National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Apps under the medical devices legislation

RIVM Letter report 2018-0083
A. van Drongelen et al.

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Colophon

A. van Drongelen (author), RIVM
A. de Bruijn (author), RIVM
B. Roszek (author), RIVM
R. Vonk (author), RIVM

Contact:
Arjan van Drongelen
arjan.van.drongelen@rivm.nl

Synopsis

Apps under the medical devices legislation

Increasing numbers of people are using digital tools (including apps) to check their health or lifestyle, or for assistance with a disease. There is a wide range of such tools on offer, ranging from tips for stopping smoking or a tool for measuring heart rate, to help with mental health problems. The majority of health and lifestyle apps are free of charge. The Dutch Ministry of Health, Welfare and Sport would like to know what products are available and whether these products are placed on the market according to the applicable legislation for medical devices. RIVM has therefore carried out an exploratory study to see what is on offer in the Netherlands, investigated whether the apps qualify as medical devices and if so, whether they have the CE mark. This mark shows whether a product has been placed on the market as a medical device.

A medical device is a tool, device or equipment (including software) that a manufacturer has developed in order to make a diagnosis or to prevent or treat diseases or problems. Whether a product is a medical device is based on rules. The manufacturer is in the first instance responsible for the quality and safety of the medical devices, the Health and Youth Care Inspectorate (IGJ) handles the market surveillance. Based on limited available information, 21 per cent of the 271 apps examined turned out to be a medical device. The requisite CE mark was not identified on over half of those. Despite the rules, there is still room for interpretation when establishing whether an app is a medical device.

The new legislation for medical devices, which will become mandatory in 2020, has consequences for the risk classification of health apps. Software, and therefore also apps, will be classified in risk classes based on other rules. Many of the apps that are considered medical devices will be classified in higher risk classes under the new regulations. A more stringent market authorization procedure will then apply and additional approval by an external party (known as a 'notified body') will be required. Manufacturers may continue to carry out the market authorization procedure themselves for apps that are low risk

Keywords: apps, software, Medical Devices, Medical Devices Directive, Medical Devices Regulation, legislation, classification, notified body, CE mark

Publiekssamenvatting

Apps onder de medische hulpmiddelen wetgeving

Steeds meer mensen gebruiken digitale hulpmiddelen, waaronder apps, om hun gezondheid of levensstijl in kaart te brengen, of als ondersteuning bij een ziekte. Het aanbod van dergelijke tools is groot en varieert van tips om te stoppen met roken, een tool om de hartslag te meten tot hulp bij psychische problemen. De meeste apps over gezondheid en lifestyle zijn gratis. Het ministerie van VWS wil weten welke producten verkrijgbaar zijn en of deze producten volgens de voorschriften voor medische hulpmiddelen in de handel zijn gebracht. Het RIVM heeft daarom in een verkennende studie gekeken naar het aanbod in Nederland, onderzocht of de apps medische hulpmiddelen zijn, en zo ja of een CE-markering aanwezig is. Deze markering geeft aan dat een product als medisch hulpmiddel op de markt is gebracht.

Een medisch hulpmiddel is een instrument, toestel of apparaat (inclusief software) dat een fabrikant heeft ontwikkeld om een diagnose te stellen, ziekten of gebreken te voorkomen of te behandelen. Op basis van regels wordt bepaald of een product een medisch hulpmiddel is of niet. De fabrikant van een medisch hulpmiddel is verantwoordelijkheid voor de kwaliteit en veiligheid ervan; het toezicht ligt bij de Inspectie Gezondheidszorg en Jeugd (IGJ). Op basis van de beperkte beschikbare informatie bleek 21 procent van de 271 onderzochte apps een medisch hulpmiddel te zijn. Bij ruim de helft van dit percentage was de benodigde CE-markering niet te vinden. Ondanks de regels voor medische hulpmiddelen blijft er ruimte voor interpretatie of apps eronder vallen.

De nieuwe regelgeving voor medische hulpmiddelen, die in 2020 in werking treedt, heeft gevolgen voor de risicoclassificatie van gezondheidsapps. Dan wordt software, en dus ook apps, op basis van andere regels ingedeeld in risicoklassen. Een aanzienlijk deel van de apps zal hierdoor in een hogere risicoklasse vallen. Daarvoor geldt een zwaardere toelatingsprocedure en is een extra goedkeuring door een externe partij, een zogenaamde notified body, nodig. Voor apps met een laag risico mogen fabrikanten zelf de toelatingsprocedure blijven uitvoeren.

Kernwoorden: apps, software, medische hulpmiddelen, Richtlijn medische hulpmiddelen, Verordening medische hulpmiddelen, wetgeving, classificatie, notified body, aangemelde instantie, CE merk

Contents

1 Introduction

1.1 Regulatory background

Since the revision of the Medical Device Directive (93/42/EEC, MDD) in 2007 (1), stand-alone software has been recognized as a medical device. In the MDD, software is considered an active medical device for classification purposes (see Annex I). Medical devices are divided into four risk classes, Class I (lowest risk class), Class IIa, Class IIb and Class III (highest risk class). This classification is based on different aspects, such as invasiveness, connection to a power supply and duration of use. These risk classes determine which conformity assessment procedures are applicable for market access. For Class I medical devices, there is self-certification by the manufacturer, where there is no involvement of a third party, a so-called notified body. From Class IIa to Class III devices, the involvement of the notified body in the conformity assessment procedure increases. For a Class III device, the notified body undertakes a full review of the design of that specific device.

