Quality, Safety and Ethics

Lessons from safety of medical devices

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Recommendation

It is recommended that:

a category of health telematics products be defined to encompass those that may cause significant harm to an individual if they malfunction; and that such products be brought under the control of regulations covering medical devices
“Member States shall grant the right to every person not to be subject to a decision which produces legal effects concerning him or significantly affects him and which is based solely on automated processing of data intended to evaluate certain personal aspects relating to him”
EU Directives

- 1984 Electro-medical
- 1990 Implantable medical devices
- 1993 Medical Devices
- 1998 In Vitro diagnostics
- 2000 Blood derivatives
Accreditation?

✔ Self regulation against international standard?
✔ CE mark or equivalent?
  - self-declaration of conformity
  - product quality inspection
  - production quality inspection
✔ Clinical evidence and logic?
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Recommendation

“the preferable legal framework would be that which concentrates on quality control of Research and Development, design and 'manufacture' rather than product testing”
Possible Steps

- ISO standard on safety classification
- ISO standard on design and quality control
- Self regulation
- Legal requirements akin to medical devices later if necessary