcare setting is not a medical device.**
  
- (20) Taking account of the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement.



## Directive 2007/47/EC amending MDD and AIMD - Software

### Article 1 - Definitions, scope

"medical device" means any instrument, apparatus, appliance, **software**, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:....



## Directive 2007/47/EC amending MDD and AIMD - Software

### Annex IX – Classification

Added:

**Stand alone software is considered to be an active medical device.**



## Directive 2007/47/EC amending MDD and AIMD - Software

### Annex 1 – Essential Requirements

Added in section 12. Requirements for medical devices connected to or equipped with an energy source:

**12.1a** For devices which incorporate software or which are **medical software in themselves**, the software **must be validated** according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.



## Directive 2007/47/EC amending MDD and AIMD - Use error: Ergonomic features

Whereas:

(18) As design for patient safety initiatives play an increasing role in public health policy, it is necessary to expressly set out the **need to consider ergonomic design** in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, should be further emphasized within the essential requirements. The manufacturer should place particular emphasis on the **consequences of misuse** of the product and its adverse effects on the human body.



## Directive 2007/47/EC amending MDD and AIMD - Use error: Ergonomic features

### Annex I – Essential Requirements

Section 1 replaced by the following:

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.



## Directive 2007/47/EC amending MDD and AIMD - Use error: Ergonomic features

This shall include:

- reducing, as far as possible, the **risk of use error due to the ergonomic features** of the device and the environment in which the device is intended to be used (design for patient safety), and
- consideration of the **technical knowledge, experience, education and training** and where applicable the medical and physical conditions **of intended users** (design for lay, professional, disabled or other users).



## **Directive 2007/47/EC amending MDD and AIMD - Use error: Ergonomic features**

### **International Standards – Harmonized European Standards**

- **EN 60601-1-6:2004 (harmonized)**  
**Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability**
- **IEC/FDIS 62366 (not harmonized)**  
**Medical devices - Application of usability engineering to medical devices**



## Directive 2007/47/EC amending MDD and AIMD - Use error: Ergonomic features

### MEDDEV 2.12-1 Rev 5 Guidelines on Medical Device Vigilance

#### 4.1 ABNORMAL USE

Act or omission of an act by the OPERATOR or USER of a MEDICAL DEVICE as a result of conduct which is beyond any means of risk control by the MANUFACTURER.

Reference: EN IEC 60601-1-6

#### 4.20 USE ERROR

Act or omission of an act, that has a different result to that intended by the MANUFACTURER or expected by the OPERATOR of the MEDICAL DEVICE.



## Directive 2007/47/EC amending MDD and AIMD - Use error: Ergonomic features

MEDDEV 2.12-1 Rev 5 Guidelines on Medical Device Vigilance

### 5.1.5.1 REPORTABLE USE ERRORS

USE ERROR related to MEDICAL DEVICES, which did result in death or serious deterioration in state of health or SERIOUS PUBLIC HEALTH THREAT, should be reported by the MANUFACTURER to the National Competent Authority.



## Directive 2007/47/EC amending MDD and AIMD – Classification: Annex IX

- Stand alone software is considered to be an active medical device
- Definition of “central circulatory system”, the following vessels were added: arcus aorta, aorta descendens to the bifurcatio aortae
- New application rule (section II): Duration of use (transient, short term, long term) has to be calculated on the cumulative use of the same or an identical device



## Directive 2007/47/EC amending MDD and AIMD – Classification: Annex IX

- Rule 6:  
Surgical invasive devices for transient use are in class III if they come into contact with the Central Nervous System
- Rule 6 and Rule 7:  
Devices in direct contact with the heart or central circulatory system are in class III, if they are intended specifically to **CONTROL**, diagnose, monitor, or correct a defect of the heart or central circulatory system.



## Directive 2007/47/EC amending MDD and AIMD – Classification: Annex IX

- Rule 13 – Combination devices:
  - reference to “65/65/EEC” replaced by “2001/83/EC”
  - second paragraph replaced by “All devices incorporating, as an integral part, a human blood derivative are in class III”

**NOTE: this appears to be the exact statement which was added by directive 2000/70/EC.**
  
- Rule 15 – Devices for Disinfection:

Devices specifically intended for the disinfection of invasive devices are in class IIb.

**NOTE: classification change from IIa to IIb.**



## Directive 2007/47/EC amending MDD and AIMD – Classification: Annex IX

- Rule 16 – Device for recording of X-ray Images  
Now, also active devices, such as digital image receptors fall under this rule.



## Directive 2007/47/EC amending MDD and AIMD - Annex II

- Annex II - Declaration of Conformity  
...This declaration must cover **one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference** and **must** be kept by the manufacturer.
- Annex II - Quality System  
Quality system shall include type and extend of control applied to Outsourced Processes  
**Note: This is consistent with EN ISO 13485:2003 section 4**
- Annex II.3 (c) – Technical Documentation  
**added: - the pre-clinical evaluation**



## Directive 2007/47/EC amending MDD and AIMD - Annex II

### Sampling and Review of Technical Documentation by Notified Bodies

#### Annex II

- Added in section 3.3.  
The assessment procedure (of the notified body) must include an assessment, on a representative basis, of the documentation of the design of the products (technical file).
  
- Added in section 7 – Application to devices in class IIa and IIb  
Sampling of technical documentation during audits:
  - for class IIa, at least one representative sample for each **device subcategory**
  - for class IIb, at least one representative sample for each **generic device group**



## Directive 2007/47/EC amending MDD and AIMD - Annex II

### Sampling and Review of Technical Documentation by Notified Bodies Annex II – 7.4

Notified Body has to document its rationale for the samples taken.  
Decision shall take into account:

- novelty of the technology
- similarities in design, technology, manufacturing and sterilization
- intended use
- results of previous relevant assessments



## Directive 2007/47/EC amending MDD and AIMD - Annex II

### Sampling and Review of Technical Documentation by Notified Bodies

#### Article 1 – Definitions

- **(l) "device subcategory"** means a set of devices having common areas of intended use or common technology;
- **(m) "generic device group"** means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;



## Directive 2007/47/EC amending MDD and AIMD - Annex II

### Annex II.4

#### For combination products

- Medical devices incorporating **medicinal substances**:
  - Notified body has to consult one of the competent authorities OR EMEA (European Medicines Agency)
  
- Medical devices incorporating **human blood derivatives**:
  - Notified body has to consult EMEA (European Medicines Agency)



## Directive 2007/47/EC amending MDD and AIMD - Annex VII

### Annex VII

For sterile class I devices and class I devices with a measuring function, Annex II was added as a conformity assessment procedure.

Manufacturer can select Annex II, IV, V, or VI.



## Directive 2007/47/EC amending MDD and AIMD - Annex I

- User errors (section 1)
- Clinical evaluation for all risk classes (section 6)
- Results of biophysical or modeling research (section 7.1)
- Medicinal substances and human blood derivatives (section 7.4)
- Dangerous substances, e.g. phthalates (7.5)
- Stand alone software (section 12.1)
- Labeling and instructions for use (section 13)  
e.g. single use devices, IfU has to include information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used.



## Directive 2007/47/EC amending MDD and AIMD

### New:

- Biocidal Products Directive (98/8/EC) – Article 1  
Directive 98/8/EC excludes In-Vitro Diagnostic Medical Devices  
(per 98/79/EC)



**Thank you for your attention**

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