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학 술 논 문

Comparison of Classification Rules Regarding SaMD Between the Regulation EU 2017/745 and the Directive 93/42/EEC

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Abstract: The global market size of AI based SaMD for medical image in 2023 will be anticipated to reach around 620 billion won (518 million dollars). In order for Korean manufacturers to efficiently obtain CE marking for marketing in the EU countries, the paper is to introduce the recommendation and suggestion of how to reclassify SaMD based on classification rules of MDR because, after introducing the Regulation EU 2017/745, classification rules are quite modified and newly added compared to the Directive 93/42/EEC. In addition, the paper is to provide several rules of MDR that may be applicable to decide the classification of SaMD. Lastly, the paper is to examine and demonstrate various secondary data supported by qualitative data because the paper focuses on the suggestion and recommendation with a public trust on the basis of various secondary data conducted by the analysis of field data. In conclusion, the paper found that the previous classification of SaMD followed by the rule of MDD should be reclassified based on the Regulation EU 2017/745. Therefore, the suggestion and recommendation are useful for Korean manufacturers to comprehend the classification of SaMD for marketing in the EU countries.

Key words: SaMD (software as a medical device), MDD (medical device directive, directive 93/42/EEC) MDR (medical device regulation, regulation EU 2017/745)

I. Introduction

The traditional medical device industry focused on developing new technology to efficiently function as hardware mechanism. For instance, Imbedded Software to control the operating system of data communications is considered the representative software of traditional medical industry device [1]. However, AI medical device industry has been improved rapidly since 2018 [2] Especially, the development of SaMD (Software as a Medical Device) in the Medical device industry is accelerated because it is acknowledged as independent medical software without physical hardware. The primary function of SaMD is to analyze patient data related with medical images, biological signals, and gene data etc. in order to obtain meaningful clinical analysis result. Furthermore, it provides early diagnosis with accuracy in order to obtain remarkable values to reduce treatment period and improve patient safety [1]. For instance, the representative devices employing AI based SaMD for medical image are Computer aided diagnosis software, 'Analyser, medical image, software', and Computer aided detection software [1].

The global market size of AI based SaMD for medical image in 2023 will be anticipated to reach around 620 billion won (518 million dollars) [2]. Europe is the second largest market for medical devices worldwide. Therefore Korea manufactures should consider to market medical products to the EU countries [3].

In addition, Korea manufactures should reconsider the classification rules to obtain CE marking because of the improved version of MDD, named MDR, because MDR is not a directive not having legal force but a regulation legally forcing companies to observe the conditions to obtain CE marking.

The paper will introduce the distinctive differences of classification rules focusing on SAMD between MDD and MDR to South Korean companies related to manufacturing software medical devices.

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II. Body

Rule 11 regarding SaMD stipulated in the Chapter III of Annex VIII is newly added in the section after introduction of MDR 2017/745. According to Rule 11, the definition of SaMD deemed to be an active device is to give a direction for making a diagnosis decision or therapeutic purposes decision, which is related to seriously influencing a patient's healthy state, to operating a surgical invention, or to monitoring physiological process or vital physiological parameters [4]. According to MDCG 2019-11, SaMD designed to be independent must have a medical purpose in order to satisfy the definition of medical devices [5]. For instance, software to influence the utilization of each device without its own intended purpose may not be considered SaMD but an accessory for a hardware medical device.

1. Comparison of classification rules between MDR of Annex VIII and MDD of Annex IX

This chapter should demonstrate the classification rules related to SaMD in order to efficiently obtain CE marking. There are several rules related to the classification of SaMD. First of all, Rule 9, 10, 11, 12, 13, 15, and 22 of Classification Rules of Annex VIII should be considered in the decision of SaMD classification because SaMD shall be deemed as an active device according to Article 2(4) of Regulation in MDR 2017/745 [4]. In addition, SaMD should be classified under implementing the rule 3.5 of Annex VIII without regard to the software's location or the type of interconnection between the software and a (hardware) device. Therefore the chapter will analyze the classification rules (Rule 9, 10, 11, 12, 13, 15, and 22) regarding SaMD in order to understand the comparison of classification rules between MDR of Annex VIII and MDD of Annex IX.

