COCIR Impact Paper

Medical Device Regulation
Medical Software

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COCIR

SUSTAINABLE COMPETENCE IN ADVANCING **HEALTHCARE**

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

FOR COCIR MEMBERS ONLY

This document deals with software as a medical device (standalone) as well as software in a medical device (embedded). It contains an executive summary for senior management and a detailed analysis of the Medical Device Regulation (MDR), as published in the OJEU on 5 May 2017, for quality assessment and regulatory affairs purposes. The analysis provides information on the legislative modifications compared to the Medical Device Directive (MDD), an interpretation of the relevant articles as well as recommendations for COCIR member companies.

Please note that this COCIR Impact Paper suggests general recommendations only due to differences between companies.

Relevant articles are the following:

Article 2	Definitions
Article 6	Distance sales
Article 13	General obligations of importers
Article 14	General obligations of distributors
Article 25	Identification within the supply chain
Annex I	General Safety and Performance Requirements 14.2, 17, 23.4ab
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Executive Summary

The Medical Device Regulation (MDR) causes software to fall in higher classes than under the Medical Device Directive (MDD). Class I is reserved for products without medical purposes (products without medical purposes were added to the scope of the MDR; software may be an accessory of such products; e.g. video game software accompanying implanted electrodes for brain stimulation). All software with medical purposes falls in the higher classes. This has major implications for manufacturers that place class I software on the market under the current MDD as they will now need to engage with notified bodies, rather than rely on self-certification of their software. This may have significant implications in terms of cost and time-to-market, especially as notified bodies are in short demand. Manufacturers who find that their software has been up-classified into class III are advised to make clear agreements with regards to the notified body review process to assure their urgent security and safety patches can be deployed in time.

The medical device definition changed. This however has **no impact regarding what software qualifies as a medical device**, i.e., software which today is considered a medical device under the MDD is also considered a medical device under the MDR, and vice versa; if it is not considered a medical device under the MDD, it will not be considered one under the MDR. (Article 2 Definitions). The MDR however does not just apply to medical devices. New is that **the MDR also applies to products without medical purposes, including to software** (e.g. video game software accompanying equipment to apply electrical currents that penetrate the cranium to modify neuronal activity in the brain for pleasure seeking); Article 1(2) and Annex XVI).

The MDR causes software to fall in higher classes than under the MDD. A new classification Rule 11 was introduced, dedicated to software products. Unfortunately, the rule is fundamentally flawed. (1) **Only software without medical purposes can fall in class I**. **Software with medical purposes falls in higher classes.** (2) The rule classifies based on severity of harm, with no regard of probability of harm. The classification of software may therefore not correlate well with the risk it poses. (3) The interpretation of the rule is problematic. COCIR recommends stakeholders to align following COCIR's interpretation (to be developed) in anticipation of an interpretative guidance or delegated act to be developed by the European Commission Software Expert Work Group (MDR Annex VIII Classification Rules)

Medical software is subject to the MDR regardless of whether it operates in the cloud or is based on a server outside of the European Union. As long as it is intended to provide information used in the context of diagnostic or therapeutic services to persons established in the European Union, then, that software must comply with the MDR (Article 6 Distance sales). New is that companies importing software services in the Union must now have a legal entity established in the Union and meet the importer requirements (Article 13).

Under the MDD, competent authorities had few means to enforce regulations on app developers based outside the EU. Under the Medical Device Regulation, however, competent authorities can now also address the app store to remove a non-compliant app from the market. **App stores now need to register with the authorities as distributor or importer of medical device apps**. **They need to assure they only place compliant apps on the market and they must inform the authorities if they become aware of serious risks related to the app, e.g. via app reviews or discussion forums.** Some app stores may consider the regulatory burden too high to continue distributing or importing medical apps. COCIR recommends that manufacturers that place in app stores consider the risk of some of these distribution channels becoming obsolete or changing their conditions and consider making their apps available on their website instead (Article 13 General obligations of importers, Article 14 General obligations of distributors; Addendum V).

COCIR recommends manufacturers to analyse the impact of GSPR 14.2 and 17. These requirements are specific to software and demand a manufacturer to **manage (1) security and (2) the impact of the IT platform** it is installed on: (1) manufacturers should consider certification against IEC 27001 and implementation of IEC 82304 to address information security and (2) assure they have managed and documented the impact on product performance and safety by elements such as low Wi-Fi signal strength, network speed bottlenecks, and low batteries, and they must document how their app handles incoming phone calls or deals with low memory or the impact of other applications changing aspects like the display brightness if these aspects are critical to safety and performance. In that respect manufacturers should consider compliance against IEC 82304 to address immunity or susceptibility to unintended influences. (Annex I General Safety and Performance Requirements).

Detailed Analysis

MDR	MDD-MDR Modification	COCIR interpretation	COCIR recommendation
1. Article 2 – Definitions			
'medical device' *means 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*	The medical device definition was changed. The words "prediction" and "prognosis" were added in relation to disease (first bullet), but not in relation to injury or disability (second bullet).	The words "prediction" and "prognosis" were added in order to clarify the word "diagnosis," rather than to distinguish it as distinct, mutually exclusive purposes in the spectrum of healthcare provision purposes. That these terms were added in relation to disease, but not in relation to injury or disability, does not imply that software for the prognosis or prediction of an injury or disability, rather than a disease, should not be considered a medical device. Software which today is considered a medical device under the Medical Device Directive (MDD) is also considered a medical device under the Medical Device Regulation (MDR), and vice versa: if it is not considered a medical device under the MDD, it will not be considered one under the MDR. Caveat: the scope of the MDR extends to products without medical purposes (see Annex XVI). Software can be part of or be an accessory of such non-medical software (for a discussion on the topic see the related COCIR Addendum).	Manufacturers should update their internal glossary with the new definition of medical device. Apply the definition as if the word "prediction" and "diagnosis" also applies in relation to injury or disability. Examples of software for the prediction or prognosis of an injury or disability: <u>Example 1</u> Software for the *prediction* of hip fracture due to osteoporosis, is considered to meet the definition of a medical device. This software predicts the risk of bone fracture based on a combination of bone density values, weight, age and other parameters. <u>Example 2</u> Software to make a *prognosis* of the need for hip arthroplasty based on hip wear measurements using digital images. This software is considered to meet the definition of a medical device. <u>Example 3</u> Software to *predict* stroke based on stenosis measurement using digital images. This software is considered to meet the definition of a medical device.