The new Medical Device Regulation, published in April 2017 and replacing the MDD in May 2020, puts more emphasis on software (2). General-purpose software or software for life style and well-being purposes is explicitly excluded from the MDR (see Annex 1, consideration 19). Compared to the MDD, there is an additional classification rule (rule 11) for software in the MDR, that covers other types of software, e.g. for clinical decision support (see Annex 1).

The Ministry of VWS has noticed that the legal requirements for software with a medical purpose are not known to all developers. The question arises whether marketed eHealth apps comply with current legislation. Moreover, the stricter requirements for software in the new legislation may lead to a shift in risk classification in the near future.

1.2 eHealth

Software for health care applications is often seen in the broader context of eHealth. eHealth technology can be defined as digital information and communication technology used in care. This includes web-based and mobile apps for health care providers, patients and caregivers within a treatment relationship, as well as technologies aiming to improve quality in health care (3).

The Dutch Ministry of Health, Welfare and Sport (VWS) has set goals for the application of eHealth: "The government wants eHealth to become more widely available and is encouraging the health care sector to develop it further".

The targets that the government has set in 2016 are[1]:
- At least 80% of chronically ill people should have access to their own medical records by 2019, and at least 40% of other members of the population.
- By 2019, 75% of chronically ill people and vulnerable elderly people should be able to monitor certain aspects of their own

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[1] https://www.government.nl/topics/ehealth/government-encouraging-use-of-ehealth

              health and share the data with their health provider. This would
              include aspects such as blood pressure and cholesterol levels.
- People receiving care and support at home should be able to
  communicate with their care provider 24 hours a day via a
  screen, if they wish.

To achieve this, the government has set up an online platform to
support innovators wishing to make a new digital application, and
established a start-up network to bring health care innovators and other
parties together[1].

1.3   Scope of the current study

The Ministry of VWS requested the National Institute for Public Health
and the Environment (RIVM) to undertake an explorative study to
investigate the type of eHealth products currently available, the
classification of these products under current (MDD) and future
regulation (MDR), and the value of available decision trees in the
process of classification. As eHealth is very broad, this study was limited
to apps. Available guidance documents were checked to establish
whether they provided adequate support for the classification of
software (4-6).
The quality and usability of apps was not part of this study.

2 Methods

2.1 Inventory of apps

An inventory of apps was conducted in the period November 2017 – February 2018. A limited number of web-based applications were also included. However, the term app will be used throughout this document. The following websites were consulted, as these Dutch websites provided an overview of the apps currently available:

- play.google.com/store/apps
- itunes.apple.com/nl/genre/ios/id36?mt=8
- www.zorginnovatie.nl
- www.digitalezorggids.nl
- www.icthealth.nl

Apps were searched for in specific categories for the different websites, as shown in Table 2.1.

Table 2.1 Categories used for identification of apps

Source	Category
Google Play	Health & fitness
Apple Store	Health & fitness, Medicine
ZorgInnovatie	eHealth, mHealth/apps (various combinations/spelling)
DigitaleZorgGids	Products
Website ICT & Health	All news items related to apps

Apps that did not concern health or fitness were excluded. As this study was intended as an explorative study, the inventory was stopped after approximately 250 apps were found. Information on identified apps was extracted and compiled in an Excel database. Extracted information included the name of the app, url, brief description of app, and whether the CE mark was applied or mentioned in the available information (see also 2.2). If the app was considered by the authors to be a medical device, the app was downloaded (if free of charge). No information on the suppliers was extracted. Multiple entries for one app were reduced to one. For instance, the same app found in the Apple Store as well in Google Play was only entered once in the Excel database.

2.2 Classification and categorization Classification

The authors determined whether apps were medical devices, based on the definition in the MDD, as the decision trees are also based on the definition in the MDD. This decision was based on the publically available information on the app, most often on the website. This information often contained concise information on the app. No additional information on the app was requested from the manufacturer for the classification. Each app was classified by one assessor and checked by a second assessor. It was checked whether there was a CE-mark explicitly mentioned, either on the website, on pictures of the app or in the app itself, when downloaded and opened. For apps not classified as a

medical device, any mention of a CE-mark on the website of on pictures of the app, was noted.

Subsequently, the risk class of the apps that are medical devices was determined based on the classification rules in the MDD and MDR and the available, often limited, information about the app. Every case was checked by a second assessor.

Classification issues, that could not be resolved within the assessors team, were discussed with the Dutch Health and Youth Care Inspectorate (IGJ) and decided upon in consultation. No additional information about the app was obtained for this decision. In cases of discussion, a remark was added in the Excel database substantiating the decision that the app can be considered a medical device or not or what the risk class of an app was.

Guidance documents containing decision trees published by the Dutch National ICT Institute for Care (Nictiz) (4), the UK Medicines & Healthcare products Regulatory Agency (MHRA) (5) and the European Commission (6) were also included in this study. These documents were based on the MDD. Following the classification, it was checked whether they facilitated classification and it was checked whether all relevant information was contained in the document. Annex 2 contains an example of such a decision tree.

