Experience with Directive 93/42/EEC (MDD)

A medical device manufacturer’s retrospective view on 19 years of experience with Directive 93/42/EEC

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Experience with Directive 93/42/EEC

Preliminary Remarks

Scope of this presentation is based on the Dräger product portfolio:

- **Anaesthesiology** (anaesthesia workstations, vaporizers)
- **Respiratory care** (long term lung ventilators (adult & neonatal), emergency/transport ventilators, lung monitoring)
- **Neonatal care** (neonatal incubators incl. transport incubators, warming beds, photo therapy)
- **Infrastructure Projects** (supply units, surgical lights, gas management systems for medical gases and vacuum)
- **Monitoring, Systems & IT** (Patient Monitors, IT systems, patient data management systems (PDMS) with medical intended purpose)
- **Live Cycle Solutions**: Accessories, consumables (breathing gas hoses, sensors), ward equipment (suction devices, pressure regulators, flow meters)

Only a very small portion of the entire medical device sector!

- Directive 90/385/EEC – Active Implantable Medical Devices (AIMD)
- Directive 93/42/EEC – Medical Devices (MD)
Situation in the EU for medical devices before 1995
Experience with Directive 93/42/EEC
Situation in the EU before 1995

- EU between 1986 and 1995: 12 Member States
- Market for medical devices is a highly regulated market (already before 1995)
- National approval/registration requirements for medical devices
- in some of the EU Member States only, e.g. in
  - Germany
  - France
  - UK
- Examples follow different approaches
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Germany – Approval requirements

Germany

Medizinäteverordnung – MedGV
(Regulation on Medical Devices, as of 1986-01-01)

- 4 Groups of medical devices (including active implantable medical devices)
- Authority approval by Competent Authorities of The “Laender”
- Approval requirements (based on a type examination) for Group 1 (specific devices listed in an amendment) and Group 2 (“active implants”)
- Technical type examination: Compliance with national safety standards (e.g. DIN 13254, IEC 60601-1, EMC requirements)
- Exemption: clinical trial (provided that technical safety could be demonstrated)
- Reporting of incidents to the competent authority by users (organisation)
- Focus nearly exclusively on safety of medical devices, additional surveillance of manufacture (with regard to the approved design)
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France – Approval requirements

France

Homologation of medical devices

- Authority approval by Ministry of Health and Family, based on ...
- Technical type examination by French test house (e.g. GLEM)
- Clinical test in a hospital over a period of 6 weeks (positive vote required)
- Focus primarily on safety of medical devices + results of a clinical test; clinical test was rather a performance and usability test.
United Kingdom

“Manufacturers’ Registration Scheme” (MRS)

A recommendation system for buying medical devices, not an approval system

- Voluntary certification of the quality management systems of manufacturers, covering design and production.

- Additionally, medical device evaluation program (independent advice about safety and performance of medical devices as a support for a buying decision)

- Focus primarily on quality management and partly on safety and performance
Changes introduced by Directive 93/42/EEC
of 14 June 1993
concerning medical devices
„Medical Device Directive – MDD“

Published in the „Official Journal of the European Communities 12 July 1993“

- Regulates the placing on the market of medical devices in the EU + EFTA
- Applicable as of 1995-01-01
- Transition period until 1998-06-13 (mandatory as of 1998-06-14)
- Major revision by Directive 2007/47/EC (mandatory as of 2010-03-22)
  - Increased surveillance of Technical Documentation by Notified Bodies
  - Clinical evaluation / clinical data
  - Usability; hazardous substances (e.g. leachables)
  - Software; …
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Directive 93/42/EEC (MDD)

- **New Approach Directive**
  - Harmonisation only with regard to Essential Requirements
  - Products must comply with the Essential Requirements
  - Harmonised Standards (compliance voluntary) → presumption of conformity
  - Conformity Assessment Procedures (usually several choices)

- **Deregulation:**
  - Competent Authorities act mainly retrospectively, not proactively (responsible for registration, market surveillance),
  - Notified Bodies resume tasks of Competent authorities (assessment of devices, certification of quality management systems incl. surveillance of manufacturers)
  - Manufacturer resumes high responsibility (Technical Documentation, conformity assessment, Declaration of Conformity, application of the CE mark)
Directive 93/42/EEC can be regarded as an enhanced synopsis of the various national approaches in the examples mentioned:

- **Safety** requirements on medical devices (Essential Requirements)
- **Classification system** (via classification rules and risk assessment)
- **Clinical evaluation** (data from scientific literature or results from clinical investigations), required for all medical devices
- Certified **quality management system** (mandatory for devices > Class I)
- **Surveillance** of manufacturers (by Notified Bodies and Competent Authorities)
- **Registration** requirements (Eudamed - European Database): manufacturers to register on national level
- **Reporting of incidents** and recalls to competent authorities by manufacturers
Characterized by uncertainty – What will change for manufacturers?

