

Medical App Checker: Evaluation of Mobile Medical Apps

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There are now more than 120,000 mobile medical apps available in the various App Stores and across platforms. Apps are computer programs used on mobile devices, such as mobile phones or tablets. Mobile medical apps serve a specific medical or preventive purpose, such as to inform, diagnose, support a diagnosis or clinical decision, make calculations or to decide on a diagnosis or treatment.

This Medical App Checker (hereafter: 'App Checker') is aimed at:

- ▶ Apps that must be considered to be medical devices (see Annex 1);
- ▶ Apps that facilitate the efficient tracking, storage and sharing of information (known as tracking, tracing and monitoring apps);
- ▶ Communication apps that allow patients to ask questions to their care providers, for instance.

For more information, see also part b 'Definition of terms and app types' in the Explanation section below. Many existing evaluations of mobile medical apps still lack any systematic analysis based on quality criteria. This App Checker intends to make it possible to make a more qualitative evaluation of mobile medical apps.

How does the App Checker work?

The App Checker consists of three sets of questions and offers frameworks for (1) a focused search for a suitable mobile medical app, (2) an appraisal of the reliability and the quality of a mobile medical app before it is downloaded, and (3) an evaluation of the protection and security of personal data after the app is downloaded. It is sometimes difficult to remove an app from a mobile device. Because of this, the App Checker recommends checks 1 and 2 before the app is downloaded. The questions asked in the App Checker help you to make a well-considered choice. You then need to decide for yourself which questions and answers are most relevant to you.

Guarantees

The App Checker does not give you a cast-iron guarantee of the reliability or quality of the app. For instance, if you have answered a lot of questions with 'I don't know', the outcomes will have a higher degree of uncertainty. You need to decide for yourself which questions are most relevant to you. If in doubt, it is advisable to contact the developer or an expert to find the information you need.

In your decision on whether to use a mobile medical app, the Royal Dutch Medical Association (KNMG) recommends you always consider the following factors:

- 1 Only use apps from a reliable source.
- 2 A really good app can do one thing really well¹.
- 3 Check whether a CE mark is compulsory for a mobile medical app (see Annex 1) and whether the app actually has a CE mark.

Although this App Checker is primarily intended to help doctors, it may also be useful for developers and vendors of mobile medical apps.

¹ Source: Arts & apps Gids, VvAA, 2014, Tien tips van Taubert.

CHECK 1 TARGETED SEARCH FOR A SUITABLE MOBILE MEDICAL APP

Think in advance about who you are looking for a mobile medical app for. For yourself, for your patient or for a caregiver? Also think in advance about the functions that the app should have: provide information, take measurements, support in making diagnoses, monitoring, behavioural change or something else? For which mobile device(s) do you want the app?

A number of suggestions for sources that you can consult when searching for a suitable mobile medical app can be found in the explanation (see check 1). By answering the questions below, you can check whether the app you are looking for will meet your expectations

Questions

Yes / No / Don't know

- | | | | | |
|---|--|--------------------------|--------------------------|--------------------------|
| 1 | Is it clear who the app is intended for? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2 | Is it clear who the app provider is? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3 | Does the app have the functions you are looking for (e.g. providing information, taking measurements, making a diagnosis, monitoring, behavioural change)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4 | Is the app available for the operating system of your mobile device or the patient's mobile device? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

If you have a medical app in mind and one of the answers to these questions = *No*, the app may not be suitable.

CHECK 2 EVALUATION OF THE QUALITY OF THE MOBILE MEDICAL APP

If you have a mobile medical app in mind, evaluate the app in terms of the following points before you download it (based on a preview or review, for instance).

CE mark

A CE mark is compulsory if a mobile medical app is to be used as a medical device².

An app is considered to be a medical device if it is intended to be used for diagnostic or therapeutic purposes. This is the case if a medical app can also do things other than storage, archival, data compression or simple search queries. This includes interpreting and appraising the data entered, for instance. Furthermore, the app must also be intended to produce results for certain persons, patients or groups of patients. This means that software which is intended for statistical purposes or for presenting treatment protocols are not covered by this because they are not intended for individual patients.