Categorization

Apps were assigned to purposes, such as "log (book)", "education" and "planning". The terms used to describe the purposes were chosen to be relatively wide, so it could cover a variety of apps. For example, apps can actively measure a medical parameter like heart rate, or can monitor a parameter, either by using measurements taken by the app or by using data from other systems. Both measurement and monitoring are included in one purpose "monitoring and measurement". Another example is the purpose "education", which included providing information to the user. Apps were also categorised according to medical area for use (e.g. the organ, or disorder for which they are intended).

2.3 Contacting manufacturers

For apps that were medical devices, but for which no CE mark was identified, or apps which were not medical devices, but for which a CE mark was identified, manufacturers were contacted by e-mail. The following questions were asked to the manufacturers:
- Are you familiar with the Dutch Decree on Medical Devices (in Dutch: Besluit medische hulpmiddelen), European Medical Devices Directive (MDD) and/or the new European Medical Devices Regulation (MDR)?
- Are you familiar with the fact that a health app or other software can be a medical device?
- Based on the available information, we have established that your app *<name of app>* is a medical device. However, based on the available information, your product is not CE-marked, which means that you consider this application not to be a medical device, or
  Based on the available information, we have established that your app *<name of app>* is not a medical device. However,

based on the available information, your product is CE-marked, which means that you consider this application to be a medical device.

- Can you indicate what the basis was for your decision on the product being a medical device or not?
- Did you use a decision tree to help with that decision, such as those of the Dutch National ICT Institute for Care (Nictiz) or UK MHRA?
- When placing the app on the market, did you encounter problems with the interpretation or publication of the medical devices legislation as mentioned above?
- Did you encounter problems with other applicable legislation, e.g. General Data Protection Regulation (GPDR, in Dutch: AVG) or the Digital Content Directive?
- Can you indicate what developments you expect in the next years for health apps?
- Do you have any other remarks related to health apps?

If no response was received within two months, a reminder was sent. If a respondent indicated that he was willing to be contacted for further discussion, the respondent was contacted for an interview by telephone to elaborate upon the answers provided.

2.4 Contacting other stakeholders

Furthermore, the Dutch standardization institute (NEN) was contacted to ask for developments concerning standards for health related apps. The Dutch association for organizations for ICT in healthcare (OIZ) was contacted to obtain information on issues manufacturers encounter when placing software onto the market.

3 Results

3.1 Classification as medical device and CE mark

The basis for deciding whether an app is a medical device or not, is the definition of a medical device in the MDD.

> **Definition of medical device (MDD)**
> any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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 means (1).

Other points to consider when deciding whether a product is a medical device are:
- Software that only replaces paper is not considered a medical device, as is indicated in the guidance document on borderline classification (7).
- Software that is not performing action on data (i.e. only storing data and/or communicating data) is not considered a medical device (4, 5, and 6).
- Mainly for apps related to mental health, a variety of disorders and problems were mentioned. To decide whether an application was to be considered a medical device, the medical claim was compared to the list for allowing medical claims in advertisements[2]. If it was not allowed to use a certain claim in advertisements, this claim (e.g. stress) was considered a medical claim, and the classification continued. If the claim made was not considered a medical claim, the app was not classified as a medical device.

Medical devices or not
In total, 271 apps were identified. Of these 271 apps, 56 (21 %) were considered medical devices based on the available information. The remaining apps (79 %; n=215) were not considered to be medical devices, i.e. without a direct medical purpose. For example, an app only measuring heart rate, e.g. a sports app, is not considered a medical device.

[2] https://www.koagkag.nl/indicatieve-lijst

No medical device, but CE-mark applied
For four apps not classified as medical devices, a CE mark was identified. One app presented the scores of a questionnaire on urological symptoms and quality of life. The manufacturer responded to the questions sent by RIVM that the app did perform calculations on the outcomes of the questionnaire to present the data. RIVM considered that the calculation did not change the outcome (data) of the questionnaire and therefore did not consider this app to be a medical device (see also §4.1.2). One app was a logbook for diabetes, for which no additional features were indicated that could classify this app as a medical device. Two other apps presented measurements from other devices (e.g. heartrate, blood pressure, glucose levels, weight) to provide health information to patient and forward the data to a medical professional. Such an application does not fall under the definition of a medical device (only storing or communicating data). However, there were two other instances in which the app was sold as part of a system with the measuring equipment and these apps were considered a medical device.

Medical device, but no CE-mark noticed
For 36 apps of the 56 apps classified as medical devices, CE-marks could not be found, it is possible that the CE mark has been applied, but this was not mentioned in the information assessed for this study.

Decision trees
The guidance documents and the decision trees contained therein were considered helpful tools in determining whether software is a medical device. They guide the reader through the process of establishing whether software is a medical device. Some issues were discovered, which are further discussed in paragraph 4.1.2.

