Q & A – fra webinaret «Visste du at flere apper må sertifiseres som medisinsk utstyr?»

What does the May 2021 deadline actually mean for software that might now be classified as a medical device?

Kami Faust :

- If the Software is to be classified as a Medical Device as of 26 May 2021 the Regulation will need to followed.
- If the Software is registered under the MDD, you will need to verify whether the classification has changed
- If you have a significant change in the device and will need to notify the authorities you may need comply to the new regulation.

How long will the certification process typically take?

Kami Faust :

- This is a very interesting question and it can be a grey area. It depends on the intended purpose. MDCG 2019-11 can give some clarification.

Per-Anders | Inventas :

- Good question. It all goes back to the Intended Purpose of the product, so this needs to be elaborated.
- And I agree with Kami, the MDCG 2019-11 is the guidance document to use in this process

Also a bit specific, but would any webrtc video software which is devolped for use within healthcare (for remote consultations) have to be certified as MD? In these cases, where it is software intended for doctors and other healthcare professionals, the intended purpose clearly have to be to diagnose, prevent illness and follow up patients.

Kami Faust:

- Also a great question Kristian. Does the software make any diagnosis itself? Or is this a communication platform for the patient and healthcare professional?

If I have understood correctly, software that doesn't give a diagnose etc. itself, but just provide the means of communication here, does not classify as a MD

Kami Faust:

- The first instance then I would say yes, but as a communication platform then no, it is not a MD. However this would need to be evaluated further.

Thank you for the answers! I see. In this case I was talking about a communication device. Would a remote supervision camera which does not provide any alerts or provide any "Diagnostics" or measurements fall under the same definition?

Kami Faust :

- My first thought would be no, but a thorough review would be needed to give confidence

Is a class 1 device required to do a clinical study in MDR?

Kami Faust:

- Class I does not typically require Clinical Studies but a clinical evaluation shall be conducted to meet all GSPRs

Per-Anders | Inventas:

- Independence Gear: it depends on the Clinical Evaluation and in particular on the pre-clinical research done. You may not need a clinical trial, but this really depends on the clinical data that you have that is relevant to your MD and that you can show that you fulfill the relevant GSPRs

An app gathering data (kilometers/duration of cycling, jogging, etc) intended to be visualized and reported to physiotherapists/relatives of end users in the health care, could that classify as MD?

- Kami Faust: I would not classify this as a MD. But again a full review of the intended purpose and application is needed to be confident.

Will an app predicting the date of birth and growth of a fetus be classified as MD?

Kami Faust:

- This would depend on the input data and how the app analyzes the data for output