Furthermore, apps come under the definition of a medical device even if the app itself is not a medical device, but is intended by the developer to be used together with a medical device. This applies, for instance, to an app that wirelessly reads the status of infusion pumps and sends the output to a healthcare professional.

Questions

Yes / No / Don't know

- | | | | | |
|---|--|--------------------------|--------------------------|--------------------------|
| 1 | Does the app dispense diagnostic or therapeutic advice? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2 | Is the app intended to enable the use of a medical device? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

If one answer = *Yes*, a CE mark is compulsory.

- | | |
|---|--|
| 3 | Only if compulsory: Does the app have a CE mark? |
|---|--|

If the answer = *No*, use of the app is not advisable.

² A medical app with functionality in the realm of treatment or diagnosis is covered in the Netherlands by the Medical Devices Act ('Wet op medische hulpmiddelen') and must have an official CE mark (see explanation at check 2).

Functionality

The extent to which the app provides the functions that you are looking for. Functions of the app may be: to provide information, take measurements, support diagnoses, monitoring, behavioural change, etc.

Questions	Yes / No / Don't know
4 Has the functionality of the app largely been negatively reviewed on a review site, in the app store or by some other source?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

If the answer = Yes, use of the app is not advisable.

Content quality and (clinical) relevance

The extent to which the content of an app meets medical criteria (if necessary, consult the app's website).

Questions	Yes / No / Don't know
5 Is the content of the app based on recent subject-matter knowledge?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6 Is the content of the app in line with relevant guidelines?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7 Has the app been validated by test results?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8 Are the app and its contents regularly updated?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9 Can the user be reached by the app provider in case of problems (such as erroneous measurements)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

If three answers are No or Don't know, use of the app is not advisable.

Ease of use

The extent to which an app is easy to use.

Questions	Yes / No / Don't know		
10 Is the use of the app clearly explained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11 Is a website available with additional information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12 Is the app simple to use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13 Are the app's functionalities available for offline use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14 Can problems with use of the app be reported to the app provider (phone number, email address, help function)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If two answers are *No*, use of the app is not advisable.

CHECK 3 EVALUATION OF PROTECTION AND SECURITY OF PERSONAL DATA

If after check 2 the app score is good or acceptable for the aforementioned quality requirements, you may download the chosen app. Answer the following questions before using the app.

N.B.: you can skip check 3 if it is clear that no personal data are processed by the app.

Privacy ³

The extent to which an app takes the following privacy aspects into consideration.

Questions

Yes / No / Don't know

1 Does the app include a clear, easy-to-read privacy statement?

If the answer = *No*, use of the app is not advisable.

2 Does the privacy statement do any of the following:

- ask permission to collect data?

- ask to access data on your mobile device?

- use any data (entered or released)?

- modify the data entered?

- delete the data entered, including account data?

If two answers are *No*, use of the app is not advisable.

Security⁴

The extent to which an app takes the following security aspects into consideration.

Questions	<i>Yes / No / Don't know</i>		
3 Has security of the app been subject to testing by a third party.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>If not:</i>			
4 Does the app include a security policy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 Does the security policy include information on:			
- setting up secure access?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- securing electronic communications via the app if the app uses a portal, for instance, by using https in the URL?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If two answers are *No*, use of the app is not advisable.

Final evaluation of the mobile medical app

After carrying out the three checks referred to above, you will of course want to come to a decision on whether the app you have in mind is sufficiently reliable to use it yourself or prescribe its use by a patient. As mentioned earlier, you need to decide for yourself which questions and answers are most relevant to you. Based on the outcome of this, you can make your own assessment of which scores from the App Checker determine whether you will or will not use the app or prescribe its use.