3.2   Categorization

No distinction was made between apps for consumers or apps for health care professionals. However, most apps were meant for consumers. The occurrence of different purposes is displayed in table 3.1. For all apps, the main purpose is logbook, which means that the apps allow users to document data and observations. For apps that were considered medical devices, the purpose was most often monitoring and measurement, for example for heart rate or an electrocardiogram. It should be noted that apps could be assigned to multiple purposes, and the different purposes were included in the database. As expected, some purposes are only present in apps that are not medical devices, such as e-coaching, patient support and planning.

Table 3.1 Purposes of apps

	All apps	Only medical devices
Log (book)	36.2%	17.9%
Education	27.3%	1.8%
Monitoring & measurement	25.8%	53.6%
Patient support	18.1%	5.4%
e-consult	10.3%	1.8%
Communication	8.5%	1.8%
Treatment	8.1%	12.5%
Planning	6.3%	-
Reference book / table	5.9%	5.4%
Diagnosis (support)	4.8%	12.5%
e-medication	2.2%	8.9%
Patient portal	2.1%	-
Decision support	1.5%	-
Electronic health record	1.5%	1.8%
Messaging	1.5%	-
e-coaching	1.1%	-
Data vault electronic health record	0.4%	-
Imaging	0.4%	1.8%

In table 3.2, the medical areas of the apps are given, providing insight into the disorders and complaints for which the apps can be used. Annex 3 contains a complete list.

Looking at all apps, miscellaneous was most often mentioned, but this was the case when the app was not directly related to a specific area, but more general in nature, such as a patient portal or a patient file. For specific medical areas, the apps for the skin, the cardiac system and mental health were most frequently found. For the skin, they were most often apps that keep track of skin irregularities. Some of these apps also have a function that can assess the skin irregularities and warn if the skin irregularities require medical attention. For the apps for the cardiac system, it mostly concerns apps that can measure heart rate or electrocardiograms. For mental health, it were most often apps that assist with managing mental disorders, such as depression.

For apps that are considered to be medical devices, the most frequently occurring are apps related to cardiac system. Other frequently occurring apps being a medical device are related to skin, diabetes and mental health. The number of skin apps being a medical device is considerably lower than for all apps, as most of these apps only keep track of developments of the skin irregularities and store photos without assessment of the irregularities. The diabetes apps being medical devices are not only registering the data from a blood glucose meter, but also provide advice for insulin dosage. The apps for mental health, that are medical devices, do not only provide information on the disorder but also provide treatment.

Table 3.2: Medical area of use

	All apps	**Only medical devices**
Miscellaneous	20,3%	17,9%
Skin	13,3%	10,7%
Cardiac system	12,5%	35,7%
Mental health	10,3%	7,1%
Sleep	8,1%	3,6%
Pregnancy	7,7%	3,6%
Diabetes	7,0%	8,9%
Smoking	5,2%	-
Lung diseases	4,1%	-
Gastro-entomological diseases	3,7%	1,8%
Cancer	1,8%	-
Chronic diseases	1,8%	1,8%
COPD	1,5%	-
Dementia	1,5%	3,6%
Hearing	1,1%	5,4%
Total	**100,0%**	**100,0%**

3.3 Classification in risk classes

The main change in the classification rules, comparing MDD to MDR is the addition of classification rule 11 on the use of information obtained for decisions with diagnosis or therapeutic purposes, see Annex 1. Following the MDD classification rules, most apps considered to be a medical device, were classified as Class I medical devices, followed by Class IIa, Class IIb and Class III (Table 3.3.a). According to the new MDR classification rules, most apps were classified as Class IIa medical devices, followed by Class IIb, Class I, and Class III (Table 3.3.b). Changing from MDD to the MDR more apps will be placed in higher risk classes (Table 3.3). Twenty-four Class I apps (according to the MDD) will be up classified to Class IIa or higher (MDR) and two Class IIa apps will be up classified (see table 3.3 and figure 3.1). For illustration of several examples, see textbox underneath.

Table 3.3.a: Classification of apps according to the MDD

Risk class	**N**	**%**
Class I	33	59
Class IIa	16	29
Class IIb	6	11
Class III	1	2
Total	**56**	**100**

Table 3.3.b: Classification of apps according to the MDR

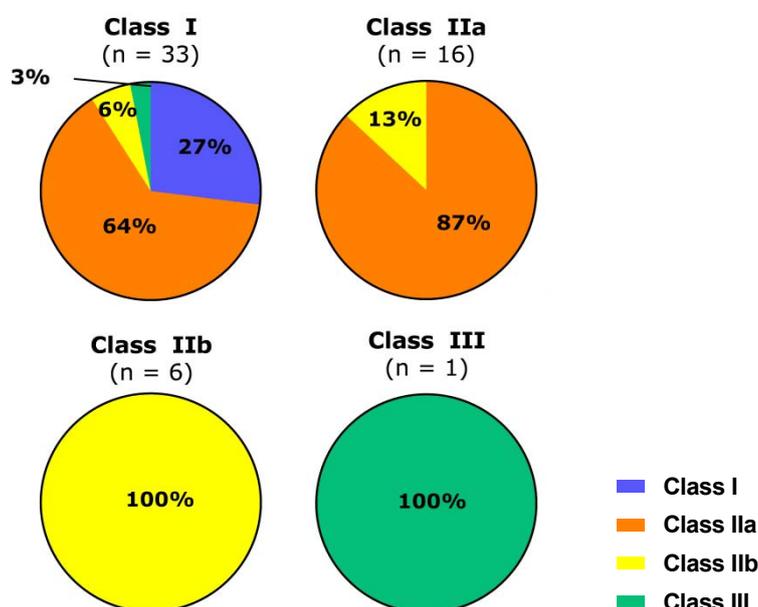| Risk class	**N**	**%**
Class I	9	16
Class IIa	35	63
Class IIb	10	18
Class III	2	4
Total	**56**	**100**

