1. Is your software/app a computer program? (cf. ISO/IEC 2382:2015) — **Yes** → **2.** Is your software/app incorporated in a medical device? — **Yes** → Your software/app is part of the medical device and placed in the same risk class as that device and CE marked together.

1. No

2. No ↓

3. Does your software/app perform an action, e.g. to support a decision or recommend actions, or does it perform a calculation? — No →

3. Yes ↓

4. Is the purpose of your software/app for the benefit of individual patients? — No →

4. Yes ↓

5. Is the purpose of your software/app to make a diagnosis or perform treatment? (cf. s. 1(2) of EO no. 1263) — No → **6.** Is your software/app an accessory to a medical device? — No →

6. Yes ↓

5. Yes →

7. Your software/app is a medical device and must fulfill the requirements of the legislation.

Danish Executive Order no. 1263 on Medical Devices

Danish Executive Order no. 1264 on Active Implantable Medical Devices

Danish Executive Order no. 1269 on In Vitro Diagnostic Medical Devices

→ **8.** Does your software/app have measuring function?

8. No / Yes ↓

9. Does your software/app serve any of the following medical purposes:

- Administer, transmit or exchange energy;
- Control, monitor or impact the performance of a Class IIb active medical device;
- Administer or remove medicines, energy or other substances to or from the body;
- Make diagnosis or monitor vital physiological parameters.

Your software/app is not covered by the medical device legislation and cannot be CE marked as a medical device.

Low risk (Class I)
Your software/app is a Class I medical device. CE marking of the device is your responsibility. Your device must meet the essential requirements in Annex 1 of the Danish Executive Order.

Low risk (Class Im)
Your software/app is a Class I medical device with measuring function. A notified body must check the documentation for the device's measuring function before it can be CE marked.

Medium to high risk (Classes IIa, IIb, III)
Your software/app is in the middle or highest risk class. Your device is to be CE marked upon certification by a notified body.

No / Yes

Software and apps – are they to be CE marked as medical devices?

Elaboration on decision diagram for software/apps

1) In order for software or apps to be defined as computer programs, they must fall within the definition in the following standard: ISO/IEC 2382:2015 – Information technology – Vocabulary. A computer program is defined as a syntactic unit that conforms to the rules of a particular programming language and that is composed of declarations and statements or instructions needed to solve a certain function, task, or problem. If your software/app is not a computer program, it is most likely a digital document.

2) If your software/app is incorporated into a medical device, it is considered to be one whole device, in which case risk classification and CE marking follow the device as a whole. Software/apps that are integrated in a medical device cannot be separated from the device. Examples are software in pacemakers, CT scanners or infusion pumps. Medical devices are classified according to the rules of Annex IX in the Danish Executive Order on Medical Devices.

3) For software/apps to be classed as a medical device, it must perform an active action, e.g. supporting or recommending a decision. Functionality that recommends an action could be aimed at a person or a medical device. A user required to act on an alarm for low blood sugar is an example of such functionality. It could also be software or an app which controls another medical device, e.g. by adjusting the dose and controlling the administration of a medicine in the patient. If your software or app performs calculations, e.g. via algorithms, or analyses patient data, then it is also a medical device. In contrast, software or apps that only perform searches, send and/or store data as well as planning tools are not considered to be medical devices.

4) Software/apps must be for the benefit of an individual patient. General guidance or information that compares to informative material and which is not aimed specifically at individual patients is therefore not considered to be a medical device with a specific medical purpose. This applies equally if your software/app is aimed at a specific patient group.

5) For software/apps to be considered as medical devices, they must satisfy one of the purposes of the Danish executive order's definition. It is the device manufacturer who decides what the purpose of the software/app is and describes the intended use of the device.

6) An accessory to a medical device is any product determined by the manufacturer to be used together with a medical device in order for the relevant software/app to be used as intended by the manufacturer. Accessories are considered to be medical devices in their own right.

7) Medical devices are regulated by the following legislation: <u>Danish</u> Executive Order no. 1263 of 15 December 2008 on Medical Devices, Danish Executive Order no. 1269 of 12 December 2005 on In Vitro Diagnostic Medical Devices and Danish Executive Order no. 1264 of 15 December 2008 on Active Implantable Medical Devices. The executive orders implement Council directives into Danish law (Directive 93/42/EEC concerning medical devices, Directive 98/79/EC on in vitro diagnostic medical devices and Directive 90/385/EEC on active implantable medical devices). Software/apps can be CE marked only if they satisfy the essential requirements relating to safety and performance described in Annex I of the three executive orders.

8) Software and apps with measuring function could be apps that measure temperature, heart rate or blood sugar when the purpose of the measurements fall within the executive order's definition of a medical device.

9) MEDDEV 2.1/6 includes the following examples of software/apps with a medical purpose: devices that can measure blood pressure and other physiological parameters during routine medical check-ups or in hospital settings, active devices, e.g. calculating the dosage of ionizing radiation or insulin dosage planning. Software, which drives a device or influences the use of a medical device, falls automatically in the same risk class as that device. The classification rules generally applied to software and apps are rules 2, 9, 10, 12 and 14 cf. Annex IX of the Danish executive order.