4 Source: Blogs on privacy and security by Rob Peters, Deloitte (www.digitalezorggids/www.smarthealth.nl)

Medical App Checker: Evaluation of Mobile Medical Apps

Explanation

A Scope and purpose of the App Checker

The App Checker is intended for doctors who want to use a certain mobile medical app themselves, want to recommend it to their patients and their caregivers, or want to evaluate a mobile medical app of their patient. It provides doctors with a tool kit to evaluate the reliability and the quality of medical apps in a more systematic way. With the App Checker, the Royal Dutch Medical Association (KNMG) wants to encourage the responsible use of mobile medical apps by doctors.

B Definition of terms and app types

Apps are computer programs used on mobile devices, such as mobile phones or tablets.

App provider: the party responsible for marketing the app (this may be the developer and/or the vendor of the app).

Mobile medical apps are apps with a specific medical purpose, such as to inform, diagnose, support a diagnosis or clinical decision, make calculations or decide on a diagnosis or treatment.

Medical device: any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but

which may be assisted in its function by such means⁵. Mobile medical apps may be categorised as medical devices when they dispense diagnostic or therapeutic advice.

Medical and preventive apps can broadly be divided into the following categories⁶:

- 1 Apps that must be considered to be medical devices (see Annex 1);
- 2 Tracking, tracing and monitoring apps: apps that facilitate the efficient tracking, storage and sharing of information;
- 3 Communication apps: these can be used by patients, for instance, to ask questions online directly to their care provider or to answer questions from researchers. This could, for instance, include apps that give patients access to their personal medical information through hospital portals.
- 4 Reference apps: apps that function as reference works for medical information. These may be intended for use by healthcare professionals or by patients.
- 5 Training apps: apps that are intended to be used by healthcare professionals for educational purposes (initial training, continuing professional education);
- 6 Productivity apps: apps that support an efficient healthcare process (not in a clinical sense but, for instance, support financial administration processes);
- 7 General apps that may also be used in healthcare settings, such as apps that make it possible to use a mobile phone as a magnifying glass, to make audio recordings, etc.

This App Checker is aimed specifically at the first three categories: apps that must be considered to be medical devices, tracking, tracing and monitoring apps, and communication apps.

c Future developments at the European level

To unlock the potential of mobile health in the EU, the European Commission, together with other stakeholders, is working on a Code of Conduct on privacy for mobile health applications. The Commission also has set up a

⁵ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

⁶ Sources: PwC interviews and a KNMG survey, 2013. US Food and Drug Administration (FDA), Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff. Silver Spring (USA), 9 February 2015, Appendix A.

working group to develop guidelines for assessing the validity and reliability of the data that health apps collect and process. As soon as these are available, KNMG will review whether there is sufficient cause to amend this guide.

D The App Checker explained

It is important to be critical when reading the outcomes of the App Checker. The App Checker does not give you a cast-iron guarantee of the evaluation of a mobile medical app. You may have responded to a number of questions with 'don't know', or the app may provide insufficient insight into the use of the data entered and/or security, etc. In that case, it is difficult to judge the level of security and the protection of personal data. In that case, you will need to decide for yourself which questions are most relevant to you. If in doubt, it is advisable to contact the app developer or an expert to find the information you need.

When making a decision, KNMG recommends that you consider at least the following aspects:

- 1 Only use apps from a reliable source.
- 2 A really good app can do one thing really well.
- 3 If a CE mark is compulsory for a medical app (see Annex 1), check whether the app actually carries a CE mark.

CHECK 1 TARGETED SEARCH FOR A SUITABLE MOBILE MEDICAL APP

Only use apps from a reliable source. Apps from fellow doctors (for example, 'iP Plaslijst, eerste hulp bij blaasproblemen'), from a scientific association (the Thuisarts app) or from a patients' association (Oefen App Beroerte) are generally more reliable than others. The examples mentioned here, are examples of Dutch mobile medical apps.

Sources for finding mobile medical apps:

- ▶ App stores have apps both for professional use as well as all kinds of self-help applications for consumers. Examples: Apple's App store, Google Play (Android), Blackberry World, Windows Store. App stores also provide app reviews.
- ▶ Websites from scientific associations in the Netherlands and other countries offer suggestions for their own fields of expertise (e.g. the Thuisarts app by the Dutch College of General Practitioners (NHG)).