(1) Rule 9 (Active devices)

In general, therapeutic devices related to this are deemed to electrical equipment used in lasers, surgical generators, etc. The rule can apply to SaMD. As shown into Table 1, there are some differences between Rule 9 of Annex VIII of MDR and Rule 9 of Annex IX of MDD. As shown into Table 1, the differences between them are below:

1) The phrase of "are in" in MDD is replaced with the phrase of "are classified as" in MDR.

The phrase of "are in" from MDD and the phrase of "are classified as" from MDR is based on the sentence of active voice and the sentence of passive voice respectively. It means that there is slightly difference of meaning between them. According to Oxford English dictionary and Cambridge English dictionary, "be" verb to complete the sentence of active voice is used to be structured of the type of "subject + intransitive verb" [6-7]. Especially, when an English sentence is struc-

Table 1. Comparison of classification Rule 9 between MDR of Annex VIII and MDD of Annex IX

MDD	MDR
3.1 Rule 9	6.1 Rule 9
All active therapeutic devices intended to administer or exchange energy are in Class IIaunless 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.	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.

tured of the type of "subject + be +prep", the meaning of "be" verb is related to "belong" or "exist". Considering the rule 9 of Classification Criteria of Annex IX in MDD, the meaning of "are in" would be similar with the meaning of "belong". In order to better understanding the issue, the paper should distinguish the meaning of "belong" from the meaning of "classify". For instance, when you used the term of "belong", there is no meaning of the classification of class, which means the meaning of "belong" is only expressed on something to be in suitable place or situation. In order words, the readers would not anticipate that there are several classifications of medical devices when reading the phrase of "are in". Therefore, the reason that The European Union replaced the phrase of "are in" from MDD with the phrase of "are classified as" from MDR would be considered to demonstrate that there are several classifications of medical devices.

2) The term of "from" in MDD is replaced with the term of "with" in MDR.

In the perspective of meaning, there are some differences between "from" written in MDD and "with" written in MDR as shown into Table 1. For instance, the phrase written in the preposition of from is "energy from the human body." On the other hand, the phrase written in the preposition of with is "energy with the human body." According to Oxford English dictionary and Cambridge English dictionary, the meaning of "from" is what the origin of something(someone) is [6-7], which means it would explain the time when something(someone) existed first or the time when something(someone) started. The meaning of "energy from the human body" would be to show the origin of energy generated from human body. However, the meaning of "with" is that somethings (somebodies) are in the place together or are implemented together or perform something together, which means, the meaning of "with", the meaning would be based on the meaning of "something (someone) together". The meaning of "energy with the human body" would be to show the energy connected with human body. The phrase of "energy from the human body" would not comprehensively include certain energy not generated or not created from the human body because there is no meaning related to "with" in the preposition of "from". On the other hand, the preposition of "with" includes a similar meaning of "from". For instance, the meaning of "I work with Samsung." is not "My partner is Samsung." but "I work in Samsung." Although there are some differences between "in" and "from", in the point of comprehensive view, the meaning of "in" would be included in the meaning of "from". Therefore, the term of "from" in MDD is replaced with the term of "with" in MDR.

3) The new article of "All active devices (…) ionizing radiation (…) as class IIb." is added in MDR.