Figure 3.1: distribution of app over the MDR risk classes for each of the MDD risk classes

Text Box 1: illustration of up-classification

Examples of up-classification from Class I tot Class IIa are an app that measures reaction time to help in diagnosing a concussion and an app that calculates the risk of having a heart attack in the next 10 years, based on cholesterol levels.
An example of up-classification from Class I to Class IIb is an app that provides information on the required dose of medicine (an anticoagulant), based on the measurement of the international normalized ratio (INR) value for blood clotting. In this case, it was assumed that the app calculates this value using an algorithm.
One app was classified as Class I under the MDD, but will be a Class III medical device under the MDR. This is an app predicting the three-month mortality risk in patients with chronic liver disease. This score is used for prioritization of donor organ allocation to patients awaiting liver transplantation.

The device identified as a Class III medical device under both the MDD and the MDR was an app developed for contraception. For medical device for contraception, a special classification rule exists (rule 14 MDD, rule 15 MDR), classifying such devices as Class III. This rule is not related to software, but should be applied if applicable and leading to a higher risk class than the rule for software. This app is a Class III medical device according to MDD and to MDR rules.

3.4 Contacting manufacturers

For sending the questionnaire, e-mail was used, as other contact information was often not available. For two apps, no contact information at all could be found. For eight apps, the app was not free or a login code or registration code was required. Also, the app could not

be downloaded in two cases or the website was no longer accessible in three case. These apps could not be checked for the CE-mark. At the time of sending the questionnaires, there was still uncertainty about nine apps being a medical device or not. For these apps, the manufacturers were not contacted. Therefore, 16 of the 40 manufacturers for which there was uncertainty about the CE mark were contacted and asked to fill in the questionnaire.

Two manufacturers responded to the questionnaire, while one manufacturer responded to the reminder. One manufacturer only responded on the issue of the classification of the software as a medical device and did not fill in the questionnaire. The manufacturer did not agree with classifying the app as a medical device by RIVM. For this app, multiple entries were identified, which were reduced to one entry. It was observed that only for the case left in the Excel-database, the information suggested the app, a heart rate monitor, to be a medical device. However, when reviewing the other entries for this app, it was clear that the app was indeed not a medical device. Therefore, the app was scored not to be a medical device.

The second manufacturer indicated that he considered the app to be a medical device, contrary to the classification by RIVM, see also 3.1. The manufacturer indicated that the decision trees were used for that decision and had consulted a lawyer for the decision to classify the app as a medical device.

The last manufacturer that responded, for which a CE mark could not be found, indicated that he was in the process of CE marking the product. Both manufacturers that filled in the questionnaire indicated that they were aware of the applicable legislation and did not encounter problems with applying the legislation.

3.5 Contacting other stakeholders

The Dutch standardization institute, NEN, was also contacted about developments in the field of standards for apps. There are a number of standards related to software, but not specifically for health and wellness apps. Recently, a European work item was accepted for "Health and wellness apps. Quality criteria across the life cycle. Code of Practice". This document will not be a standard, but a technical specification, a guidance document. The document will be based on the British PAS 277 on the same topic (9). Topics to be addressed in the technical specification are:

- Fitness for purpose;
- Quality criteria;
- App project life cycle;
- Risk management;
- App project governance
- Configuration management;
- Support.

This technical specification will take into consideration existing standards related to health software.

A representative of the association for organizations for ICT in healthcare (OIZ) was contacted. This representative indicated that the

companies that are a member of the OIZ are aware of the legal requirements and act upon that. It was also indicated that some companies placing apps and software on the market may not fulfill all legal requirements. OIZ expects that the more stringent requirements in the MDR will lead to a clearer distinction between companies fulling their legal requirements and the ones that do not. However, the transition to the MDR will also require a considerable amount of resources to implement. This was also mentioned by the manufacturer that was interviewed.

4   Discussion and conclusions

4.1   **Discussion**

4.1.1   *Inventory of apps*
Approximately 20% of all apps found during this study were considered to be a medical device using the decision rules of the MDD. This indicates that most apps currently available on the market do not have a direct medical purpose, although they might be related to medical decisions or measurements.

4.1.2   *Classification*
Several aspects can hamper the classification of software as a medical device or into risk classes. These aspects are elaborated upon below.

Medical device or not: interpretation of rules
Only software that is performing any action on data (i.e. more than only storing data and/or communicating data) is considered to be a medical device. The example from one of the respondents (preparing data for presentation, without changing the actual data, see 3.4) indicates that this is prone to misinterpretation. Additional guidance on what is meant by action on data is considered useful.

Another issue encountered during classification as a medical device was whether the disorder to be treated is considered a disease (medical condition) or not. For this study, the terminology allowed for use in advertisements was used to make that distinction. However, this might be different in other countries and European guidance on this issue should be developed. The European competent authorities for medical devices have indicated that a guidance document on software will be developed[3].