- “Self Certification”
- Conformity Assessment Procedure
- Essential Requirements
- Harmonised Standards
- Competent Authority
- Notified Bodies
- QM-System, EC Certificate
- CE Marking
- Risk Analysis
- Risk Classification of devices
- Post Market Surveillance / Vigilance system
- EU Common Market
- Clinical Evaluation, Clinical Trials, Clinical Data
- New Approach
- Deregulation
- Deadline 1998-06-13
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Situation at Dräger in 1993/1994

- Rather good level of information due to ...
- Active support and collaboration in international standardisation work,
- Active collaboration in industry associations
- Participation and collaboration in international regulatory panels

Though:
- Difference between theory and practice
- Many things had to be developed and elaborated or required some interpretation:
  - Combinations of medical devices,
  - Biocompatibility
  - Private Label products,
  - Missing harmonised standards in the beginning,
  - Nearly no additional guidance documents
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Quality Management System and Certification

Situation before 1995

- Many medical device manufacturers were certified acc. ISO 9001, in some cases also acc. EN 46001.
- Manufacturers selling in USA had a medical device reporting system in place.
- Necessary changes in the QM system (simplified):
  - new procedures regarding conformity assessment and CE marking
  - additional address for medical device reports.
- However:
  - An audit acc. Annex II.3 is more comprehensive than an ISO 9001/EN 46001/ISO 13485 audit (not only focusing on quality management)
  - EC certificate on QM system is now mandatory, and no longer voluntary!
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Safety of medical devices

**Product safety**

**Situation before 1995**
- Existing ISO and/or IEC standards, some national standards, narrow focus.

**Situation after 1995 / MDD**
- Essential Requirements have a far more comprehensive scope than pre-existing standards, e.g. taking into account the following elements
  - achievement of specification,
  - transport and aging
  - infection and contamination
  - biological characteristics (biocompatibility),
  - accompanying documents,
  - usability incl. the skills of the user
  - risk management
  - clinical data
  - risk/benefit comparison, etc.
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Safety of medical devices

- Development of a high number of harmonised European standards was in progress for demonstrating compliance with the Essential Requirements:
  - standards contain more comprehensive requirements than before, taking into account current state of the art;
  - risk management (including information from post market surveillance)
  - risk mitigation: eliminate or reduce risks, protective measures, information on residual risks
  - risk/benefit evaluation
- Both elements together brought safety of medical devices a big step forward, especially because risk analysis and risk management have become a central element in the entire lifecycle of medical devices
- Risk management file is a living document!
Combinations of medical devices

MDD Art. 12 for systems and procedure packs:

Prerequisites:
- all devices are CE marked, and
- are used within their specified intended uses

Person who configures such a system must issue a declaration that the following activities were performed:

- verification of mutual compatibility of the devices
- packaging and supply of additional information (if required) incl. original IfUs
- whole activity was subject to appropriate control and inspection

If one or more of these requirements are not fulfilled (e.g. packaging and placing on the market as a configured system):

→ Conformity assessment procedure acc. MDD Art. 11
MDD Art. 11:
Regarding the entire combination as a medical device:
→ Conformity Assessment procedure for the entire system
→ CE marking of the entire system

→ may be problematic when individual devices are placed on the market separately

What to do if system is placed on the market only partially (e.g. user already owns some devices contained in the system).
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Combinations of medical devices

Solution

MDD Annex I, Clause 9.1:

If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

Inform the user via …
- instructions for use, or
- declaration of compatibility
Opinions:
All medical devices bearing a CE mark may be put together to a system, i.e.

“CE” + “CE” = “safe”

(Only combinations of CE marked devices allowed after 1998-06-13)
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Combinations of medical devices

Safe system?
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Combinations of medical devices

A system where all devices are individually CE marked and comply with harmonised standards is not necessarily a safe system.

Therefore, additional evaluations and/or tests must be performed before a combination of two or more medical devices to a system is safe.

Example: Anaesthesia workstation + patient monitor:
- Safety of mechanical mounting of the monitor (surfaces, corners and edges);
- Functional characteristics (e.g. transfer of data)
- Electrical safety: leakage currents of the system
- Electromagnetic compatibility
- Instability (overbalance) of the system (system on inclined plane, 10°)
- “Threshold test” (horizontal obstruction with a height of 20mm)
- "Crash test" (maximum forces on castors and trolley)
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Combinations of medical devices

Result of a „threshold“ test (door sill)
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Combinations of medical devices
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Clinical Evaluation

- Clinical evaluation / clinical data - a weak point in the Technical Documentation.
- Commission and Competent Authorities have responded on this deficiency:
  - Stronger requirements in Directive 2007/47/EC on clinical evaluation
    - enforced claim that clinical evaluation is necessary for all medical devices
    - drastically limits references to similar devices in literature
    - will make more clinical investigations necessary
    - requires post-market clinical follow-up
    - will focus the Notified Bodies on clinical data (during surveillance audits)
- Regulations on and control of clinical investigations were increased in nearly all Member States + new MEDDEV Guidance on clinical trials.
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Medical Device Vigilance

... This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: (i) any malfunction or deterioration ...