MDR	MDD-MDR Modification	COCIR interpretation	COCIR recommendation
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' *means 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);*	The accessory definition was refined and now includes an extra condition: "to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);"	In a world of interconnected software where the output of one software application serves as input to another software application the term "accessory" is challenging. COCIR interprets the term "specifically" to mean that it is up to software manufacturers to declare when a software is an accessory of a hardware or another software. This interpretation aligns with the modular principle employed today in MEDDEV 2.1/6, i.e., it is up to software manufacturers to define where the boundaries of their software application are situated, i.e., when one software is an accessory or part of another.	Manufacturers should update their internal glossary with the new definition of accessory. It is up to the manufacturer to define where one software application stops and the other begins. This means that it is up to the manufacturer to determine when software is an accessory of other software or a hardware device. Examples: 1. A general purpose mobile phone is not an accessory of the medical app running on it, even if the manufacturer claims the medical app is compatible with that type of phone. 2. A Hospital Information System (HIS) that manages the workflow and organizes the data management of its modules is not an accessory of the Intensive Care Unit (ICU) software running on the HIS, except if the HIS manufacturer declares it an accessory of the ICU software. 3. A rules engine is not an accessory of the intensive care unit software relying on it, unless if the manufacturer claims it to be an accessory of the ICU software.
"system" *means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose*	The MDR introduces a definition for system, where previously the MDD and related guidance lacked one. The requirements for systems are similar in MDD and MDR.	It is not sufficient for two software programs to be connected, interoperable or safe to use together to be considered a system in the regulatory meaning of the term. To be considered a system two combined software programs must act together (there has to be a functional	Manufacturers to add the definition of "system" to their internal glossary and update the statement bearing the CE marking of the system so it refers to the MDR rather than the MDD.

MDR	MDD-MDR Modification	COCIR interpretation	COCIR recommendation
		synergy) to achieve a specific, overarching medical purpose. Two connected or interoperable software programs each fulfilling (without needing functional synergy to do so) their own intended purpose are therefore not considered a system. The software programs must act together to fulfil a specific, overarching medical purpose. In other words: the whole must be greater than the sum of the parts. If the combination of different software programs meets the definition of "system" then the integrator must meet the obligations of MDR Article 22, i.e., draw up a statement bearing a CE marking, similar as under the MDD.	
*(33) '**importer**' means any natural or legal person established within the Union who places a device from a third country on the Union market;* *(34) '**distributor**' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market, up until the point of putting into service;* **Article 13 General obligations of importers** **Article 14 General obligations of distributors** **Article 25 Identification within the supply chain**	Definitions for distributor and importer were introduced. New requirements were added for distributors and importers with regards to registration on the Union market, labelling, complaint handling, vigilance and traceability.	App stores and website owners offering medical apps on the Union market are considered distributors or importers and are therefore subject to the MDR. See the related COCIR Addendum for a discussion on the definitions of distributor and importer and on how these relate to app stores, website owners and Internet Service Providers. See the related COCIR Addendum for a requirement checklist intended for distributors and importers of software medical devices.	Manufacturers should add to their internal glossary the definition of importer and distributor. Companies acting as distributors or importers of third party products should implement the checklist (see related COCIR Addendum) in their quality system to demonstrate they meet the distributor or importer requirements. App stores are subject to MDR distributor and potentially importer requirements if they distribute medical apps. Some app may no longer wish to offer medical apps or revise their conditions with regards to the distribution of such apps on the Union market. COCIR recommends that manufacturers that rely on app stores for the distribution of their medical apps closely monitor the app store plans.

MDR	MDD-MDR Modification	COCIR interpretation	COCIR recommendation
2. Article 6 – Distance Sales			
1. ***A device offered by means of information society services****, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.* 2. *Without prejudice to national law regarding the exercise of the medical profession, **a device that is not placed on the market** but used in the context of a commercial activity, whether in return for payment or free of charge, for the **provision of a diagnostic or therapeutic service offered by means of information society services** as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 or by other means of communication, **directly or through intermediaries**, to a natural or legal person established in the Union shall comply with this Regulation.* Article 1(1) of Directive 2015/1535 says: *(b) 'service' means any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.* *For the purposes of this definition:* *(i) 'at a distance' means that the service is provided without the parties being simultaneously present;* *(ii) 'by electronic means' means that **the service** is sent initially and*	Information society services refers to a.o. services provided by means of cloud computing. MDR Article 2(1) implies that medical device software placed on the European market must comply with MDR. Art 6 and specifies that **software not placed on the European market must also comply with the MDR** if offered, directly or through intermediaries, to a person established in the Union. This concept was already present under the MDD, but not explicitly worded. The MDR not only describes it explicitly, it also broadens the concept. Now, under the MDR, software should not even be directly accessible through a portal to be considered subject to the regulation. It is sufficient for an intermediary to provide the software indirectly to a person established in the Union.	COCIR interprets "software offered through intermediaries" as applying to software accessible through web portals, application interfaces, but also people. COCIR interprets "a person established in the Union" as a citizen of the Union or somebody with a residence permit. This article impacts medical device software which resides in the cloud. If such software operates on servers outside the Union, but is accessible through a web portal in the Union, it must comply with the MDR. See the COCIR Addendum for a more elaborate discussion on the interpretation.	COCIR recommends that the manufacturer's webmasters carefully control in which countries they give their users access to their cloud based software. Making medical software accessible on the web without proper regulatory certification can be considered a violation of the regulation. COCIR also recommends that companies add a caution to their labelling to indicate the software or its output is not intended to be offered to persons established in the Union until product certification is finalized. E.g. "Pending CE-certification this product must not be used clinically by persons established in the EU". This is similar as the "pending 510(k) clearance" or "pending FDA approval" cautions added to products not yet available on the US market for use in clinical practice.

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received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means; *'at the individual request of a recipient of services' means that the service is provided through the transmission of data on individual request.*			

3. Annex VIII Chapter III Classification Rules

Chapter II Implementing Rule 3.3
Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.

Active devices 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

The MDR introduces a classification rule dedicated to software products.

Implementing Rule 2.3 (now 3.3) was changed. A second sentence referring to the independence of software was added so it reads:

"Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right."

While Rule 11 is intended for software products, the other rules for the classification of active devices must also be considered. If more than one rule applies the strictest rule must be used, i.e., the highest class must be attributed.

Software which drives or influences the use of a device falls in the same class of that device, software that is independent of any other device, must be classified in its own right. What this means and how these implementing rules relate to implementing Rule 3.3 will be elaborated in a COCIR interpretation paper.

Class I is reserved for software which does NOT provide information intended for diagnostic or treatment decisions, i.e., software that is not a medical device, but part of or an accessory of a non-medical product listed in Annex XVI. E.g. software for the planning of surgical interventions with cosmetic purposes.

Decisions must be interpreted as decisions made by users, software or hardware.

Except for software without medical purposes all other software that meets the definition of a medical device ends in a class higher than I and therefore will require a notified body before it can be placed on the market. COCIR advises medical software manufacturers to search and engage with a notified body if they don't have one yet.