- ▶ Relevant sections and articles in Dutch journals, such as ‘Arts en Auto’ and ‘Medisch Contact’.
- ▶ Websites such as www.Zorgvisie.nl.
- ▶ Blogs by medical practitioners. Example: On www.geneeskunde.com, a Dutch emergency physician maintains a list of apps he uses.
- ▶ App annual 1 (2014) and 2 (2015) for Dutch medical practitioners, VvAA.
- ▶ MobileDoctors.nl of the Dutch VvAA.

The following websites ask experts and/or users to review mobile medical apps:

- ▶ On www.iMedicalApps.com, doctors and medical students evaluate mobile medical apps in terms of their usability in day-to-day practice. N.B.: These apps are targeted towards English-speaking countries where other protocols apply and medicines and dosages may vary.
- ▶ On the Dutch website www.digitalezorggids.nl, there are around 8,500 mobile medical apps and reviews by professionals and consumers.
- ▶ The Dutch website Appill.nl gives you access to the mobile medical app library of EverywhereIM.

CHECK 2

EVALUATION OF THE RELIABILITY AND THE QUALITY OF THE MOBILE MEDICAL APP BEFORE DOWNLOAD

Relevant legislation

Below is a summary of the current legislation that is relevant in assessing whether a CE mark is compulsory and the personal data protection and security aspects.

Compulsory CE mark for medical devices

The question of whether a CE mark is compulsory or not is relevant because as a doctor you could be fined if you use an app as a medical device and it does not have a CE mark. Read more below on the CE mark and the law regulating its use. The European Medical Devices Directive (Directive 93/42/EEC) was transposed into Dutch national law by the **Medical Devices Act** (‘Wet op de medische hulpmiddelen’) and some delegated legislation. This Act defines a medical device as ‘any instrument, device or appliance, any software, substance or any other item that is used alone or in combination, including any accessory and the software needed for its effective operation, which is specifically intended by the manufacturer to be used for diagnostic or therapeutic purposes’. The Medical Devices Act is important because mobile medical apps which provide diagnostic or treatment

functionality are governed by it and must have an official CE mark. CE marks are not a judgement of the accuracy of the information provided by the app. The CE marking indicates that a product is in conformity with European regulations relating to safety, health, environment and consumer protection. Examples of CE-certified Dutch mobile medical apps are (correct as at December 2015): iP Plaslijst, Moet ik naar de dokter? And OWise breast cancer.

CHECK 3 EVALUATION OF PROTECTION AND SECURITY OF PERSONAL DATA

Personal Data Protection Act

Data security and personal data protection are regulated in the Netherlands by the Personal Data Protection Act ('Wet bescherming persoonsgegevens' – 'Wbp'). Personal data is data that can be used directly or indirectly to identify an individual natural person. According to the Act, the processing of personal data includes every action or series of actions relating to personal data, such as collection, recording, storage, retrieval, consultation, use, disclosure, etc. Anyone who decides on the purpose of and the means to process personal data is responsible for this. The Wbp does not ban the processing of personal data outright, but sets the conditions under which data may be processed.

In 2013, the so called 'Article 29 Working Party' of European personal data protection authorities published their 'Opinion 02/2013 on apps on smart devices'.⁷ The group identified the following privacy risks that the use of apps on mobile devices can entail:

- 1 Lack of transparency for the user on the processing of personal data.
- 2 In part as a result of this, there is a lack of free and informed consent of the user for the processing of personal data.
- 3 Poor security measures that may lead to unauthorised processing, of healthcare information for instance, possibly as the result of a data breach.
- 4 Use for other purposes (due to either ignorance or intention) other than the purpose for which the personal data was collected.

⁷ Article 29 Data Protection Working Party, "Opinion 02/2013 on apps on smart devices" (Adopted on 27 February 2013).

Privacy

An app on a mobile device can process various kinds of personal data, including: location, contacts, IMEI or mobile number, identity of the owner, name of the device, credit card and payment data, call logs, text messages, browser history, emails, photos and videos, fingerprints and face recognition. Mobile medical apps may also process healthcare information. This may vary from substantial quantities of data to less sensitive personal data.