Another issue is whether the app only presents data or also provides diagnostic or therapeutic support for the user. Examples are apps for skin irregularities that also assess whether the skin irregularity require medical action. Although this is considered action on data, additional guidance or examples to elaborate on this situation is considered beneficial.

An app is also not considered a medical device if it is only replacing paper. Therefore, an app that allows easy access to a digital form or a book is not a medical device. In addition, an app that presents a result taken from a digitalized table is not a medical device, while apps that present results obtained using algorithms are considered medical devices. This rule is elaborated upon in the borderline classification manual (7) but is only mentioned in the MHRA guidance document (5).

One of the questions in the decision trees (4, 5, and 6) is, whether the software fulfils the requirements in the definition of a medical device.

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[3] https://www.camd-europe.eu/wp-content/uploads/2018/05/NEWS_171107_MDR-IVDR_RoadMap_v1.3-1.pdf

This requires careful assessment by the person making the decision. For example, an app to prevent sunburn is not considered to be a medical device, as prevention of an injury is not within the definition of a medical device from the MDD and MDR, contrary to the prevention of a disease.

For some apps, it was indicated that the app is not a replacement for a physician's advice. This suggests that the app should not be considered a medical device. This information was not taken into consideration when deciding whether an app was a medical device or not.

Classification in risk classes
With regard to classification, there is room for interpretation in rules 10 and 11. This especially concerns the distinction whether 'variations observed could result in immediate danger to the patient' (rule 10), or 'could result in serious or immediate danger to the patient or a surgical intervention' (rule 11). Such serious consequences will lead to an app being classified a Class IIb or even Class III. In all other cases, the software is classified as IIa.

Rule 11 can be interpreted very strictly. Rule 11 starts with "Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes". For such apps, this leads to an app being classified at least as Class IIa, but this can increase to Class III, depending on the possible consequences. Software intended to provide information which is used to take decisions can be interpreted as encompassing nearly all measuring devices. As the measurement results will often be used for a medical decision, it can lead to an even higher classification than using rule 10. This way of interpreting rule 11 should be elaborated upon in a European guidance document. Currently, work is carried out to write a guidance document on classification of software into risk classes.

Guidance documents on classification
The decision trees in the guidance documents (4, 5, 6) were considered helpful tools, as they guide the user, especially manufacturers, through the process of deciding whether software is a medical device. The decision trees included in this study have the same purpose, but there are some differences in the way they are set up. Also the decision points, such as replacing paper or not, which are not laid down in the MDD and MDR are included in this process. During this study, several issues were identified for which inclusion in, or changes to, guidance documents should be considered.

Although an app can be an accessory to a medical device, it is possible that the app is considered not being a medical device using the decision trees of the European Commission (6) and NICTIZ (4). An example from this study is an app that is used in conjunction with a lens that is used to capture images of potential skin tumours with a mobile phone. This lens is a CE-marked medical device. Following the decision tree, the app is not classified as a medical device, as one of the first questions is whether other actions are performed on the data different form storage, archival, communication or simple search. The negative answer then results in the app not being considered a medical device. Only the decision tree in the MHRA guidance (5) includes a step to identify an

accessory. A change to the other decision trees should be made accordingly.

The change from MDD to MDR also requires changes to the decision trees, as there are some changes to the definition of medical device, which requires the definition in these document to be updated. For example, prediction of a disease has been included as a possible purpose of a medical device in the MDR.

For the guidance by NICTIZ, inclusion of apps that are in vitro diagnostic medical devices (IVDs) could also improve the usability of this decision tree. The other two documents include IVDs in the decision tree or have a separate decision tree for IVDs. As a number of apps were identified related to blood glucose monitoring systems, the inclusion of IVDs in the decision tree is considered helpful.

Issues concerning determining whether software is a medical device or not, that will benefit from inclusion in a guidance document to provide additional guidance or examples are:
- Just replacing paper or not
- Action on data
- When is a disorder or health problem considered to be a medical condition
- Updating the definition of medical device to the MDR definition
- Inclusion of IVDs
- Checking correct inclusion of accessories

Having all issues related to classification of an app as a medical device or not in one document, will facilitate consistent application of the rules. If such a document would also include guidance on the classification into risk classes, such guidance document would provide more assistance to manufacturers.

Changes to apps
As apps are regularly updated, which also allows for changing features, an app which was previously not a medical device can become a medical device due to the additional feature added during the update. This will require a market authorisation procedure to be initiated, which can take considerable time and could delay the release of the update.

4.1.3   *CE mark*
The absence of a CE mark can be valid in case the app has not been developed for the European market. A device for a non-European market might be available for European consumers. The fact that apps available on the internet can be accessed anywhere makes it more difficult to ensure that only appropriately CE-marked apps are made available to European consumers. It is noteworthy that for one app found during this study there was a disclaimer: "No medical advice". "If you access this application from other locations (and outside the USA), you are responsible for compliance".

Moreover, it is unknown whether apps that are made available through app stores are checked for regulatory compliance by the webstore or

whether other requirements for regulatory compliance of apps are in place for webstores.