Note that today manufacturers of class I software self-certify their product to bring it on the market. Due to more software falling in the higher classes **many software manufacturers will for the first time need a notified body** before they can bring their product on the market; this brings a significant increase in regulatory burden and may negatively impact time to market and cost. Furthermore, **smaller companies may find it particularly hard to hire a notified body** as their numbers have significantly dwindled over the last few years, and are expected to decrease further. The notified bodies that remain are often at the limit of their capacity, some even no longer accepting new

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to the patient, in which case it is classified as class IIb.		COCIR is currently developing further guidance on classification of software.	customers. Notified bodies need to have in-house expertise to handle particular products. Many notified bodies are revising their portfolio and are in the process of hiring medical professionals for those products they wish to handle under the MDR. Manufacturers should ask their notified body if it plans to handle software under the MDR. Also, if under the MDR a manufacturer ends up with Class III software then it should **make clear agreements with its notified body to assure it has a review process in place that is sufficiently quick, so urgent security and safety patches can get to the field in time.**
4. Annex I General Safety and Performance Requirements			
*14.2(d) the risks associated with the possible negative interaction between software and the **IT environment** within which it operates and interacts;* *17. Electronic programmable systems – devices that incorporate electronic programmable systems and software that are devices in themselves* *17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to assure **repeatability, reliability** and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.* *17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in*	The MDR adds many new General Safety and Performance Requirements (GSPR), of which the requirements 14.2(d), 17 and 23.4(ab) relate specifically to software. COCIR recommends software manufacturers to evaluate the impact of all GSPR, not just those specific to software.	These requirements pertain to security, the effects of hardware, the IT platform and the network on which the software operates and its use environment. Manufacturers must consider elements such as IT network speed bottlenecks, communication latency, low Wi-Fi signal strength, battery life, handling of exceptions caused by other applications (such as an incoming phone call), low-memory errors, display/backlight setting changes by other applications, accuracy of users entering data or performing measurements using touch screens, liquid dropping on touch screens and activating functionality, security, mobile use, et. if these elements can impact the safety or performance of their software.	Manufacturers must consider the new requirements during the design and development of their software and inform the user of ways to further reduce the impact of the IT platform and network, security issues and hardware on the safety and performance of the software. COCIR recommends manufacturers to implement: - EN ISO 14971:2012 Medical devices. Application of risk management to medical devices. - IEC 82304-1:2016 Health software – Part 1: General requirements for product safety - IEC 27001:2013 Information technology security techniques

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*accordance with the state of the art taking into account the principles of development life cycle, risk management, including **information security**, verification and validation.* *23.4. (ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning **hardware, IT networks characteristics and IT security measures**, including protection against unauthorized access, necessary to run the software as intended.*			

Addendum I
Life-style and Well-Being Apps

1. Life-Style and Well-Being Apps

Life-style and well-being apps are generally not considered medical devices. Whether such a software qualifies as a medical device depends on the intended use and the claims made by the manufacturer, not on how the software may be misused or on whether the information provided by the software is stored in an electronic patient file.

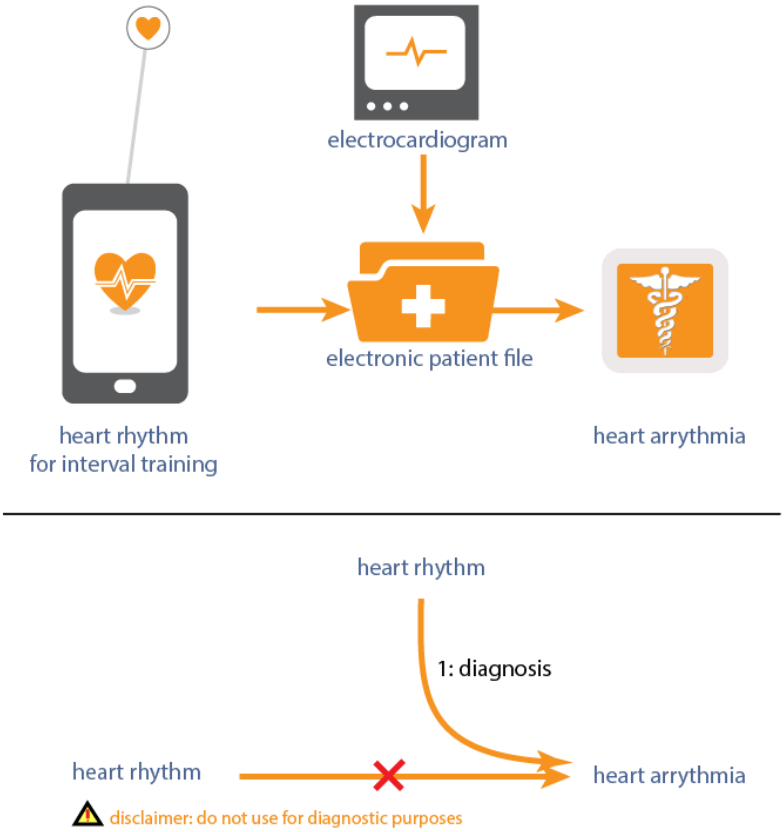

Figure 2: Electrocardiogram software is intended to detect heart arrhythmia. Users could misuse software measuring the heart rhythm for interval training for that same medical purpose. Whether the interval training software is a medical device however depends on its claims and intended use, not on how it can be misused or on whether the software output is stored in the electronic patient file. COCIR advises manufacturers to make their claims clear, concise and persistent throughout their advertising, user manuals and other publications. COCIR also recommends manufacturers to protect their liability by providing a clear disclaimer against reasonable foreseeable misuse, e.g. Warning: do not use for diagnostic or therapeutic purposes. Figure ©Koen Cobbaert/Creative Commons/CC-BY-SA-3.0

Software intended to monitor life-style choices, and encourage a person to maintain a general state of health or healthy activity does not qualify as a medical device. Wellness software that comes with diagnostic and treatment claims, e.g. for the diagnosis, prevention or treatment of specific diseases or medical conditions, is considered a medical device in the European Union.

Note: Software for the prevention or treatment of certain chronic diseases or conditions by monitoring and influencing life-style choices, is considered a medical device per the MDR even if it may not be considered a medical device in the United States[1] and elsewhere.

[1] FDA Guidance on General Wellness: Policy for Low Risk Devices. July 29, 2016.