App developers have to meet at least the following data protection requirements:

- 1 Ask for consent to process personal data before the app takes data from the device or stores information on it;
- 2 Separately ask for consent for personal data about someone's health that is processed by the app;
- 3 Indicate clear and easy-to-understand purposes for which the personal data will be used and do not later change these purposes;
- 4 Offer users the opportunity to withdraw their consent, to uninstall the app and to delete the previously collected data;
- 5 Only collect data which is genuinely needed for the desired functionality;
- 6 Provide easy-to-read, easy-to-understand and easily accessible *personal data protection* conditions.

Information Security

Information Security is related to personal data protection, but we discuss it separately here. Data protection legislation provides that personal data must be protected against loss and unlawful access by anyone not authorised to do so by taking appropriate organisational and technical measures (section 13 of the Wbp). Some important concerns relating to the security of personal data in apps include:

- 1 The app developer must decide in advance where the personal data will be stored: on the user's device, in the cloud, or a combination of the two.
- 2 Rules and complexity of the codes must be minimised using built-in control mechanisms to prevent personal data from being altered or unintentionally provided to third parties.
- 3 Application of an adequate security patch management strategy.
- 4 Application of regular independent system audits.
- 5 Security of personal data during the transport of the data and after storage.

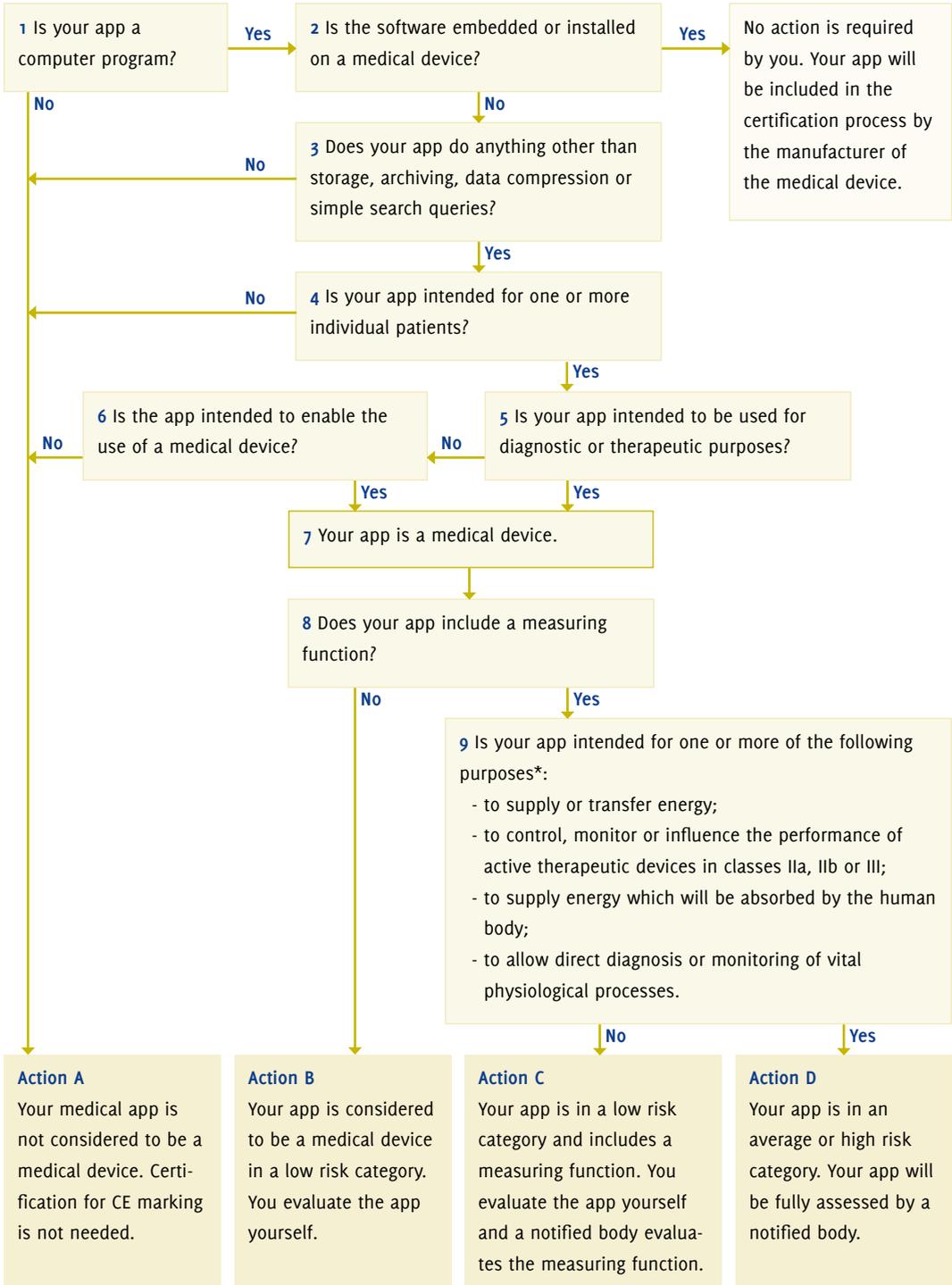
- 6 Security of apps against malware and other harmful software.
- 7 Do not use hidden features in apps.
- 8 Give careful consideration to which forms of identification and user authentication will be used.
- 9 User names and passwords must be encrypted before being stored.
- 10 Actively inform users if the app has been affected by a security incident (data breach).

