Better healthcare through better IT

Nictiz

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 medial 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.

* 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.

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.