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Software as Medical Devices

A 'Provider' view – Sweden

*CEN/TC251 and ISO/TC215 JWG meeting
2010-10-10*

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The Borderline & Classification Group has presented information on:



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"Guidelines for the qualification and classification of software used in healthcare environment within the regulatory framework of medical devices"

The Working Group was headed by
Lennart Philipson, Swedish MPA

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The Guidelines, first draft were mainly based upon former Swedish work and position that defining guiding rules on which software products can be determined to fall within the scope of the Medical Device directives or not.

From the preamble of Directive:

"It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device"

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Guidelines in two versions:

- Version April 12, 2010
Informal distribution within the WG
- Version July 12, 2010
Open for comments in October 2010



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Guidelines Version July 12, 2010:



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Software intended only for processing, storing and archiving patient data file should not be qualified as medical device, providing that there is no manipulation of data. Software can not be considered as a medical device simply because of the risk to affect data during handling (storage, transfer.....) due to a malfunction of the software.

Functions such as display and search functions of the software do not make this software a medical device.

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Guidelines Version July 12, 2010:

Note on Page 7:



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This means that "putting into service" relates to the actual device being made available in the Community market (and not only the results processed by a device).

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Guidelines Version July 12, 2010:

Qualification criteria for IVD:

- 1. IVD analysers with integrated expert software.. **Regarded as MD***
- 2. Standalone software necessary to be used together with an IVD **Regarded as being accessory to IVD devices***
- 3. Standalone software necessary for archiving patient results or transfer of results from the outpatient to the healthcare provider. The results are readable and understandable by the user without the intervention of the software. **Not regarded as MD***



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Guidelines Version July 12, 2010:
Annex 1: Illustrative examples

1. Electronic Patient Records

Qualification and classification:

*Electronic patient records should be qualified as
medical devices/not medical devices.*



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Guidelines Version July 12, 2010:
Annex 1: Illustrative examples

Parts 2 to 15

In every part on

Qualification and classification:

*..... should be qualified as medical devices/not
medical devices.*



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In conclusion:

Guidelines of the qualification and classification on software used in healthcare environment within the regulatory framework of medical devices



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If the document will have any impact, it must be revised or rewritten to be clearer and make the specifications distinct and correct

Otherwise it is of no use!!

Therefore – Please make comments for change today!

Send the information to the Commission or to the CEN/CLC
SAMD Group: MelvinR@AMS-Consulting.co.uk

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