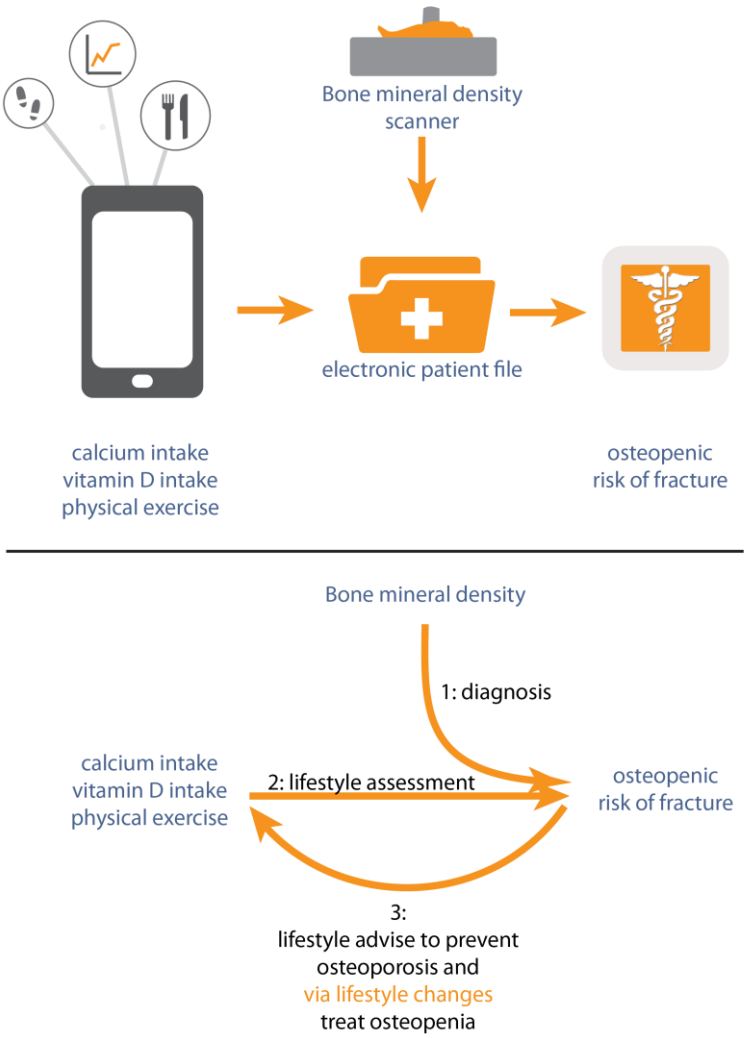

Figure 3: during the provision of healthcare to an osteopenic patient, the doctor (1) diagnoses osteopenia based on how the patient's bone mineral density compares to that of a reference population. The doctor then (2) consults the information provided by a life-style tracking app intended to document and monitor calcium intake, vitamin D intake and physical exercise in order (3) to provide life-style advice to prevent the patient osteopenia worsening into osteoporosis and to bring the patient's bone mineral density up to normal levels. The doctor does not use the information provided by the life-style app for diagnostic purposes (osteopenia is diagnosed using bone mineral density instead). The doctor uses the information provided by the life-style tracking app to analyse the life-style of the patient and give life-style advice (as per the intended use of the app). The doctor's aim of this life-style advice is to treat the patient. Despite treatment being a purpose listed in the medical device definition, the life-style tracking app does not qualify as a medical device as it is only intended to document life-style changes and give patient advice to what healthy levels of calcium intake, vitamin D intake and physical exercise are. The manufacturer took care for the life-style tracking app not to come with any claims about treatment or diagnosis of any specific disease or medical condition like osteopenia or osteoporosis. If the manufacturer would have claimed the app is intended to give the patient specific guidance on what healthy levels are of calcium and vitamin D intake to get a osteopenic bone densities back to normal again or if the app gives the patient exercises specifically to treat osteopenia, then the app qualifies as a medical device as the claims are linked directly to a specific disease, rather than a general healthy lifestyle. © Koen Cobbaert/Creative Commons/CC-BY-SA-3.0

2. Summary

Not medical devices	Life-style or wellness software intended to maintain and encourage a general state of health or healthy activity - These apps do not reference diseases or conditions - E.g. weight management, sleep management, physical fitness, relaxation, stress management, recreation, mental acuity, self-esteem tools
While not considered medical devices in the US, these may be considered medical devices in the EU.	Life-style or wellness software intended to reduce risk or impact of certain chronic diseases or conditions - These apps reference diseases or conditions - Are not intended to diagnose these diseases or conditions - Are intended to monitor and influence life-style choices - E.g. to reduce heart disease, high blood pressure, prevent diabetes in pre-diabetic patients

Addendum II
Software Accessories and Systems Definitions

1. Articles

MDD Art. 1 "accessory"	MDR Art. 2 "accessory for a medical device"	MDR Art. 2(11) "system"
An article which while 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;	An article which, whilst **[Condition 1]** not being itself a medical device, is **[Condition 2a]** 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 **[Condition 2b]** to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s); Note: Compared to the MDD the accessory definition was reworded and **[Condition 2b]** was added.	A combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose Note: Compared to the MDD the system definition was added.

2. Interpretation of 'accessory'

[Condition 1]: The product is not a medical device in its own right

Software: The medical device definition changes introduced by the MDR have no significant impact for software, therefore the interpretation provided by MEDDEV 2.1/6 broadly stands: software is a medical device in its own right when it is (1) not put on the market as part of a medical device and (2) provides information intended to be used for one or more medical purposes, except if its functionality is limited to store, communicate or simple search.

Software platforms: general purpose mobile phones and information technology platforms are not medical devices as they come with no medical claims.

[Condition 2]: The product is intended to [2a] specifically enable or [2b] specifically and directly assists a medical device to fulfil its intended purpose.

> COCIR interprets "**intended**" as referring to the claims made by the manufacturer, i.e., it is up to the software manufacturer to define the purpose of the software, i.e., to define whether software is an accessory of another medical device or not.

In other words: software is only an accessory of a medical device if the manufacturer claims it to be an accessory of that device.

The claim must only be made if the software "specifically enables" or "specifically and directly assists" the medical device to fulfil its intended purpose. In the software context, these terms may relate to software providing information, functionality, processing power, memory, user or other interface so the medical device can fulfil its intended use.

Claiming that a software is compatible or interoperable with a platform does not make the platform an accessory of that software. IT hardware, operating systems, IT platforms, databases, workflow engines, dynamic link libraries, rules engines etc. are often needed for medical software to operate and fulfil one or more medical purposes. Only when the manufacturer claims it is an accessory of a medical device, is it an accessory.

2.1 Accessory examples

Example 1 Virus scanner software for a medical device

[Condition 1] The virus scanner is not a medical device in its own right. Condition 1 is not met.

[Condition 2] The virus scanner is intended to ensure the medical device is free of viruses. The virus scanner does not directly enable or assist the medical device to fulfil its intended purpose. **Neither the virus scanner nor the medical device manufacturer claims the virus scanner is an accessory of the medical application**. Condition 2 is not met.

