Medical Device Software: A new challenge

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Main issues

Q.1 – Is a software application used in healthcare a Medical Device (MD)?

Q.2 – Is a software a component/part of a MD or a stand alone application?

Q.3 – What about patient safety?

Q.4 – Do standards and guidelines help manufacturers/software engineers and authorities to safeguard patient safety?
Main issues

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Q.1 – Definition

MD definition
“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application”
(MDD 2007/47/EC)

MD software definition
“a software system that has been developed for the purpose of being incorporated into the medical device being developed or that is intended for use as a medical device in its own right”
(IEC 62304, 2006)

“software for general purposes when used in a healthcare setting is not a medical device”
(MEDDEV 2.1/6 – January 2012)
Q.1 – Qualification of MD software

Software is a MD if it is intended for the:

- Analysis of patient data generated by MDs with a view to diagnosis and monitoring
- Use for/by patients to diagnose or treat physical or medical ailment

Including

- SW that manipulate and analyse clinical data
- SW that generate images with measurements of region of interest

Excluding

- SW used for healthcare administrative settings
- SW used for epidemiological studies and statistics
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Q.2 – Some examples: stand alone

**Picture Archiving and Communication System (PACS)**

- a MD

**Digital Imaging and Communications in Medicine (DICOM)**

- NOT a MD

**Risk classification:**

1. viewing, archiving and transmitting images ➔ I
2. driving a MD or influencing the use of a source MD ➔ IIa or IIb
3. not the above and allowing direct diagnosis ➔ IIa
4. image enhancing by controlling image acquisition ➔ MD class
Q.2 – Some examples: modules

Electronic Patient Record (EPR) Systems

- Storage, archival, and simple search of data and documents

Specific EPR component

- Module that supports diagnostic or therapeutic decisions

Risk classification:
- Based on Active MD rules

(Enforcement discretion)
Q.2 – Some examples: components & stand alone

SW component of a MD

Risk classification:
Same as MD

Risk classification:
Based on Active MD rules

SW stand alone
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Some statistics:

- 33.4% of total recalls concerns MD using software
- 33.7% of total recalls are due to software failure
- Constant increase of software failure in the period 1999-2005 (Bliznakov Z. et al., 2007)
- 24% of total recalls in 2011 are due to software failure (Roberts P., 2012)

- validation of software become on of the MD essential requirements
- risk management should be applied to software, considering patient safety
- application of policies, procedures and practices to analyze, evaluate, control and monitor risks
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## Q.4 – Standards of the MD SW domain

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<td>Guidance for the content of pre-market submissions for software contained in medical devices, 2005</td>
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<td>Software lifecycle</td>
<td>IEC 12207:2008 System and software engineering</td>
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<td>IEC 62304:2006. Medical device software. Software lifecycle processes</td>
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Q.4 – Risk management within software lifecycle

Risk management represent a complex activity that provides input to model the application

The detection of new hazards triggers again the risk management process

(IEC 62304:2006)
Conclusions

Q.1 – Is a software application used in healthcare a Medical Device (MD)?

- Software qualification and classification require further specific and formal definitions and the implementation of harmonized procedures.

Q.2 – Is a software a component/part of a MD or a stand alone application?

- Software is considered stand alone if it is not incorporated in a MD when placing on the market.
- Intended use as defined by the manufacturer is relevant for the qualification of software as a MD.
Conclusions

Q.3 – What about patient safety?

- Software applications provide new preventive, diagnostic and therapeutic means in the clinical domain
- Software quality and safety are difficult to be fully checked due to software complexity, easiness of updating, difficulty in tracing different copies produced without supervised management

Q.4 – Do standards and guidelines help manufacturers, software engineers and authorities to safeguard patient safety?

- Regulation is progressively adapting old rules in the MD software domain
- Need to increase specialized competences for manufacturers, software engineers and authorities
Thank you for your attention!

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Q.5 – MD software marketing process

1. **Qualification**
   - Is it a medical device?

2. **Classification**
   - Which is its risk class?
   - Which is the risk class of the device in which the software is embedded?

3. **Evaluation**
   - Is it a secure and effective method?
   - Are there risks that have to be mitigated or eliminated?
   - Which is the security level of a software?
   - Is it possible to mitigate or eliminate risks directly modifying the source code?

4. **Pre-marketing procedures**
   - Is the authorization of a Notified body necessary?
   - Is it similar to a device already commercialized?
   - Does it require a clinical investigation?

5. **Post-marketing procedures**
   - Are there any changes in its performance?
   - Has it caused any harm to the patient's health?
   - Are there any further actions on the product required?
Q.4 – MD SW risk management

Safety: freedom from unacceptable risk

- measure of the expectation that an event will occur
- combination of the probability of occurrence of harm and the severity of that harm
- measure of the possible consequences of a hazard