In terms of radiation, Article 11(2) to 11(5) stipulated in MDD is demonstrated precisely. Especially the article of ionizing radiation is stipulated in the Article 11(5) of MDD. As per the Article 11(5), medical devices designed for emitting ionizing radiation must be followed in the specific process in order to minimize radiation exposure of the patient and user [8]. What the article should be noticed is that an auxiliary verb of "must" is used in the Article 11(5), which means it is anticipated that the observation of the process to manufacture medical devices intended to emit ionizing radiation would strongly be related to humans' health. According to OSHA(Occupational Safety and Health Administration) in US, when people are continually exposed to ionizing radiation in several ways, depending on the duration of exposure, their work environment, the amount of radiation, and the type of radiation source, people's health would seriously deteriorate due to getting temporary or permanent sterility, cataracts, skin reddening, cancer, genetic effects, etc [9]. Even though emitting ionizing radiation is in the seriously potential danger, active devices related to ionizing radiation are mentioned only one time in the Rule 10 of Annex IX of MDD. Furthermore, at the time when Directive 93/42/EEC was published, there was no regulation of emitting ionizing radiation for therapeutic purposes. In addition, Independent *in-vivo* dosimeters for the purpose of radiotherapy treatment should be qualified as a medical device intended for emitting ionizing radiation according to Manual on Borderline and Classification in The Community Regulatory Framework for Medical Devices [10]. At the time that it was issued, the report suggested that Independent *in-vivo*

dosimeters should be classified as class IIb based on the regulation of Rule 10 of Annex IX of MDD [10]. However, after issuing Regulation (EU)2017/745, the device would be considered Rule 9 and Rule 10 at the same time. Considering all the factors, the new article of "All active devices … as class IIb." is added in MDR.

4) The new article of "All active devices … as class III." is added in MDR.

In terms of new article stipulated in the Rule 9 of MDR, active medical devices related to the new article are classified as class III. Before issuing Regulation (EU) 2017/745, there were no appropriate classification rules related to active medical devices intended to control, monitor or directly influence the performance of active implantable devices. If there is no appropriate classification rules related to active medical devices due not to the addition of new article in Rule 9 of MDR, the devices would be in Rule 10 of MDD and MDR. However, there was no rule related to class III in Rule 10 of MDD and MDR. In terms of Rule 10 of MDR, it is "Active devices (…) including devices which control or monitor (…) directly influence their performance (…) class IIb"[4]. The article of Rule 10 of MDD and MDR is very similar with new addition article of Rule 9 of MDR. However, the article stipulated in the Rule 10 of MDD and MDR is the explanation of active medical devices classified as class IIb, not class III. Therefore, understanding the difference between the existing article stipulated in the Rule 10 of MDD and MDR and new addition article of Rule 9 of MDR would be important why the new article of "All active devices … as class III." is added in Rule 9 of MDR. The difference between them is the type of active medical device. The active medical device of new addition article in Rule 9 of MDR is "active implantable devices". On the other hand, the active medical device of existing article in Rule 10 of MDD and MDR is "interventional radiology devices". According to TUV SUD [9], Regulation EU 2017/745 is based on Directive on medical device 93/42/EE and Directive on active implantable medical device 90/385/EEC [11]. In terms of Annex 1 of Directive 90/385/EEC, an auxiliary verb of "must" is used in the most articles of Annex 1, which means active implantable devices would be related to class III with high risk perceived by impairment of human health. When it comes to active implantable devices set out in new addition of Rule 8 in MDR, it is classified as class III. Therefore, This is why the new article of "All active devices … as class III." is added in MDR because the addition of article would be considered the qualification of active medical devices related to Rule 8, Rule 9, and Rule 10 at the same time.

(2) Rule 10 (Active devices)

In general, active devices designed for diagnosis and monitoring are ultrasound diagnosis, therapeutic and diagnostic radiology, etc. The rule can apply to SaMD.

As shown into Table 2, there are some differences between Rule 10 of MDR of Annex VIII and Rule 10 of MDD of Annex IX. The differences between them are below:

1) The phrase of "are in" in MDD is replaced with the phrase of "are classified as" in MDR.

The related analysis is already done in section 2.1. of 1) in the paper.

2) The new term of "monitoring" is added in MDR.

The investigation of the term of "monitoring or monitor" set out in the active devices' rules would be better understanding why the new term of "monitoring" is added in Rule 10 of MDR. In the Rule 9 to 13 related to active devices, the term of "monitoring or monitor" is written 7 times (3 times in the Rule 9, 2 times in the Rule 10, and 2 time in the Rule 11). As per Rule 10 added in the new term of "monitoring", the active medical devices are classified as class IIa. Therefore, in the 7 times where the term was written, the paper should find out which articles are related to class IIa. To be more specific, firstly, in the Rule 9, the articles written in the term of "monitor or monitoring" are related to class IIb and III. Secondly, in the Rule 10, the articles written in the term of "monitor or monitoring" are related to class IIb. Lastly, in the Rule 11, the articles written in the term of "monitor or monitoring" are related to class IIa and IIb. Considering all the factors, the addition of "monitoring" in the Rule 10 of MDR would be considered the SaMD of new Rule 11

Table 2. Comparison of classification Rule 10 between MDR of Annex VIII and MDD of Annex IX

MDD	MDR
3.2 Rule 10	6.2 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 thenature 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.	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 issuch 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.

of MDR that is “software (…) to monitor physiological processes is (…) as class IIa” because SaMD is classified as active medical devices.

3) The phrase of “used to” in MDD is replaced with the phrase of “intended to” in MDR.

There are some differences between the phrase of “devices used to illuminate” and the phrase of “devices intended to illuminate. According to Oxford English dictionary and Cambridge English dictionary, the meaning of “use” cannot include the meaning of “intend”. For instance, the phrase of “used to” is the abbreviation of “which is used to” [6-7]. In other words, the meaning of “used to” is based on the passive voice in simple present tense, which means there is no meaning of “future tense” in the phrase of “used to”. On the other hand, the phrase of “intended to” is the abbreviation of “which is intended to”. Although it is same as the passive voice in simple present tense, the phrase of “intended to” is to include the meaning of not realizing what one wants yet regardless of what tense it is. After all, the phrase of “used to” cannot include the meaning of “intend” that is not to realize what one wants yet. In conclusion, this is why the phrase of “used to” in MDD is replaced with the phrase of “intended to” in MDR in order to expand the scope of the situation to use active medical devices.

4) The term of “where” in MDD is replaced with the term of “and” in MDR.

The term of “where” is classified as a relative adverb of the English grammar. In the sentence of “vital physiological parameters, where the nature of (…) to the patient” in the Rule 10 of MDD, the role of “vital physiological parameters” is considered an antecedent to make an adjective clause of “where the nature of (…) to the patient”. Therefore, it consists of one sentence. On the other hand, the term of “and” is the conjunction of the part of speech. In the sentence of “vital physiological parameters, and the nature of (…) to the patient” in the Rule 10 of MDR, the role of “and” is a connector between the sentence of “they (…) parameters” and the sentence of “the nature of (…) to the patient”. In other words it consists of two sentences, not one sentence after changing “where” into “and”. Considering all the factors, the reason that the term of “where” in

MDD is replaced with the term of "and" in MDR would be the different meaning between physiological parameters and the nature of variations of those parameters.

5) The new article of "they are intended for … immediate danger," is added in MDR.

A clinical situation is related to patient procedure, clinical investigation or patient diagnosis according to NHS Data Model and Dictionary. Based on the new article, the examples of medical devices for patient diagnosis should be investigated to demonstrate why the new article of "they are intended for … immediate danger," is added in MDR. According to MEDDEV 2.4/1 Rev.9, class IIb medical devices related to Rule 10 of MDD consist of blood pressure, temperature, and oxygen saturation of intensive care monitoring and alarm devices, biological sensors, blood gas analyzers used in open heart surgery, cardiosopes, apnoea monitors, etc [12]. The examples of medical devices is related to variations in cardiac performance, respiration, and activity of CNS(Central Nervous system). When it comes to the examples, those would not only have the function of monitoring but have the multifunctional devices with monitoring and diagnosis. Thus the devices would also be considered to be intended for diagnosing the clinical judgement in immediate danger of patients' life and health, depending on situation. In addition, the new Rule 11 of SaMD should be considered the reason to add the term. Furthermore, based on the article of "if (…) intended to allow direct diagnosis or monitoring of (…)", it would be reasonable to add the term of "diagnosis in clinical situation." Therefore, The new article of "they are intended for … immediate danger," is added in MDR.

6) The new term of "therapeutic radiology" is added in MDR.

The related analysis is already done in section 2.1. of 4) in the paper.

(3) Rule 11 (Active devices)

As shown into Table 3, the new Rule 11 is added in MDR compared to MDD. According to MDCG 2021-24, the Rule 11 of MDR is intended to describe and categorize the risk of SaMD in order to provide appropriate information to make a reasonable decision with diagnosis and in order to monitor physiological processes [13]. In addition, in the Rule 11 of MDR, there is comparison between SaMD intended to monitor non-vital physical process and SaMD intended to monitor vital physical process. Some examples of SaMD are Clinic Information System (CIS), Clinical Decision Support Systems (CDSS), Radiology Information Systems (RIS, Laboratory Information System (LIS) etc. in addition, SaMD are deems as active devices under Article 2(4) of MDR. Therefore, when it comes to SaMD, it should be considered from Rule 9 to Rule 13 related to active medical devices. There are classification articles from Rule 9 to Rule 13. Lastly, based on the analysis of Rule 11 of MDR, classification rules regarding SaMD are introduced in the Table 4.

Table 3. Comparison of classification Rule 11 between MDR of Annex VIII and MDD of Annex IX

MDD	MDR
	6.3 Rule 11
NO Regularion	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.

Table 4. Classification Rules regarding SaMD of Annex VIII in Regulation EU 2017/745

	SaMD of Europe (MDR): class IIa (Medium risk perceived)	
1	Active therapeutic devices designed for administering or exchanging energy (Rule 9)	에너지 투여 또는 교환을 위해 설계된 능동치료 기기(규칙 9)
2	Active devices specifically designed for monitoring and diagnosis (Rule 10)	모니터링 및 진단을 위해 특별히 설계된 능동기기 (규칙 10)
3	Software for the purpose of providing information influencing the decisions with diagnosis or therapeutic purposes (Rule 11)	진단 또는 치료 목적의 의사결정에 영향을 미치는 정보를 제공하기 위한 소프트웨어 (규칙 11)
4	Active devices aiming at administering and/or removing medicinal products, body liquids or other substances to or from the human body (Rule 12)	인체에(로부터) 의약품, 체액 또는 기타 물질을 투여 및/또는 제거하는 것을 목적으로 하는 능동기기 (규칙 12)

	SaMD of Europe (MDR): class IIb (Medium/high risk perceived)	
1	Active therapeutic devices to administer or exchange energy with the human body in a potentially hazardous approach, taking into consideration of the nature, the density and site of application of the energy (Rule 9)	에너지의 특성, 밀도 및 적용 면적을 고려하여 잠재적으로 위험한 접근 방식으로 인체에(with human body 와 in human body 와 into human body를 연구) 에너지를 투여하거나 교환하는 능동 치료 기기(규칙 9)
2	Active devices designed for monitoring or controlling the performance of active therapeutic class IIb devices including devices directly influencing the performance of such devices (Rule 9)	의료 기기 성능에 직접적 영향을 끼치는 기기를 포함해 능동 치료 등급 IIb 기기의 성능을 모니터링 또는 제어하기 위해 설계된 능동 기기(규칙 9)
3	Active devices designed for emitting ionizing radiation for therapeutic purposes including devices monitoring or controlling such devices, or directly influencing their performance (Rule 9)	의료 기기 성능에 직접적 영향을 끼치거나 기기를 모니터링 또는 제어하는 기기를 포함하는 치료 목적 이온화 방사선을 방출하기위해 설계된 능동 기기(규칙9)
4	Active devices specifically intended for monitoring vital physiological parameters (Rule 10)	생명 유지에 관련한 생리학적 매개변수를 모니터링하려고 특별히 설계된 능동 기기(규칙 10)
5	Active devices specifically intended for monitoring the nature of variations of those parameters that could result in immediate danger to the patient (Rule 10)	환자에게 즉각적인 위험을 초래할 수 있는 매개변수들의 변화 특성을 모니터링하려고 특별히 설계된 능동 기기(규칙 10)
6	Active devices designed to emit ionizing radiation for diagnostic or therapeutic radiology including interventional radiology devices and devices monitoring or controlling such devices, or directly influencing their performance (Rule 10)	의료 기기 성능에 직접적 영향을 끼치거나 기기를 모니터링 또는 제어하는 기기 및 중재적 방사선 기기를 포함하는 진단용 또는 치료용 방사선학을 위한 이온화 방사선을 방출하기 위해 설계된 능동 기기(규칙 10)
7	Software that may cause a serious deterioration of a patient's state of health or surgical intervention (Rule 11)	환자의 건강 상태의 심각한 악화를 야기하거나 외과적 개입을 야기하는 소프트웨어(규칙 11)
8	Software intended for monitoring vital physiological parameters (Rule 11)	생명 유지에 관련한 생리학적 매개변수를 모니터링하기 위해 설계된 소프트웨어(규칙 11)
9	Software intended for monitoring the nature of variations of those parameters that could result in immediate danger to the patient (Rule 11)	환자에게 즉각적인 위험을 초래할 수 있는 매개변수의 변동 특성을 모니터링하기 위해 설계된 소프트웨어(규칙 11)
10	Active devices aiming at administering and/or removing medicinal products, body liquids or other substances to or from the human body are completed in a manner that is potentially hazardous taking into consideration of the nature of the substances involved, of the part of the body concerned and of the mode of application (Rule 12)	적용방식, 관련한 인체의 부분 및 물질의 특성을 고려한 잠재적으로 위험한 방식으로 완료된 인체에(로부터) 의약품, 체액 또는 기타 물질을 투여 및/또는 제거하는 것을 목적으로 하는 능동 기기(규칙 12).

(4) Rule 12 (Active devices)

In general, active devices are designed for administering and/or removing medicinal products, body liquids or other substances to or from the human body.

Table 4. Continued

	SaMD of Europe (MDR): class III (High risk perceived)	
1	Active devices directly designed to control, monitor, or influence the performance of active implantable devices (Rule 9)	능동 이식형 기기의 성능을 제어, 모니터링 또는 영향을 미치도록 직접 설계된 능동 기기(규칙 9)
2	Software designed for providing information to take decisions causing death or an irreversible deterioration of patient's health (Rule 11)	사망 또는 되돌릴 수 없는 환자 건강 악화를 초래하는 의사결정을 하기 위한 정보를 제공하는 목적으로 설계된 소프트웨어 (규칙 11)

Table 5. Comparison classification between Rule 12 of MDR of Annex VIII and Rule 11 of MDD of Annex IX

MDD	MDR
3.3 Rule 11	6.4 Rule 12
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 thisis done in a manner:	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 thesubstances involved, of the part of the body concerned and of themode of application in which case they are in Class IIb.	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.

The rule can apply to SaMD. As shown into Table 5, there are no differences between Rule 12 of MDR of Annex VIII and Rule 11 of MDD of Annex IX.

(5) Rule 13 (Active devices)

The rule can apply to SaMD. As shown into Table 6, there is a slight difference between Rule 13 of MDR of Annex VIII and Rule 12 of MDD of Annex IX. The differences between them are below:

1) The phrase of "are in" in MDD is replaced with the phrase of "are classified as" in MDR.