Conclusion: the virus scanner is NOT an accessory of the medical software it operates in conjunction with.

Example 2 Smart phone running a medical app

[Condition 1] The smart photo is not a medical device in its own right. Condition 1 is met.

[Condition 2] The manufacturer of the medical app makes no claims that the phone is intended to specifically enable or directly assist medical device apps. The manufacturer of the medical app tested the phone under varying light levels and claims that the smart phone provides an image quality that is adequate to use the application for diagnostic purposes. **Neither the smart phone nor the medical application manufacturer claims the smart phone to be an accessory of the medical application**. Condition 2 is not met.

Conclusion: the smart phone is NOT an accessory of the medical software operating it.

Note: as per Annex I General Safety and Performance Requirement 17, the manufacturer remains responsible to assure the medical device software safety and performance in light of the smart phone influence on the medical device software.

Example 3 An operating system or web browser able to run a medical app

A medical app can be used in several types of operating systems and web browsers.

[Condition 1] Operating systems and web browsers typically are general purpose products, not medical devices. Condition 1 is met.

[Condition 2] The manufacturer of the operating system makes no specific claims as to which medical software can be used with it. The web browser manufacturer on the other hand offers the medical app in its app store, claiming it is compatible with its web browser. The medical app manufacturer claims the

medical application is capable of running on a specific operating system and web browser. **None of the manufacturers however claim that the web browser or operating system are accessories to the medical application.** Condition 2 is not met.

Conclusion: the operating system and the web browser are NOT accessories of the medical device software operating it.

Note: as per Annex I General Safety and Performance Requirement 17, the manufacturer remains responsible to assure the medical device software safety and performance in light of the web browser influence on the medical app.

Example 4 The hospital information system and the intensive care unit software running on it

A manufacturer makes a Hospital Information System (HIS). The HIS drives workflow and organizes data. It contains specific modules for accounting, stock management, bed occupation management, etc. as well as a few modules with medical device functionality.

[Condition 1] The HIS is not a medical device in so far as its functionality is limited to driving workflow and organising data. Condition 1 is met.

[Condition 2] The HIS specifically enables or directly assists the ICU software to fulfil its intended purpose. The manufacturer claims interoperability, **but does not claim the HIS is an accessory of the ICU software**. Condition 2 is not met. If the manufacturer claims the HIS is an accessory of the ICU software, then condition 2 is met.

Conclusion: the HIS is NOT an accessory of the ICU software, UNLESS the manufacturer claims the HIS is an accessory of the ICU software.

Note: as per Annex I General Safety and Performance Requirement 17, the manufacturer remains responsible to assure the medical device software safety and performance in light of the HIS influence on the medical device software.

Example 5 Rules engine used by intensive care unit software

A rules engine module is embedded in a Hospital Information System (HIS). The rules engine is used by several other modules of the HIS, e.g., to calculate reimbursement schemes, to make appointments, to handle resources, etc. It is also used by Intensive Care Unit (ICU) software to enable its medical functionality. The HIS, rules engine and ICU software are made by the same manufacturer.

[Condition 1] The rules engine is not a medical device as it does not come with any specific medical claims. Condition 1 is met.

[Condition 2] The rules engine enables the ICU software to fulfil its intended purpose. It is not an accessory of the ICU software, **unless the manufacturer claims it to be an accessory.**

Conclusion: the rules engine is NOT an accessory of the ICU software, UNLESS the manufacturer claims the rules engine is an accessory of the ICU software.

Note: as per Annex I General Safety and Performance Requirement 17, the manufacturer remains responsible to assure the medical device software safety and performance in light of the rules engine influence on the medical device software.

3. Interpretation of 'system'

The MDR introduces a definition for system, where previously the MDD and related guidance lacked one:

MDR Art. 2(11) "System" means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose.

If the combination of different software programs meets the definition of "system," then the integrator of these software programs must meet the obligations of MDR Article 22, i.e., draw up a statement bearing a CE marking. This requirement is similar to MDD Article 12.

> COCIR interprets a **software system** as two or more combined software programs that act together (there must be a functional linkage) to achieve a specific, overarching medical purpose that is greater or different from the intended purpose of the individual products.

Figure 4: Integrators install medical device software on IT platforms that are or are not medical devices in their own right. Integrators also connect different software products to assure the right information is available to the right user at the right time in the clinical workflow. The act of connecting these software applications does not necessarily mean the combined whole is considered a system in the regulatory meaning of the term. © User: Yorge25/Wikimedia Commons/CC-BY-SA-3.0

It is not sufficient for two software programs to be connected, interoperable or safe to use together to be considered a system in the regulatory meaning of the term.

Two connected or interoperable software programs each fulfilling their own intended purpose (but not functionally linked to together to meet a specific, overarching medical purpose) are therefore not considered a system. In other words: the whole must be greater than the sum of the parts, or the intended use arising from the combination of these products must be more or different than the intended use of the individual products.

3.1 Examples

Example 1 Melanoma detection software on an operating system

An integrator installs melanoma detection software on a general-purpose operating system. The melanoma software is intended for diagnosis, the operating system for general use. No new intended use or indications for use arise from the combination of the software program on the operating system. In terms of intended purpose the whole is not greater or different than the sum of the parts. The combination is not a system.

Example 2 CAD engine plugin for a PACS

An integrator embeds a computer aided detection (CAD) plugin onto a Picture Archiving System (PACS). The PACS system is intended for (1) general diagnosis. The CAD engine is intended for (2) mammography screening. The combination of these two software products is intended for (1) general diagnosis & (2) mammography screening. No new, different or more specific intended use or

indications for use arise from the combination of the two products. The PACS system first displays the image for diagnostic purposes, the CAD plugin then identifies the tumour. In terms of intended purpose the whole is not greater or different than the sum of its parts. The combination is not a system.

Example 3 Rules engine connected to a clinical knowledge database

An integrator connects a programmable general purpose rules engine that operates on a Hospital Information System (HIS) with a knowledge database with domain specific information and in doing so creates a clinical decision support and reporting tool. The rules engine is intended for (1) general purposes. The knowledge database is intended for (2) clinical reference purposes, similar as a medical handbook. The combination matches patient information with information from the knowledge database and (3) proposes the medical professional with diagnostic pathways (differential diagnosis) for individual patients. The combination provides for a new intended purpose, because contrary to the knowledge database which contains generic clinical information, the combined product can now be used to the benefit of individual patients. The combination meets the definition of a system. Note that in this example neither the rules engine nor the knowledge database in themselves are medical devices.

