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E-labeling

An innovative solution

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The Directives

AIMD 90/385/EEC

Annex 1, Section 15

"… each device must be ***accompanied*** by instructions for use…."

MDD 93/42/EC

Annex 1 Section 13.1:

"…each device must be ***accompanied*** by the information needed to use it safely…"

"…the information must be set out in the ***leaflet*** supplied with one or more devices"

IVDD 98/79/EC

By its omission of explicitly stating otherwise, it allows for supply of the IFU by other means

Electronic labeling allowed

Meaning of Electronic “Labeling”

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- **Instructions for Use, Manuals, etc., provided by manufacturer to user in electronic format**
- **Information must satisfy all provisions of various regulations**
- **General term “electronic” labeling is preferred to specific terms such as:**
  - **CD ROM, Website downloadable, within device**

Why E-Labeling and why now?

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- Manufacturer cost burden
- Worldwide technology capabilities
- Environmental strain
- New member impact

EU proposed conditions

- Restricted to professional users in healthcare facilities
- Exclude
  - Small Field Offices
  - Patients

EU proposed conditions

- Paper format
  - Upon request
  - No cost to user
  - Immediate
    - Definition
    - Distributors
    - Print on demand
  - Challenges

EU proposed conditions

- Easy to access
  - Simple log-in interface
  - Language interface consideration
- Easy to print
  - Common printer
  - Standardized size for EU
- PDF suggested
  - Free downloadable
  - Standard graphic capability

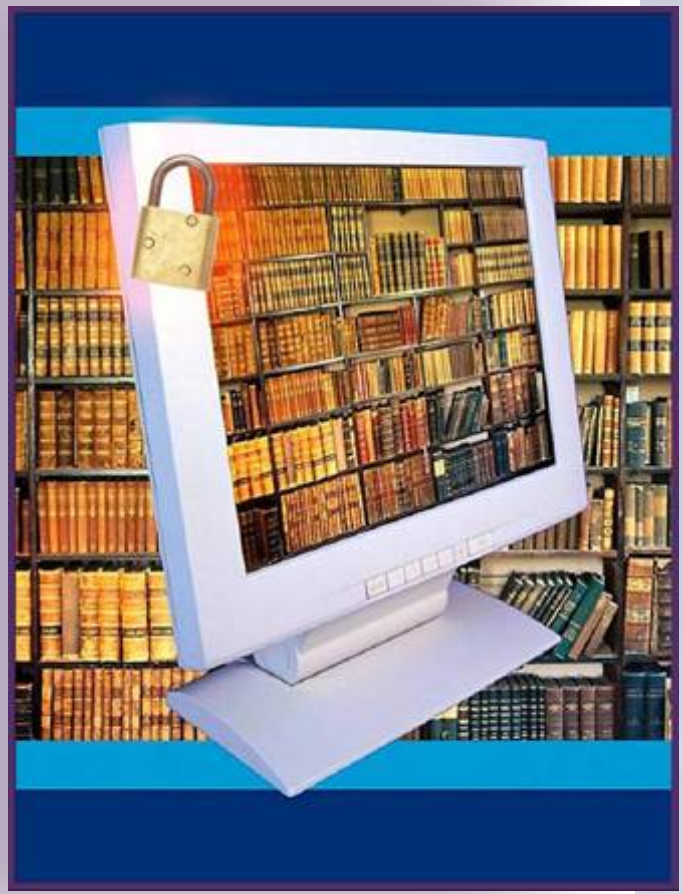
EU proposed conditions

- Fulfill all labeling requirements
- Transport and sterile packaging indicate:
  - Electronic format
  - Identify device, IFU version and required software
  - Provide manufacturer website info where labeling is maintained