4.1.4 Up-classification

The classification of apps that are medical devices indicates that changing from the MDD to the MDR will lead to up-classification for a considerable number of apps, especially apps that are currently classified as Class I and to a lesser extend Class IIa. This will result in more involvement of notified bodies in the market authorization procedure for software.

4.1.5 Methodology

The conducted inventory provides a general overview of available apps. It does not provide an in-depth insight into the current market of apps. Moreover, as apps can be developed relatively quickly, it can be assumed that there will be many changes in the available apps. An inventory will therefore only be a snapshot of the period investigated. Unfortunately, there has been limited response from manufacturers, so limited insight was gained into problems that manufacturers encounter and their interpretation of classification rules. The response to the reminder was also limited.

The decision whether an app is a medical device and its subsequent risk classification was based on the information that was available in the webstore or website. This information can lack specific details that could alter the classification. Notwithstanding these limitations, the aim of this study was to provide a general overview on current situation on apps and provide an insight into issues related to CE-marking.

Information on the CE-mark was not always available to the authors. In some cases, it was not possible to check the app itself to verify the presence of the CE-mark in the app itself. It could be possible that for some of these apps, a CE-mark is present. It is therefore possible, that the number of apps that are CE marked is higher than indicated in this report. To eliminate the uncertainties on the presence of CE-marks, a much more in-depth assessment is needed, which was outside of the scope of this explorative study.

For several apps, it was difficult to establish what the exact purpose and operating mechanism of the app was, which hampered the decision whether an app was a medical device. For one app, it was indicated that the app identified results deviating from normal values, which would allow the health care professional to take action. However, it was unclear whether it was the app itself or the health care professionals who made the distinction between 'normal' and 'deviating'. It was decided that this app was not a medical device, as it was only presenting measurements and allowing communication to the health care professional. The general descriptions of apps used for this investigation was often insufficient to establish the difference between an app applying an algorithm or an app taking data from a table.

4.1.6 Other issues

One manufacturer indicated that he had developed a general platform. This platform could be used for a range of health apps, which other

parties, e.g. hospitals could adapt to their specific purpose. It was unclear for the manufacturer whether or how such a general platform can be CE-marked, as it is envisaged that every different application will have to be separately CE-marked. A general CE-mark could facilitate the CE marking of the other applications.

The start of the development of a guidance document by NEN for health and wellness apps is a positive development, as this will standardize the requirements for such apps.

4.1.7 Conclusions

The aim of this study was to study the type of health apps currently available, the classification of these apps under current (MDD) and future regulation (MDR), and the value of available decision trees in the process of classification.

The general inventory shows that there is a wide variety of apps available on the (digital) market, yet most of these apps are not medical devices under current (MDD) or future (MDR) legislation. Roughly 20% of the apps found in this study were judged to be medical devices. For more than 50% of these apps, it was not clear whether the apps were CE-marked.

A considerable part of the apps that are medical devices will be up classified as a consequence of the transition from MDD to MDR.

Existing decision trees included in this study are useful tools for establishing whether or not software should be considered a medical device. Minor improvements can be made, to include IVDs and all rules related to classification as a medical device. The interpretation of classification rules and rules about whether software is a medical device or not, will benefit from European guidance, preferably in one document.

The global nature of the market for apps makes it difficult to ensure that only appropriately CE-marked apps are made available to European consumers.

5   References

1   Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. OJ L 169, 12.7.1993. Amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007. OJ L 247, 21.9.2007.

2   Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. OJ L 117, 5.5.2017.

3   RIVM Report 360127001/2012, Risks related to the use of eHealth technologies; An exploratory study, H.C. Ossebaard, A.C.P. de Bruijn, J.E.W.C. van Gemert-Pijnen, R.E. Geertsma

4   Ekker A and van Rest B. Medische apps, is certificeren nodig? In 7 stappen naar een CE-markering voor uw app. NICTIZ, Den Haag 2013.

5   MHRA. Guidance: Medical device stand-alone software including apps (including IVDs). Version 1.04, September 2017.

6   EUROPEAN COMMISSION, DG Internal Market, Industry, Entrepreneurship and SMEs, MEDICAL DEVICES: Guidance document; Qualification and Classification of stand-alone software, MEDDEV 2.1/6, July 2016

7   MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.18 (12-2017)

8   EUROPEAN COMMISSION, DG HEALTH AND CONSUMER. MEDICAL DEVICES: Guidance document - Classification of medical devices, MEDDEV 2. 4/1 Rev. 9, June 2010

9   PAS 277:2015, Health and wellness apps – Quality criteria, across the life cycle – Code of practice, BSI, 2015

Annex 1: Definitions and classifications

Applicable definitions from the MDD as revised in 2007:

Medical device
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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 means.

Accessory
an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device

Classification rules in the MDD as revised in 2007

Active medical device
Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand-alone software is considered to be an active medical device.

Additional rules applicable to active devices

Rule 9
All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.
All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.

Rule 10
Active devices intended for diagnosis are in Class IIa:
- if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,
- if they are intended to image in vivo distribution of radiopharmaceuticals,
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

Rule 11
All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:
- that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.

Rule 12
All other active devices are in Class I.