- Post-market surveillance, vigilance system, reporting of incidents, and recalls are not always popular with manufacturers.

But:

- Post-market surveillance (and related corrective action) helps to eliminate risks not detected during design and development incl. verification and validation, to improve current devices and to avoid similar risks in future devices.

- A good manufacturer acts before he is forced to do so by a Competent Authority!
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EU Market Access

Situation before 1995:
- National approvals/registrations (where required)

Situation in 1995 (MDD):
- CE marking of medical devices allowed for direct market access in EU Member States and EFTA countries
  - EU: 15 Member States
  - EFTA: Switzerland, Liechtenstein, Norway, Iceland
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EU Market Access

**Situation 2012:**

- Number of Member States increased from 15 to 27 Member States
  - + EFTA countries (Norway, Switzerland, Liechtenstein, Iceland)
  - + Pre-accession countries (Turkey, countries from former Yugoslavia, Iceland).
  - → 39 countries

**Consequences:**

- Increased language requirements on labelling
  - → use of symbols where possible
Alignment of Member States, pre-accession and candidate countries becomes more critical

- 27 Member States + 3 EFTA and 9 pre-accession or candidate countries develop just as many individual opinions and interpretations, e.g.:
  - Accreditation and surveillance of 76 Notified Bodies (which also show individual behaviour …)
  - Registration of medical devices (due to the inadequate performance of Eudamed)
  - Classification of some “Borderline” products, e.g.
    - pipeline systems for medical gases (central gas supply systems)
    - supply units
  - Market surveillance, field corrective actions …
Conformity Assessment

Is the current system safe and reliable?

- Manufacturers are classifying their medical devices by themselves.

- Manufacturers with a full QM system are allowed to demonstrate compliance with the Essential Requirements by themselves (e.g. via Harmonised Standards); (up to risk class IIb, design dossier examination by Notified Body required for Class III devices).

- Increased risk of fraud (classification into lower class, incorrect data in the Technical Documentation)?

But:

- Manufacturers of devices in Class IIa or higher are under periodic surveillance by their Notified Body (at least annually).

- Amendments from Directive 2007/47/EC request a defined sample for detailed investigation of the Technical Documentation during the surveillance audits.
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Adequacy of legislative framework

Is the current system safe and reliable?

- PIP scandal, breaking hip implants and some other negative examples have recently led to concerns
- Political request for “immediate” corrective measures:
  - stricter approval requirements
  - authority approval of high risk devices
  - PIP: criminal energy, fraud
  - Deficiencies in market surveillance by Competent Authorities
  - Hip implants: complex situation; improvements feasible
- Faster market access in Europe than in the US and many other countries
- Without loss of product safety
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Summary and perspectives

- Adequate legislative framework (increasing involvement of NBs with increasing risks)
- Safe medical devices due to
  - generic but comprehensive Essential Requirements
  - Risk Management
  - Vigilance
- Allowing for direct market access in 27 Member States, 4 EFTA countries and 8 pre-accession and candidate countries + further countries using the CE mark as a basis for registration
- Allowing for faster market access without loss of safety (confirmed by BCG study and PWC scorecard)
- Facilitating innovation and making new devices available to the patients as early as possible
- Manufacturers have assumed and are aware of their responsibility
Deficiencies, room for improvement

- Several EU enlargements raised no. of Member States from 15 to now 27 (plus 12 EFTA countries and pre-accession or candidate countries)
- Considerable fragmentation regarding …
  - Behaviour of Member States and their Competent Authorities (e.g. individual registration requirements → unproportionate burden for manufacturers)
  - Fragmentation regarding Notified Bodies (accreditation, surveillance), missing centralised oversight on all NBs
- Resulting in diverging interpretations and requirements for manufacturers, importers or distributors.
- Market surveillance activities by Competent Authorities are sometimes inadequate and not aligned.
- Control of the entire legislative framework.
Expectations from the new Regulation on MDs and AIMDs

- Eliminate the weaknesses without damaging the benefits, i.e. …
- Better alignment of Member States and Notified Bodies, but …
- Keep costs and regulatory burden at lowest possible level.
- Maintain competitiveness and facilitation of innovation.
- Maintain the advantage of the faster market access of the European system.
Thank you for your Attention!
Questions?