EU proposed conditions

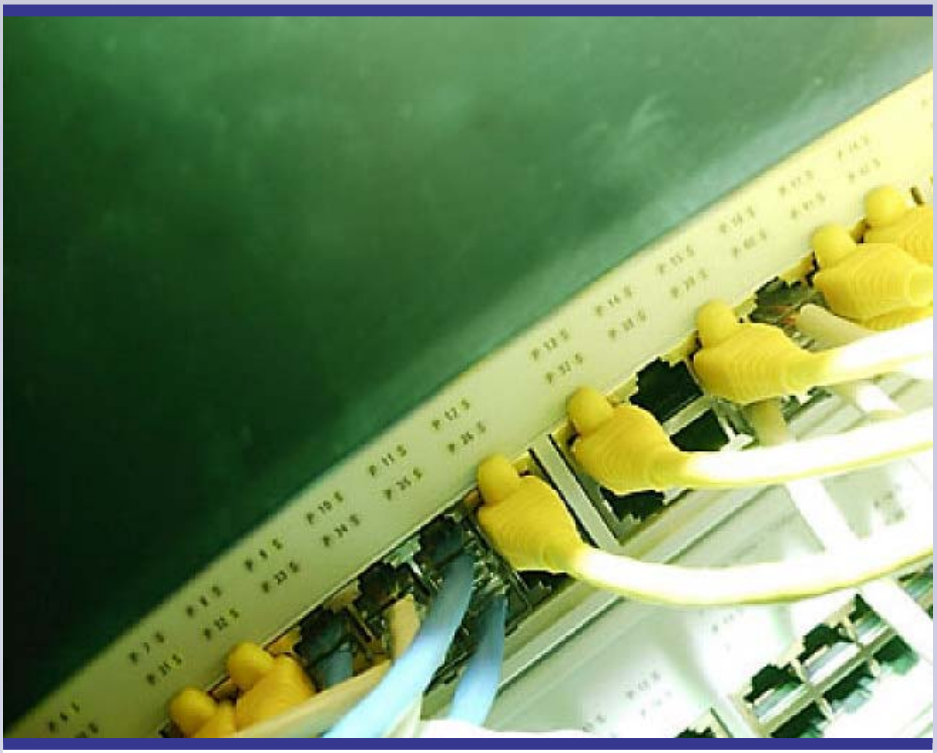
- Updates/Enhancements
  - Must be updated in timely manner
  - Providing via internet: utilize e-mail notification
  - Providing via CD-Rom: subsequent CD-ROMs or e-mail notification

EU proposed conditions



- Internet Security
  - Physical
  - Access
  - Content integrity
  - Validation procedure
- Commission for IVD
  - European Diagnostic Manufacturers Association (EDMA) Guidelines

Data integrity requirements



Physical Security

- Validation
  - Proven
- Web Server
  - Recover plan
  - Intrusion
  - Viruses

Data integrity requirements

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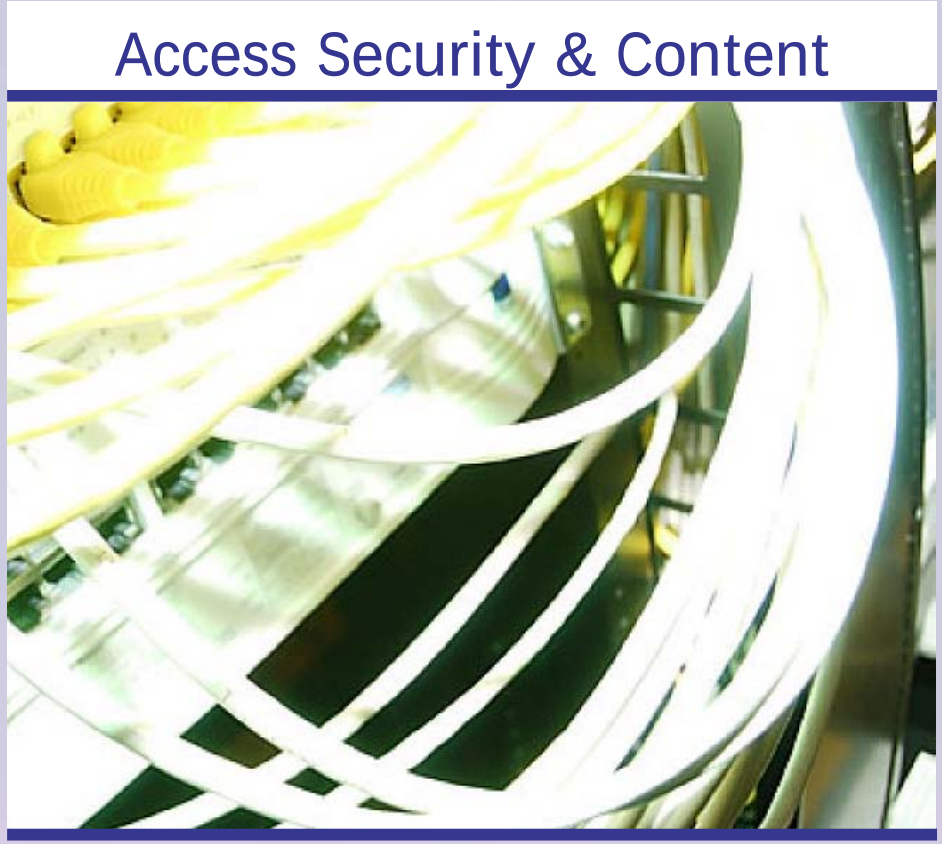
- Access security
  - Secured access
  - Site certification
  - Validated
- Content integrity
  - Read only
  - Unauthorized protection
  - Validated



EU proposed conditions

- Transition to e-labeling
  - Perform risk analysis
  - Product on market
    - No prior approval
    - Present to NB during routine audit
  - New product on market
    - Provide NB with proposed IFU

Where are we with E-Labeling

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Updates

- Current Pilot Studies
- EUCOMED Position
- Global Harmonization Task Force Proposal

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