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Changes to the Medical Devices Directive and affect on Manufacturers

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2. Medical Devices Directive & its evolution

The original Directives for medical devices:

- **Active Implantable Medical Device Directive (90/385/EEC)**
  - Date of Publication: 1990-06-20
  - Mandatory: 1994-12-31

- **Medical Device Directive (93/42/EEC)**
  - Date of Publication: 1993-06-14
  - Mandatory: 1998-06-14

- **In-vitro Diagnostic Medical Device Directive (98/79/EC)**
  - Date of Publication: 1998-10-27
  - Mandatory: 2003-10-27
2. Medical Devices Directive & its evolution

Changes to the MDD over last 14 years:

- **98/79/EC** *(in-vitro diagnostic)*
- **2000/70/EC** and **2001/104/EC** *(incorporating stable derivatives of human blood/plasma)*
- **2003/12/EC** *(breast implant reclassification)*
- **2003/32/EC** *(animal origin)*
- Regulation (EC) No **1882/2003** *(amended articles 6 & 7)*
- **2005/50/EC** *(large joint reclassification)*
- **2007/47/EC** *(Amending directive for AIMD, MDD, Biocides Directives)*
2. Medical Devices Directive & its evolution

Amending Directive 2007/47/EC:

- Amends three directives:
  90/385/EEC (AIMD), 93/42/EEC (MDD), 98/8/EC (Biocidals)
- Important dates:
  - 21 September 2007 date of publication in OJEU
  - 11 October 2007 came into force
  - 21 December 2008 deadline for transition into national laws by EU member state
  - 21 March 2010 becomes mandatory
Why changed?

- Directives are reviewed a number of years after implementation to see if they were effective.
- Goal of EU Directives: Market access / High level of safety
- Clarify existing requirements
- Clarify responsibilities
- Improve implementation
- Stronger emphasis on managing risk including clinical evaluation and post market follow-up
- More transparency
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3. Details of key changes for Manufacturers

Details of key changes for Manufacturers (1/2):

• No dramatic changes ???
  – Depends on the products you make
• On the whole, can be viewed as clarification and beefing up the requirements to more clearly spell out what should have been done already.
• Much stronger emphasis on clinical evaluation (which is part of the whole risk management process)

• Not all changes are discussed in this presentation
3. Details of key changes for Manufacturers

Details of key changes for Manufacturers (2/2):

a) Clarifications
b) Personal Protective Equipment / Machinery Directives
c) Classification
d) Essential Requirements & Labelling
e) Technical Documentation & Notified Body assessment
f) Declaration of Conformity
g) European Representative
h) Clinical Data & Post Market Clinical Follow-up
i) Other (record retention, EC certificate validity)
3. Details of key changes for Manufacturers

a) Intention of legislator 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
• Article 12,3: Conformity assessment for **sterilizing** companies is now directly limited to Annexes II and V
• 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
3. Details of key changes for Manufacturers

b) PPE / Machinery Directives:

- Mutual exclusion between MDD & **Personal Protective Equipment Directive** (PPE) is removed; if both directives apply, one CE marking only (if more than one Notified Body (NB), both NB numbers beside the CE marking) (Article 1, 6)

- Medical devices that 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)
c) Classification (1/4):

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” corrected:
  – All parts of the aorta are now belonging to the central circulatory system (including arcus aorta, aorta descendens to the bifurcatio aortae) (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)
c) **Classification (2/4):**

- **Rule 5 (invasive, body orifice)**
  - A gap has been closed: Invasive devices with respect to body orifices intended for connection to a class I active medical device (*which have not been classified at all before*) are now included in classification (III, 2.5). *They can be class I, IIa or IIb depending on duration of use.*
3. Details of key changes for Manufacturers

c) Classification (3/4):

- Rule 6 (surgically invasive, transient use)
  - “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 case 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).
c) Classification (4/4):

- **Rule 7** (surgically invasive, short-term)
  - “To control” has been added to “diagnose, monitor or correct” (III, 2.3, 1st indent).

- **Rule 15** (disinfecting devices)
  - “… 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** (recording X-ray images)
  - 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).
3. Details of key changes for Manufacturers

d) Essential Requirements (1/4):

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).
3. Details of key changes for Manufacturers

d) Essential Requirements (2/4):

II. Requirements Regarding Design and Construction
Chemical, Physical and Biological Properties

• ..... 

• Consideration of risks from leaking substances is emphasized, especially from carcinogenic mutagenic reprotoxic substances (CMR). Devices containing phthalates must be labelled 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 pre-cautionary measures must be described (7.5).
3. Details of key changes for Manufacturers

d) Essential Requirements (3/4):

II. Continued

• **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).
3. Details of key changes for Manufacturers

d) Essential Requirements (4/4):

II. Continued

Information supplied by the manufacturer:

- Not only medicinal substances (as up to now), but also human blood derivates 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)
3. Details of key changes for Manufacturers

e) Technical Documentation (1/3):

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).
3. Details of key changes for Manufacturers

e) Technical Documentation (2/3):

For Annexes II, V, VI, Quality Systems:

• Technical file audit 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)
3. Details of key changes for Manufacturers

e) Technical Documentation (3/3):
Consequences of changes:

• Notified Bodies (NB) ask for detailed list of technical files
• More detailed description of device families including GMDN codes (~9000 GMDN codes in ~1000 “collective codes”)
• NB to audit at least one representative sample of technical documentation for each device sub category (class IIa) and for each generic device group (class IIb)
• Expect more files to be audited (depth of review unlikely to change) but costs likely to increase
f) Declaration of Conformity:

