

Defining an approach to qualify software components for telemedicine in an open source community

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Approach

Background

- Production gap ahead
- Numerous implementations of technology-based innovations
- Medical Device Directive (EU) often omitted (USA: Health Insurance and Portability and Accountability Act HIPAA)

Objective

To assure quality of software for rapid deployment of telemedicine from an open source software community

Method

- Inventory of quality management principles
- Experimental framework based on ISO 9000-2000/ 9004-2000
- Specific quality standards selected for software development and publication
- Detailed test planning, user instructions and training, public trust mark

Results

- Self certification of software components with external reference (ISO)
 - Install a notified body function at the software publisher
 - Provide standards, norms, procedures, etc. to the notified body function
 - Certification of the notified body function by a notified body
 - Self-certification of software components by the notified body function when components pass a test
- Specific requirements from:
 - Medical Device Directive (EU) – to connect to derive at risk class of application
 - E-Commerce directive (EU) – to connect to computer systems
 - Digital signature legislation – to connect to unique users
 - ISO/ IEC 17799 code for information security – to protect data
 - ISO 13485:2003 harmonised medical device regulatory requirements – to connect to diagnostic devices
 - ISO IEC 9126 quality in information technology – to link requirements to the software components to the telemedicine application at hand

Conclusions

- Tested in EU project (PICNIC project)
- Quality management is in control of the publication process
- Easy to operationalise; easy to operate
- Low cost
- Applicable to any type of :
 - software
 - type of development team (open, closed) communities
 - software application – also (particular !) in high risk class