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Software as a medical device; regulatory framework

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Titel van presentatie | datum van presentatie



Definition part one

Medical device means any instrument, apparatus, appliance, **software**, material or other article, whether used alone or in combination, **including the software** intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:



Definition part two

- **diagnosis**, prevention, monitoring, **treatment** or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;



Software

- The definition includes:
 - Embedded software used for diagnostic and/or therapeutic purpose AND necessary for the proper application of the medical devices
 - Stand alone software
 - › Is now defined as an active medical device if it fulfils the definition of a medical device!



New ? NO

- Stand alone software was already a medical device under the old regime, based on the old definition of **any article** which includes software.
- Problems on the borderlines with general purpose software like operating systems and general computer systems used in hospitals for logistic and/or financial purpose.
- Different approach between member states (MS) on borderlines and on classification issues
 - Some MS's s.a. software was class I (rule 12, Annex IX)
 - Most of the MS used a risk based approach (IIa and higher)



During the Review (2007/47 EU)

- Software became an active medical device (by definition)
- With its specific classification rules (rule 9 -12 under Annex IX)
- CE mark
- Notified Body involvement required(class IIA and higher)
- New borderlines discussion
- New questions and answers



Getting to market

Class I self certification

Class IIa and higher: involvement of a Notified body mandatory.

Due to the 2007/47 and the change of classification more stand alone software became a higher class device

In the 2007/47 all higher class devices are subject to a intensified notified body surveillance and an initial check on technical documentation.

These changes were felt as a additional hurdles to market.



Example

Electronic Patient records

A medical device?

Yes or No?

- Is the paper version of a patient record a medical device?

NO!

In that case the software equivalent is not a medical device.

- If the software equivalent is a dynamic system that combines different data source and takes decisions and/or combines data to one data sheet.

YES



What about.....

Interconnectivity

- within the same brand/system

- between different brands

- between different stand alone software systems

- combinations

I Phones

Expert systems

Data loggers

Data retrieval systems

O.S.

- Open source versus closed source codes



Conclusion

- Software and stand alone software have been a medical device since 1993.
- After 21st of March 2010 it is an active medical device with its own classification rules.
- Borderlines questions were already existing borderline issues.
- Software just for archiving is not a medical device (yet).
- Software with dynamic interference, collecting and presenting of data, data sources, expert systems are medical devices.
- Still questions on operating systems and hospital systems which interfere with the medical device software e.g. logistic patient data, insurance codes, name, date of birth.....