Applicable definitions from the MDR

Medical device
any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:
- devices for the control or support of conception;

- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Accessory for a medical device
an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).

Active device
means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device;

Consideration 19 to MDR:
It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a health care setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

Classification rules in the MDR
The classification rules from the MDR for active medical devices, in which group software is placed, see above, are included underneath. Rules 10 and 11 are the most applicable to software.

Rule 9
All active therapeutic devices intended to administer or exchange energy are classified as Class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as Class IIb.

All active devices intended to control or monitor the performance of active therapeutic Class IIb devices, or intended directly to influence the performance of such devices are classified as Class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as Class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as Class III.

Rule 10
Active devices intended for diagnosis and monitoring are classified as Class IIa:
- if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as Class I;
- if they are intended to image *in vivo* distribution of radiopharmaceuticals; or
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as Class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as Class IIb.

Rule 11
Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause:
- death or an irreversible deterioration of a person's state of health, in which case it is in Class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as Class IIb.

Software intended to monitor physiological processes is classified as Class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as Class IIb.
All other software is classified as Class I.

Rule 12
All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as Class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as Class IIb.

Rule 13
All other active devices are classified as Class I.

Annex 2: example of a decision tree

Decision tree for software as a medical device, taken for the guidance document published by the European Commission (6)
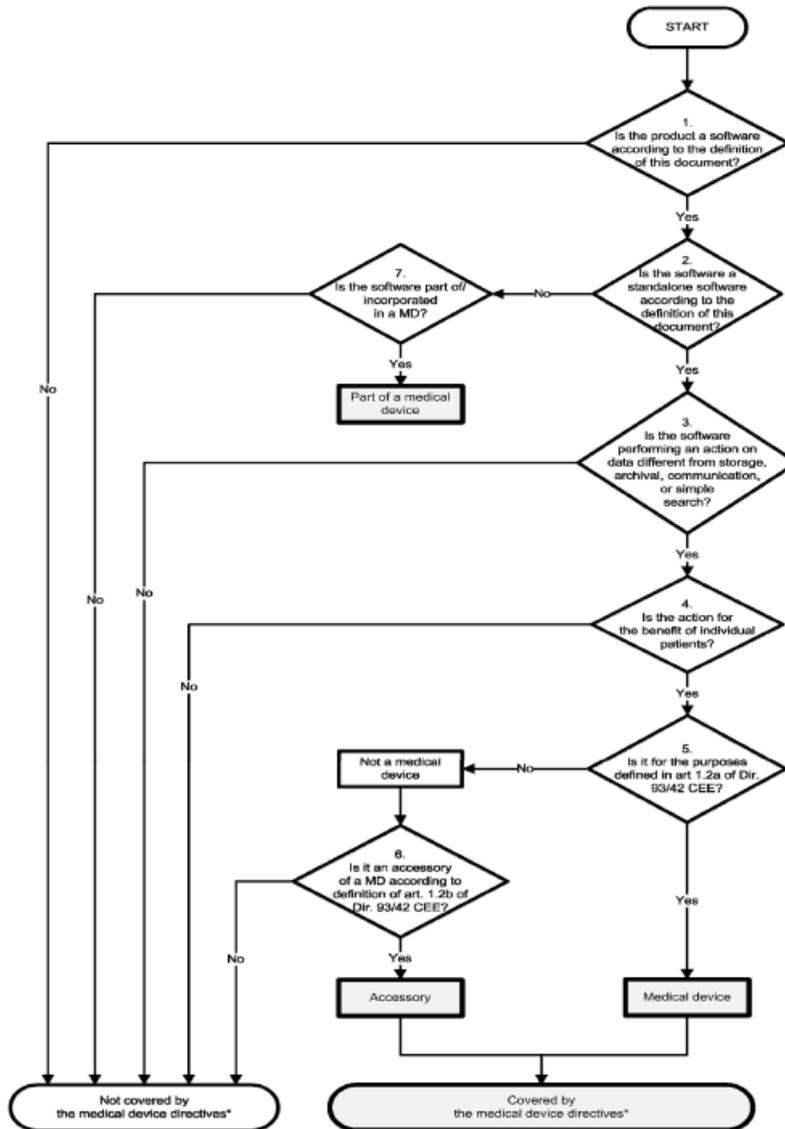

Figure 1: A decision diagram to assist qualification of software as medical device

Annex 3: full table of medical areas

Full table of medical areas of apps, for which a shorter version is included as table 3.2.

Medical areas of the app	All apps	Only medical devices
Skin	36	6
Miscellaneous	35	1
Cardiac system	34	20
Mental health	28	4
Sleep	22	2
Pregnancy	21	2
Diabetes	19	5
Smoking	14	-
Lung diseases	11	-
Gastro-entomological diseases	10	1
Cancer	5	-
Chronic diseases	5	1
COPD	4	-
Dementia	4	2
Hearing	3	3
Balance management	2	1
Eyes	2	1
Liver	2	2
Neurology	2	1
(De)hydration	1	-
Allergies	1	-
Intravenous injections	1	1
Life style	1	-
Logopedics	1	-
Musculoskeletal system	1	-
Oral system	1	1
Pain management	1	1
Reanimation	1	-
Temperature	1	1
Thrombosis	1	-
Urinary system	1	-