Introduction

With the developments of Software as Medical devices and the interconnectivity of systems, connection of Medical Devices to networks containing Medical Devices becomes a current practice. This connection raises discussions on regulations: do we have to manage the network as a whole? Can we bring parts of the network to the market as stand alone applications? Is there any influence between the parts on their respective classifications?

The platform Software as a Medical device (SAMD) of the NEN discussed the contamination of (European) classification in a network including medical devices (CE) in its meeting of June 1rst 2015. The main question is what happens with the classification of a medical device (a software) when it is added to a network including other medical devices.

The detailed questions are:

- Can the medical device change of directive?
- Can the classification be impacted by the classification of other parts of the network?

Definitions and considerations.

Definitions

- The 'Software' is the software in focus that is connected to a network including medical devices. This is stand-alone software and consists of one module.
- The 'Network 'is an assembly of more Software and hardware components, brought to the market by multiple organisations
- 'Contamination' takes place when the classification of a medical device in the Network influences the classification of the Software or when the classification of the Software influences the classification of other parts of the Network.

Considerations

- Connecting the Software to the Network can change the intended use of the Software. If there is a change of intended use the Software has to be classified with the new intended use. After that the contamination can be studied.
- Medical software that is not a Medical Device can become a Medical Device when the intended use changes, due to changes of intended users for instance. In this case the medical device can be first classified in its own rights and then classified as a part of the Network.

Conclusion

If there is no change of the intended use of the medical device being added to a network there is no change of directive or classification.

General description

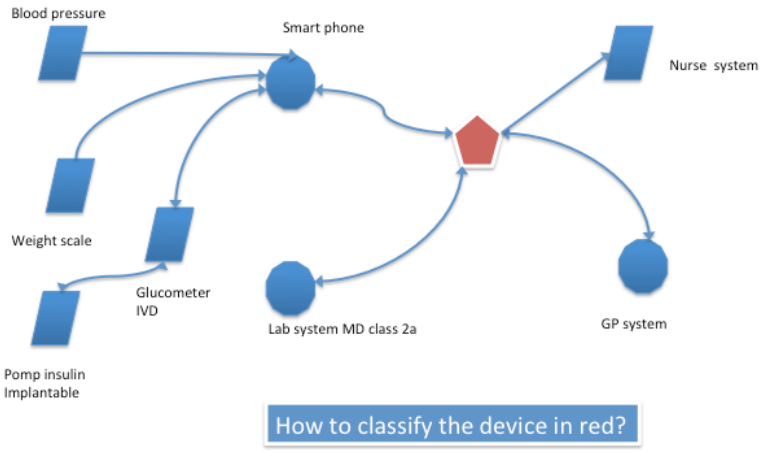
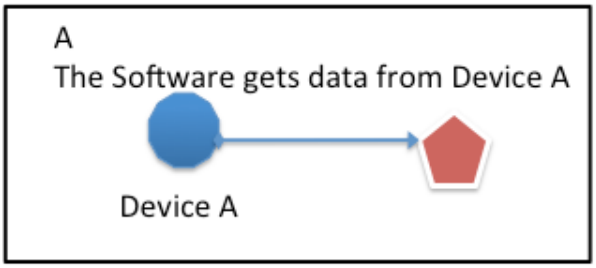


Figure 1: A simple Network of medical devices

The figure 1 gives a representation of a very simple network. For the analysis we take the device in red as the Software.

In this network we have IVD's (Glucometer), Medical devices (Blood pressure) and medical applications (GP System). This network configuration can be represented by two situations: one situation where the Software gets data from another part of the Network (situation A) and a situation where the Software gives information to another part of the Network (situation B).



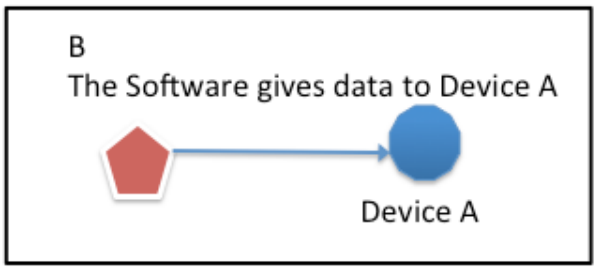
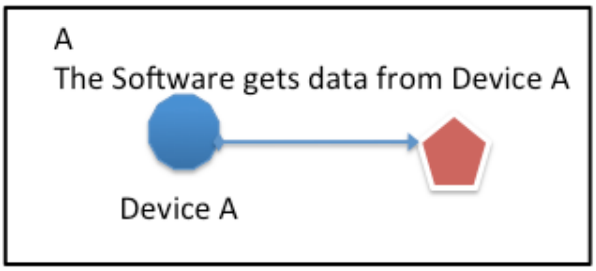


Figure 2: the basic configurations

The main questions can be answered for the two situations.

Situation A: the Software gets data from a Device A



Contamination of Directive:

If the intended use doesn't change there is no contamination of Directive. The software doesn't supply IVD information. It just may use IVD information. If the intended use doesn't change there is no contamination of Directive.

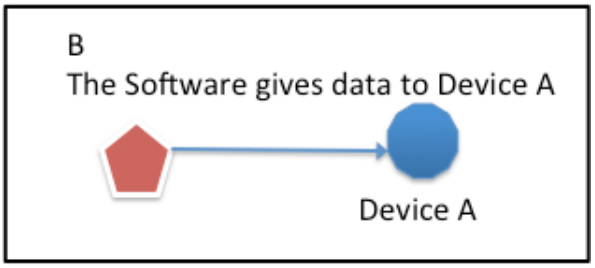
Contamination of classification:

There is no effect of the classification of Device A on the classification of the Software. This under the condition that there is no change of the intended use of the Software.

Situation B: the software gives data to an other device A

Contamination of Directive:

There is no influence of the Directive of Device A on the Software.



Contamination of classification:

If there is no change of the intended use of the Software there is no change of the classification of the Software. If there is a change of Intended use due to the connection the classification has to be done for the new intended use and the classification will probably be the classification of Device A.

Bibliography

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MDD: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

IVDD: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices