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Impact of Class I Software as Medical Devices (SaMDs) on Public Health

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Abstract. There exist numerous low-risk class I SaMDs with CE marking under European Medical Device Directives (MDD). However, if the manufacturers will make any significant change to these class I SaMDs, the manufacturers shall comply with Medical Device Regulation (MDR) 2017/745 classifications. Class I SaMDs are self-declared without the need for notified body involvement. It is unclear how these devices are monitored if they will undergo any significant changes. Significant change may shift existing low-risk class I SaMDs to higher risk classification. In another hand, it is not clear if all class I SaMDs that are certified under MDD are registered with relevant EU Competent Authorities. Class I SaMDs may have an impact on public health if they are not known and monitored by European competent authorities.

Keywords. SaMDs, Risk, Public Threat.

1. Introduction

All manufacturers of medical devices are required to have CE mark certificates prior to marketing their devices in the European Union (EU) as per article 17 of MDD [1] and article 20 of MDR [2]. Medical devices CE mark certificates with high risk are gained through an organization called Notified Body (NB) as per article 11 of MDD [1] and 56 of MDR [2]. NB is designed by an EU Competent Authority (CA) to issue CE mark certificates for medical devices as per article 11 of MDD and article 35 of MDR [2]. Class I medical devices do not require the involvement of NB to issue a CE mark certificate as per the second paragraph on page 2 of MDD [1] and section (60) on page 8 of MDR [2].

Symptom checkers software are eHealth (online) care services that fall into the category of SaMDs under article 1 section 2 (a) MDD [1] and article 2 section (1) of MDR [2]. Symptom checkers are classified as class I medical devices. The focus of this paper is on eHealth care services symptom checkers that are certified as class I under MDD [1].

Research questions of this paper include 1) what risk is imposed by symptom checkers class I on public health if they will undergo a significant change 2) is the current monitoring of self-declared symptom checkers class I medical devices sufficient. The goal of this paper is to assess the potential risk on public health of several existing symptom checkers class I SaMDs that are currently used in the EU market.

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2. Methods

The material of this research consists of assessing ten examples of existing symptom checkers SaMDs that are currently in the EU market (see table 1). The assessment criteria are CE mark, compliance with European Norms (EN) ISO 14971 standard, and device accuracy. CE mark is used by medical device manufacturers to communicate to CA and the public that their devices conform with MDD [1] or MDR [2]. EN ISO 14971 standard is used by medical device manufacturers to demonstrate the application of risk management through the entire life cycle of their devices. The accuracy of the medical device is a piece of important information that needs to be communicated to users.

The assessment criteria are entered as yes or no in table 1. CE mark and accuracy are verified through the websites of each manufacturer. Yes, refers to the criteria being indicated on the manufacturer's website and no refers to the criteria not being indicated on the manufacturer's website. The accuracy criterion is documented in table 1 if it is indicated by the manufacturer. If the accuracy criterion is not indicated by the manufacturer the indication record in table 1 is documented as "no".

3. Results

Table 1 shows the result as follows. All the selected ten software as SaMDs were indicated to bear CE marking under MDD. Only one manufacturer indicated the use of EN ISO 14971. Two out of ten manufacturers disclosed the accuracy of their devices.

Table 1. Ten symptom checkers SaMDs examples that are currently in the EU market.

Symptom checkers SaMDs	CE mark	EN ISO 14971	Accuracy
Infermedica [3]	Yes	No	93%
Symptoma [4]	Yes	No	No
Quin [5]	Yes	No	No
My digital doctor [6]	Yes	No	No
Ada [7]	Yes	No	No
Docline [8]	Yes	No	93%
Nubentos [9]	Yes	No	No
Apimedic [10]	Yes	No	No
Omaolo [11]	Yes	No	No
Duodecim [12]	Yes	Yes	No

4. Discussion

MDR [2] replaces MDD. Manufacturers are allowed to continue to market their medical devices with valid CE mark certificates that were issued under MDD until 27 May 2025

as per section 4 of article 120 of MDR [2]. However, if the medical devices undergo any significant change, the manufacturers will be forced to comply with section 3 of article 120 of MDR [2].

According to annex I of both MDD and MDR, manufacturers of medical devices must ensure the safety of their medical devices. This safety is demonstrated by using the EN ISO 14971 standard that represents the application of risk management to medical devices. From table 1, one out of 10 manufacturers indicated using EN ISO 14971. Furthermore, according to annex I section 12.1a of MDD manufacturers must validate the software according to the state of art. The state of the art implies using the latest standards in the software development lifecycle, risk management, validation, and verification. The requirements laid down in annex I section 12.1a of MDD is not followed by the manufacturer of Duodecim [12]. The reason is that Duodecim [12] refers to EN ISO 14971:2012 and current standard that represents state of the art is EN ISO 14971:2019+A11:2021 and not EN ISO 14971:2012. Additionally, the manufacturer of Duodecim refers to Valvira [12] the wrong name of the Finnish competent authority. The current name of CA responsible for medical devices is FIMEA in Finland [14]. Referring to old EN ISO 14971:2012 and wrong CA suggests that the manufacturer of Duodecim is not serious about the potential risk their medical device might cause to the public. FIMEA should act against the manufacturer of Duodecim to enforce the correct implementation of MDD. The lack of such actions shows that CA does not have full monitoring of class I medical devices.

It was understood that the symptom checkers [3, 4, 5, 6, 7, 8, 9, 10, 11, 12] help patients to estimate their current state of health and take actions based on the assessment outcome of these SaMDs. Eight out of ten manufacturers in table 1 provide no indication about their medical devices' outcome accuracy. Two out of ten manufacturers in table 1 indicate that their medical devices are 93% accurate. When European Commission permitted a grace period to use class I SaMDs under MDD, there was no indication that the world will experience COVID-19 crises. All the selected SaMDs in this paper offer COVID-19 symptom checkers. The issue here is that the two medical devices in table 1 with an accuracy of 93% have to be considered as inaccurate. Inaccurate results of 7% may cause a public health threat. This public threat can be attributed for example to spreading viruses such as COVID-19. Symptom checkers encompass a risk that contracting COVID-19 cannot be guaranteed by the result of the software as it was proven that people can contract COVID-19 without showing any known symptoms of this virus [15]. In such a situation a patient can spread the virus to other people that may encounter serious deterioration in their state of health. Following MDR classification rule 11, symptom checkers SaMDs in this case are classified as class IIb.

The risk activities are important aspects to address the public health impact of SaMDs accuracy and changes while adhering to state of the art. It is important that manufacturers follow and indicate the use of latest EN ISO 14971:2019+A11:2021. The compliance with EN ISO 14971:2019+A11:2021 may force the manufacturers to modify device software that can be regarded as a significant change. As result, the manufacturers are required to comply with stringent MDR [2] where the risk is mentioned 248 times in comparison to MDD [1] where the risk is mentioned only 56 times. Furthermore, according to a study published in 2021 [16] "all software functionalities that classify as class I devices under FDA regulation are classified as at least class IIa devices under MDR". The inaccuracy and significant change [16, 17] are enough to shift the classification of SaMDs from low-risk class I to higher risk class IIa, or class IIb or class III. It is not clear how the EU CAs will monitor and assess changes of class I SaMDs that

are currently certified under MDD. Especially, if the manufacturers will not report these changes to applicable CAs.

5. Conclusion

Current class I SaMDs that are self-certified by the manufacturers under MDD shall comply with MDR if they will undergo a significant change. Significant change will force class I SaMDs manufacturers to comply with stringent requirements of MDR. Changes to class I SaMDs that cannot be captured represent a real public threat in EU states. Current class I SaMDs symptom checkers will be re-classified to a higher risk class under MDR. EU CAs are urged to establish the mechanism of monitoring and assessing changes of class I SaMDs that are currently certified under MDD. The mechanism of monitoring and assessing the changes of class I SaMDs will ensure that all changes are reported by manufacturers duly to CAs.

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