For Annexes II, V, VI, Quality Systems:

- Declaration of Conformity must clearly identify the product(s) it relates to (2, each Annex)

Consequences of changes:

- Existing declaration of conformities will **not** become invalid on March 20, 2010 as first thought
- Between now and 21 March 2010, the Declaration of Conformity can have a statement that the requirements of 2007/47/EC are fulfilled in addition if compliance can be demonstrated.
- From 21 March 2010 only 93/42/EEC is necessary
g) European Authorised Representative:

- Manufacturers shall designate a single authorized representative (per device). (If manufacturer is based outside the EEA or Turkey)
- 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)
h) Clinical Data & Post-Market Clinical Follow-up:

Clinical Investigation

- Member states will inform each other of clinical investigations refused, modified, or interrupted.
- Sponsor to inform Competent Authorities about the end of this investigation and justify early terminations.
- Registration of data in the European Database on Medical Devices (EUDAMED) is now necessary for devices for clinical investigations.
h) Clinical Data & Post-Market Clinical Follow-up:

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 (PMS) (1.1c).

• If no post-market clinical follow-up (as part of PMS) – documented justification needed
3. Details of key changes for Manufacturers

h) Clinical Data & Post-Market Clinical Follow-up:

Annex X: Clinical Evaluation

Consequences of changes:

• More detailed records of clinical evaluation
• Expect more emphasis on PMS and it to have been regularly updated
• Post market clinical follow-up records or documented justification
• These will be looked at during surveillance audits
3. Details of key changes for Manufacturers

i) Other:

Record Retention: Annexes II-VII

- Retention period for documents for implantable devices extended to 15 years (from five years) (6.1, 7.3, 7, 5.1, 5.1, 2)

New EC certificates from a Notified Body:

- Existing EC certificates will remain valid after March 20\textsuperscript{th} 2010 – new certificates referencing 2007/47/EC are not needed
- Scopes may need to be more detailed
- Class 1 devices (sterile/meas.) can be on Annex II certificate
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4. Challenges for Manufacturers

Challenges for Manufacturers:

Timescales:
• Full compliance with new requirements by 21\textsuperscript{st} March 2010
• Your Notified Body will be busy at this time

Interpretation:
• The Commission have not clarified some aspects; risk of different interpretations

Reclassification & new conformity assessment:
• Some devices now class 3 and require a design dossier review

Clinical Data & risk management:
• More substantial data required
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5. What to do now

Next steps – the process:

1) Start working on implementation of the new Directive, **NOW**.
2) Understand the issue & impact on your company.
3) Convince Top Management that this is a big change requiring resources – form a team to manage it.
4) Prepare timetable for assessment of technical documentation for each product or product group with dates, responsibilities and milestone reviews.
5) Implement the project plan.
6) Accompany implementation of the new requirements with internal quality management tools such as quality planning, internal audits and management reviews.
7) Stay in close contact with your Notified Body.
5. What to do now

Next steps – the details (1/3):

1) Check your devices for any re-classifications and changes to the conformity assessment routes, e.g. class I to IIa *(redefinition of continuous use)*, IIa to IIb *(rule 15, e.g. endoscope washer/disinfectors)* or IIb to III *(redefined Central Circulatory System, e.g. Catheter used in aorta descendens)*

2) Speak to your notified body about these and agree a timetable. Where an intensive assessment by a Notified Body is mandatory *(e.g. Annex III, Annex II.4)*, make sure these new assessments are planned well in advance so that you have the necessary EC certificates by 21/03/2010
Next steps – the details (2/3):

3) Identify devices that overlap with the Machinery or PPE Directives & assess the additional essential requirements

4) Review all technical files:
   - Clear product description, identification, GMDN/UMDNS codes, intended use, classification (incl. rules)
   - Revised essential requirements (incl. PPE/Machinery)
   - Revised labelling/IFU (& stocks of old ones)
   - Clinical data (consider MEDDEVs 2.7.1 & 2.12-2 but note their issue dates)
5. What to do now

Next steps – the details (3/3):

5) EU Representative – review options if more than one for any individual device.

6) Review & update quality system documentation:
   – Procedures defining content of Technical Files
   – Record retention times (implants >15 years)
   – Procedures for Post Market Surveillance to include Post Market Clinical Follow-up.

7) Define requirements for clinical evaluation to ensure consistent and sufficient detail in Technical Files.

8) Check compliance through internal audits
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### Summary:

- **Medical Devices Directive** – 8th, but most significant, amendment to the Directive
- Safety of Medical Devices based on effectively managing risk which includes evidence in the form of clinical data
- Mostly beefing up and clarifying......but big changes for some devices and companies
- Deadline is looming – **must plan for compliance now & work with your notified body**
- Non-compliance on 21st March 2010 means devices can no longer be marketed
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Further Information:

European Commission Website for medical devices:
• http://ec.europa.eu/enterprise/medical_devices/index_en.htm

Notified Body Oversight Group:
• http://www.nbog.eu/2.html

TÜV Product Service Ltd / TÜV SÜD Product Services GmbH:
• http://www.tuvps.co.uk/home_en/industries/medical_health
• http://www.tuev-sued.de/industry_and_consumer_products/_branches/medical_industry
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