Addendum III
Software as a Service and Cloud Computing
Definitions and Requirements

1. MDR Article 6 Distance Sales | MDR Article 6

1. **A device offered by means of information society services**, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.
2. Without prejudice to national law regarding the exercise of the medical profession, **a device that is not placed on the market** but used in the context of a commercial activity, whether in return for payment or free of charge, **for the provision of a diagnostic or therapeutic service offered by means of information society services** as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 or by other means of communication, **directly or through intermediaries**, to a natural or legal person established in the Union shall comply with this Regulation.

2. Directive 2015/1535 Information Society Services | Article 1(1)

(b) 'Service' means any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

For the purposes of this definition:

[…]

'at a distance' means that the service is provided without the parties being simultaneously present;

'by electronic means' means that **the service** is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means;

'at the individual request of a recipient of services' means that the service is provided through the transmission of data on individual request.

3. Interpretation

MDR Article 2(1) implies that **medical device software placed on the European market must comply with the MDR.** Article 6 adds that **software not placed on the European market must also comply with the MDR** if offered, directly or through intermediaries, to a person established in the Union.

> COCIR interprets "**software offered through intermediaries**" as applying to software accessible through web portals, application interfaces, but also people. COCIR interprets "**a person established in the Union**" as a citizen of the Union or somebody with a residence permit.

This article impacts medical device software which resides in the cloud. If such software operates on servers based outside the Union, but accessible, through for example a web portal, to a person present in the European market then it must comply with the MDR. It does not matter if the portal is a separate product, a medical device or not a medical device. It suffices for the software on the server to be a medical device and intended to be accessed from within the Union, through electronic means or intermediaries, for it being subject to the MDR.

Figure 5: Information services may be provided by software hosted on servers located outside the Union. This image serves as an illustration to the examples provided below. © Koen Cobbaert/Creative Commons/ CC-BY-SA-3.0

Example 1 Software on a US server accessible from within the Union – MDR applies

Heart function analysis software operates on a server in the US. The software is connected to a smart phone carried by a European citizen present in the European Union. By reading sensor data, the application can tell when a person is about to suffer cardiac arrest. The software automatically alerts the patient, nearby medical professional and the patient's family.

Conclusion: the medical device software operates on a server outside the Union, but is intended to be used by a person established in the Union. A person can access the software from within the Union through a web portal or other electronic means. The software must comply with the MDR.

Medical device software residing outside the Union is already regulated under the MDD if it is accessible via electronic means. The concept is already today applicable under MDD through the use of the words 'placing on the market' and 'putting into service'.

> 'Placing on the market' is a legal term; it does not require physical placing on the market. It means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished. (MDD Article 1(h))
>
> 'Putting into service' refers to the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose. (MDD Article 1(i))

In MDR Article 6 the concept is now described more explicitly and the scope was broadened. The software should not even be directly accessible through portals to be considered subject to the regulation. It is sufficient for an intermediary to provide the software to a person established in the Union.

Example 2 Software on a Chinese server accessible via an Australian doctor – MDR applies

A European cancer patient sends his/her x-ray exam to a qualified Australian doctor. The doctor sends that x-ray exam to a software application hosted on a server in China. The software analyses the x-ray exam. The software generates a report with recommendations to adapt chemotherapy. A qualified Australian doctor forwards that information to the person established in the Union and provides additional medical consulting based on the outcome of that report. The medical device software operating on the server in China, with its portal accessible in Australia, but not in Europe, must comply with MDR as the service offered by the software is offered through an intermediary to a person established in the Union.

Note that national law often limits the exercise of the medical profession to those doctors that are qualified in that country. The above example assumes the Australian doctor is qualified to exercise the medical profession in the country of the cancer patient.

The MDR subjects software services to the same requirements as medical devices, therefore MDR requirements for importers also apply to importers of medical software services (see COCIR Addendum related to distributors, importers and their requirements). The importer definition (MDR Article 2(33)) implies that **the legal entity of an importer of medical software services must be established in the Union**, regardless of whether the software providing a web service is hosted on a server located in or outside the Union. Note that software services can be distributed from a server based outside the Union if an importer established in the Union is identified on the labelling (see related COCIR Addendum for a discussion on distributors and importers).

Companies are at risk of enforcement action if intermediaries offer their not (yet) compliant software to persons established in the Union. **COCIR recommends that company webmasters limit access to those countries in which their software service has been regulatory cleared or to add a caution to their labelling to indicate the software or its output is not intended to be offered to persons established in the Union until product certification is finalized.** E.g. "Pending CE-certification this product must not be used clinically by persons established in the European Union". This is similar as the "pending 510(k) clearance" or "pending FDA approval" cautions added to products not yet available on the US market for use in clinical practice.

Note that while the MDR intends to encompass software services, there is not necessarily a way to detect software services entering the European Market. It's not clear how competent authorities can enforce the regulation on software accessed by means of Virtual Private Networks that also change your IP address to one outside the Union, for software accessed via SmartDNS, a Tor browser or via a person through teleconference.

Example 3 Person travels outside the Union – MDR does NOT apply

A variant of example 1. A person established in the Union travels outside Europe for medical consultation or treatment. The person is diagnosed and treated using medical device software residing outside the Union. The medical device software does NOT need to comply with the MDR as the software service does not enter the Union market.

Example 4 Person enters the Union – MDR does apply

If an American citizen enters the Union and accesses the software via a software portal from within the Union, then that medical device software service is considered to have entered the Union and must comply with the MDR, even if used by a person not established in the Union.

Addendum IV
Software Related to a Non-Medical Product listed in MDR Annex XVI

1. Software and Annex XVI

Software without a medical purpose that is placed on the market as a product in its own right does not meet the definition of a medical device, nor does it meet any of the Annex XVI categories. Such software therefore is not subject to the MDR. However, software without a medical purpose can be part of or be an accessory of a product listed in Annex XVI. It is an accessory (Article 2(2)) if it specifically enables that product to be used in accordance with its intended purpose (e.g. software for the planning or execution of cosmetic surgical interventions). Such software is subject to the MDR.

Software that is an accessory of a product listed in Annex XVI must be classified in its own right, separately from the device with which it is used (Annex VIII Implementing Rule 2.2; consequently Rule 11: all other software must be considered class I), except if (Annex VIII Implementing Rule 2.3) such software drives or influences the use of such product, then it must be classified in the same class as the product. Note: for a discussion of the term accessory please see the related COCIR Addendum.

2. Examples

Example 1 Software as an accessory of an Annex XVI product

Software intended to plan cosmetic breast or lip augmentation surgery. Cosmetic breast or lip implants are examples of Annex XVI products without medical purposes. If the manufacturer determines the planning software to be an accessory of the breast or lip implant, then that software must be classified in its own right according to MDR Annex VIII Implementing Rule 2.2. In this case, the last paragraph of MDR Annex VIII Rule 11 applies (software providing information not for diagnostic, treatment or monitoring purposes). The software is class I.