These information security concerns apply in particular to app developers. However, app stores, operating system developers, device developers and certain third parties are also bound by a duty of care to take sufficient personal data security measures where this is achievable.

The following website is an example of expert testing in the field of security and data protection:

www.assuringapps.com is an initiative of Deloitte which seeks to test apps/portals or other devices in terms of security, privacy, CE marks and usability. Deloitte tests various functionalities, but also tests whether the app would be compliant in a NEN or ISO certified environment.

ANNEX 1 Flow chart CE-mark



* Question 9 sets out only the most relevant criteria. For the full criteria, see additional rules 9 to 11 for active devices in Annex IX of the Medical Devices Directive.

This flow chart was produced by Nictiz based on the general MEDDEV documentation for medical devices. The purpose of this chart is to clarify the evaluation specifically for medical devices. This chart is not intended to serve as a basis for a legal evaluation. In that case, you should refer to the decision tree in the official MEDDEV documentation.

Notes on the flow chart

- 1 With respect to the word ‘computer program’, MEDDEV refers to the following definition in ISO/IEC 2382-1:1993:
‘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 the software is not a computer program, it is likely to be an electronic document containing a treatment protocol or a list of results.
- 2 If the software is part of a medical device as such, the software will be evaluated in accordance with the guidelines of the device. Any updates of the software will then count as updates of the device.
- 3 Other actions will be considered to be actions taken in relation to data or the interpretation and appraisal of data. These are actions that consist of more than the mere bidirectional transmission of data.
- 4 The software must be intended to produce results for certain persons, patients or groups of patients. Software which is intended for statistical purposes or, for example, the presentation of treatment protocols is not covered by this. These are not intended for individual patients.
- 5 The key here is the intention with which the software was developed. If the app is intended for diagnostic or therapeutic purposes, how a user decides to use the app is irrelevant in the eyes of the law.
- 6 This refers to software which itself is not a device, but is intended by the manufacturer to be used with a device. An example of software which is not itself a medical device, but does influence the intended use of a medical device is an app that wirelessly reads the status of an infusion pump and sends it to the care provider.

- 7 Your app will be considered to be a medical device and therefore comes under the scope of the Medical Devices Act.
- 8 Software with a measuring function is an app, for instance, that presents glucose values in the form of a chart and compares it to 'normal' values.
- 9 MEDDEV gives examples of this: presentation of the heartbeat or other physical parameters during a routine examination, monitoring in an intensive care department, a planning system for radiotherapy that is used to calculate the dose of ionizing radiation, or software to plan an insulin dose.

