MEDICAL APPS, IS CERTIFICATION REQUIRED?
CHECK WHETHER YOUR APP REQUIRES CE MARKING

Consumers and healthcare providers increasingly use medical apps. Some medical apps are considered as medical devices. CE marking ensures that medical devices comply with the European requirements. This infographic shows whether a medical app needs CE marking. After going through the flow chart you will also know which risk categories the app comes under and what form of certification is required.

Nictiz has drawn up this flow chart on the basis of the general MEDDEV documentation for medical devices. The aim of this chart is to explain the assessment specifically for medical apps. This chart is not intended to serve as a full legal assessment and does not reflect the classification rules in full detail. Please refer to the decision trees in classification guidance document MEDDEV 2.4/1 documentation and Annex IX of the MDD for this purpose. The chart furthermore does not address classification of in vitro diagnostic standalone software, see Annex II (IVD) directive and MEDDEV 2.1/6, p. 13 in this respect.

1. Is the software a computer program? NO
2. Is the software incorporated in a medical device? NO
3. Is the software performing an action on data different from storage, archival, location compression, communication or simple search? NO
4. Is the action for the benefit of individual patients? NO
5. Is the app intended to be used for the purpose of diagnosis or treatment? NO
6. Is the app an accessory of a medical device? NO
7. Is the software regulated as a medical device? NO
8. Does the app contain a measurement function? NO
9. Does the app have one of the following medical purposes*?
   - Intended to administer, supply or exchange energy;
   - intended to control, monitor or influence directly the performance of a class IIb active medical device;
   - administer or remove medicine, energy or other substance to or from the body;
   - intended for direct diagnosis or monitoring of vital physiological processes.

Action A: The app is not in the scope of medical devices regulation. CE marking as a medical device is not necessary.
Action B: The app is not considered as standalone software. The app must be evaluated as part of that medical device in the regulatory process of that device.
Action C: The app is considered to be a medical device with a low risk. For CE marking, the manufacturer has to follow the procedure of Annex VII MDD (self-certification).
Action D: The app is considered to be a medical device with a medium or high risk. A notified body will check your app and provide it with a CE mark.

* Question 9 only states the most relevant criteria for medical apps. For the ‘complete criteria’ see the additional rules for active devices 9 to 11 in Annex IX to the Medical Devices Directive.

www.nictiz.nl
@Nictiz
Nictiz