Example 2 Software driving or influencing the use of an Annex XVI product

Software intended to drive or influence the use of stimulation equipment applying electrical currents that penetrate the cranium and modify neuronal activity for pleasure seeking purposes. This software is not a medical device, but an accessory or an integral part of an Annex XVI product category. As the software drives or influences the use of the equipment it must, if it is an accessory, be classified in the same class as the equipment, i.e., class III as per Rule 7. If it is an integral part, it does not require a separate CE-marking, but is considered part of the medical device.

Addendum V
General Obligations of app stores and website owners

1. Definitions | MDR Article 2

(27) '**making available on the market**' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(28) '**placing on the market**' means the first making available of a device, other than an investigational device, on the Union market;

(29) '**putting into service**' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(33) '**importer**' means any natural or legal person established within the Union who places a device from a third country on the Union market;

(34) '**distributor**' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market, up until the point of putting into service;

(35) '**economic operator**' means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3)

Note: Article 22(1) and (3) refer to "Natural or legal persons [that] combine devices bearing a CE marking" and "a natural or legal person who sterilises systems or procedure packs".

2. Interpretation

Distributors make a device available on the market, up until the point of putting it into service. In case of medical apps, the last economic operator is often the app store or the website owner providing the app for download. Usually the consumer puts the app into service by installing it. As app stores and website owners make the device available on the market they consequently meet the definition of distributor and are therefore subject to the distributor requirements (MDR Article 14). Contrary to importers distributors don't have to be established in the Union. A web store established in for example Australia, but accessible from within Europe, can therefore still be considered distributor in Europe.

Importers place a device from a third country on the Union market. Placing on the market is a legal term and does not require physical crossing of the border into the EU: it means the first making available of the software, i.e., the supply of the software for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. The supply chain of software is often very short, i.e., the app goes straight from software manufacturer into the app store or on a website and from there it can be downloaded or accessed by the consumer. This implies that if a software manufacturer is based outside the Union, that the app store or website owner is also importer of the software app in the Union. The importer requirements then apply (MDR Article 13).

Contrary to distributors importers have to be established in the Union. A web store established in for example Australia, is therefore not legally allowed to import a medical app in Europe. The importer's legal entity must be established in the Union.

There's a caveat: if an importer established in the Union places an app on the European market, then uploads it to an Australian app store from which it is downloaded by a user established in the Union, then that Australian app store is considered a distributor (not necessary an importer) and must not be established within the Union.

Some app stores may consider the regulatory burden too high to continue importing or distributing medical apps (see related COCIR Addendum for discussion on distributor and importer

requirements). COCIR recommends that manufacturers that distribute apps via an app store consider the risk that some of these apps stores may no longer wish to distribute medical apps or may wish to change their conditions for distribution of medical apps.

Note that the MDR subjects software services to the same requirements as medical devices (MDR Art. 6). The legal entity of the importer of software services must therefore also be established in the Union, regardless of whether the software providing a web service is hosted on a server located in or outside of the Union.

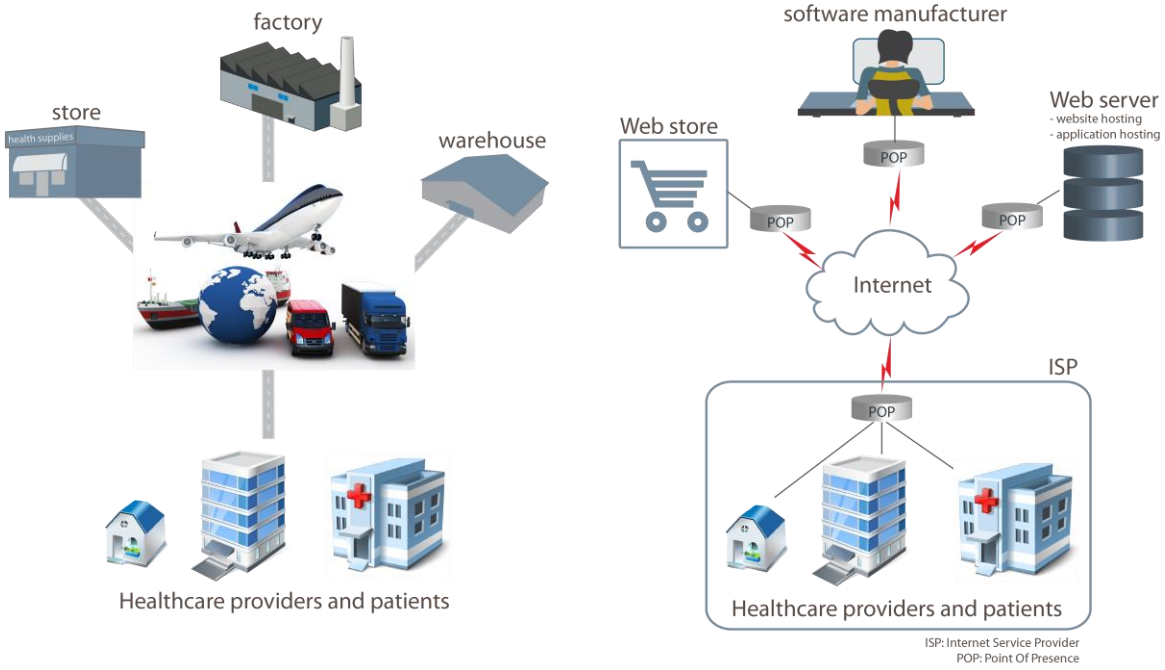

Figure 6: the distribution channel model is different for software than for traditional medical devices. On the left the model for traditional medical devices, on the right for medical software. Traceability has to be assured from manufacturer all the way to the health institution, healthcare professional, app store or website that makes the medical device software available. Traceability of medical software must not be assured to the patient. The aim is traceability of the distribution chain while respecting the privacy of the patient. © Koen Cobbaert/Creative Commons/CC-BY-SA-3.0

Before the app reaches the app store or the website from which it can be downloaded, the app may have been routed over many computers and networks, including those of the Internet Service Provider (ISP) that makes the web store or website available to the consumer for download on a smart phone or other IT platform. COCIR considers IT infrastructure providers such as ISPs to be the equivalent of the infrastructure managers of roads, railroads, ports, toll bridges and tunnels in the context of traditional medical devices. While the software travels over their network COCIR considers Internet Service Providers to NOT be subject to the MDR distributor or importer requirements.

Addendum VI
Requirements for Software Distributors and Importers

This checklist is intended for software distributors and importers. It lists their responsibilities as defined in MDR Article 13 and 14 and the referenced Article 10 and Annex I Section 23, and of Article 25 and 30. The requirements were aligned, interpreted and reworded to make them more specific to distributors and importers of software. Requirements not applicable to software were omitted.

#	Reference	Requirement	Importer	Distributor
1	Article 13.4	Register yourself in EUDAMED.	x	
2	Article 30.2	Register yourself (in EUDAMED?) if a Member State in which you put the software on the market has related national provisions. No provisions are known at the time of writing.		x
3	Article 13.1	Only place MDR compliant software on the market:	x	
4	Article 10.8 Article 13.2(a) Article 14.2(a)	- Verify whether the medical device software comes with an EU declaration of conformity and make sure you keep it available at least ten years after you placed the last software covered by the declaration on the market. On request provide it to competent authorities.	x	x
5	Article 14.2(b) Article 10(11) Annex I Section 23(b)	- Verify if product name or trade name and its build or release number are communicated via the About box, start-up screen or similar user interface.		x
6	Article 13.2(a) Article 13.2(b) Article 13.2(d) Article 14.2(a) Article 14.2(d)	- Verify if CE mark, manufacturer, authorized representative (if applicable) and Unique Device Identifier (UDI) are identified in the About box, start-up screen or similar user interface. It should be easy for the user to find this information.	x	x
7	Article 13.3 Article 14.2(c)	- Verify if importer name, registered trade mark and registered place of business and address at which importer can be contacted is identified the About box, start-up screen or similar user interface.	x	x
8	Article 13.2(c)	- Verify if the instructions for use are available. For class I and IIa software it is allowed that there are no instructions for use if the software can be used safely without.	x	
9	Article 14.2(b) Article 10.11	- Verify if the user interface and the instructions for use are available in an official language(s) of the Member State(s) where you place the software on the market; For class I and IIa software it is allowed that there are no instructions for use if the software can be used safely without.		X

10	Article 14.2 Article 10.11 Annex I Section 23	- Verify if intended purpose, intended users, their training requirements and qualifications, patient target group or groups, specifications of clinical benefits or the absence thereof, performance characteristics, limitations, contra-indications, undesirable side-effects, residual risks, precautions or warnings are communicated, as appropriate. - Verify if international symbols are used and explained, as appropriate. - Verify if class III software user documentation contains a link to the summary of safety and clinical performance. - Verify if the degree of accuracy is communicated if the software contains a measuring function. - Verify if minimum IT network, platform and hardware specifications are communicated as well as connectivity and interoperability characteristics. - Verify if information on known restrictions to combinations with other devices and equipment is communicated, as appropriate. - Verify if preparatory treatment/handling, configuration and calibration instructions and the frequency of calibration are communicated, as appropriate. - Verify if the details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection is communicated, as appropriate. - Verify if IT security measures, protection against unauthorized access are communicated, as appropriate, to assure the software can be used as intended. - If the software is intended to be used by lay persons, verify if the circumstances are communicated in which the user should consult a healthcare professional, as appropriate. - Verify if date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use is communicated. - Verify if the user and/or patient is notified that he/she should notify the manufacturer and the competent authority of the Member State in which the user and/or patient is established in case a serious incident has occurred in relation to the software.		x
11	Article 13.4	- Verify if the software is registered in EUDAMED	x	
12	Article 25.2	Keep a log available for at least ten years after you placed the last software on the market. The log must document the UDI of the software and any economic operator to whom you directly supplied the software, any economic operator who directly supplied you with software and any health institution or healthcare professional to which you have directly supplied a software. Note that patients are not considered	x	x

		economic operators (see MDR Article 2 (35)). The aim is traceability of the distribution chain while respecting patient privacy (traceability excluding the patient).		
13	Article 13.6 Article 14.5	Keep register of complaints, non-conforming software versions, recalls and withdrawals. If requested provide any information requested to the manufacturer, authorized representative, importer or distributor to allow them to investigate complaints.	x	x
14	Article 13.8 Article 14.5	Immediately inform manufacturer, authorized representative (if applicable) and importer if healthcare professionals, patients or users signal a suspected incident.	x	x
15	Article 13.2 Article 13.8 Article 14.2	Immediately inform authorized representative, manufacturer and importer if you have reason to believe software is not MDR compliant. Do not bring the software on the market until it is brought in compliance.	x	x
16	Article 13.7 Article 14.4	Cooperate with authorized representative, manufacturer and competent authorities to bring the software in conformity via an update, or by withdrawing or recalling the software. Keep manufacturer, authorized representative and importer informed of recalls and withdrawals so they can monitor progress. Provide them with any information upon their request, including information required to achieve an appropriate level of traceability.		
17	Article 13.2 Article 14.2	Inform competent authority of the Member State in which you are registered if you consider or have reason to believe that a software presents a serious risk, is falsified (false presentation of identity, CE-marking certificates or related) or is not MDR compliant. Give details of the issue and of any corrective action taken. On their request cooperate with competent authorities to eliminate or if not possible mitigate the risk of the software which you placed on the market.	x	x
18	Article 13.8	Related to the above immediately inform the notified body that issued the certificate.	x	
19	Article 13.10 Article 14.6	If requested by competent authority of the Member State where you are registered, then provide them the software free of charge or grant access to the software.	x	x

Addendum VII
Importers and distributors can have obligations that apply to manufacturers

In accordance to Article 16 you carry the obligations of manufacturer if you as importer or distributor:

1. make software available on the market under your own name, registered trade name or registered trade name except if you have an agreement with the manufacturer to do so and the manufacturer is identified in the About box, start-up screen or similar (**rebranding**)
2. If you change the intended use of the software (**making new claims**)
3. If you modify or configure the software in ways that go beyond the change permit, i.e., beyond what the manufacturer documentation allows for (**modifying or configuring for new uses**)

These requirements are new compared to the MDD.

Addendum VIII
Translations

Related to Article 16, if a distributor translates the user interface or information provided by the manufacturer (e.g. under his supervision), than this is not considered a modification. It does not bestow distributors, importers or other natural or legal persons with the manufacturer obligations. However, if a distributor or importer provides translations of user interface or information supplied by the manufacturer for the products they place on the market and make available, then

a) they need to have a quality system in place that, among others, assures the accuracy of these translations, and get it certified by a notified body
b) they need to list in the About box, the start-up screen or similar user interface your name, registered trade name or registered trade mark, registered place of business and the address at which you can be contacted
c) they need to inform the manufacturer and the competent authority of the Member State in which you plan to make the device available, and, upon request, provide them with a copy of or access to the translated software, instructions for use and your notified body certificate

These requirements are new compared to the MDD.

Addendum IX
Software Classification

Currently being developed
(target July 1, 2017)