The related analysis is already done in section 2.1. of 1) in the paper.

(6) Rule 15 (Special rules)

In general, the devices of Rule 15 are designed to be used for prevention of sexually transmitted diseases or contraception. The types of devices in the Rule 15 are invasive, non-invasive devices for transient or short term use classified as class IIb and invasive, non-invasive for long term use or implantable medical devices classified as class III according to MDCG 2021-24 [13]. The rule can apply to SaMD. As shown into Table 7, there is a slight difference between Rule 15 of MDR of Annex VIII and Rule 14 of MDD of Annex IX. The differences between them are below:

Table 6. Comparison classification between Rule 13 of MDR of Annex VIII and Rule 12 of MDD of Annex IX

MDD	MDR
3.4 Rule 12	6.5 Rule 13
All other active devices are in Class I.	All other active devices are classified as class I.

Table 7. Comparison classification between Rule 15 of MDR of Annex VIII and Rule 14 of MDD of Annex IX

MDD	MDR
4.2 Rule 14	7.2 Rule 15
All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.	All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.

Table 8. Comparison of classification Rule 22 between MDR of Annex VIII and MDD of Annex IX

MDD	MDR
	7.9 Rule 22
NO Regulation	Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

Table 9. The term of "therapeutic" (MDR, 2017)

The term of "therapeutic"	
(Rule 9) All active therapeutic devices intended to administer or exchange energy are classified as class IIa	(Rule 10) 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 9) All active devices intended to control or monitor the performance of active therapeutic class IIb devices.	
(Rule 9) 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.	(Rule 11) Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa.

1) The phrase of "are in" in MDD is replaced with the phrase of "are classified as" in MDR.

The related analysis is already done in section 2.1. of 1) in the paper.

(7) Rule 22 (Special rules)

As shown into Table 8, the new Rule 22 is added in MDR. The article of the Rule 22 is related to active therapeutic devices with an incorporated or integrated diagnostic function. As shown into Table 9, there are some rules of MDR related to the term of "therapeutic". For instance, the term of "therapeutic" is discovered in the Rule 9, The Rule 10 and Rule 11 of MDR. Compared to the Rule 22, there are no regulation of an incorporated or integrated diagnostic function to significantly change the way of the patient management and no regulation of the classification rule of class III in the Rule 9, Rule 10 and Rule 11 of MDR. According to MDCG 2021-24 [13], the example of an incorporated or integrated diagnostic function is closed loop systems to automatically monitor relevant biological conditions in order to sustain a specific physiological state by adjusting a therapy. Generally, the devices with closed loop systems are customized in specific use for personalized therapies in order to achieve optimal therapeutic efficacy. The classification of autonomic pharmacological (drug-delivery) and neuromodulation systems is also covered in the Rule 22 of MDR [4]. As a practice issue of classification, it is mentioned that the meaning of "an incorporated or integrated diagnostic function" is the system consisting of sensors such as the AED electrodes or pads designed for recording changes in the specific physiological state of patients and for using a feedback control to process. The meaning of "diagnostic function" can be physically integrated or a component of an external sub-system. Considering all the factors, according to TUV SUD, systems for controlling the temperature in the baby incubators by means of skin sensors, systems for regulating ultrafiltration in dialysis depending on the blood pressure of patients, and systems for automatically adjusting ventilation patterns under the patient's state will be covered in the Rule 22 of MDR [11], because medical devices with automatic external defibrillators and medical devices with closed loop system are covered in the Rule 22 of MDR. The rule can apply to SaMD.

III. Conclusion

Key changes of classification rules regarding SaMD between MDD and MDR are below:

1. Prediction of patient's state of health

As demonstrated in the Rule 11 of MDR, the prediction of patient's state of health is included in the active medical devices of SaMD. For instance, as shown into the Rule 11, the phrase of "such decisions have an impact that may cause: — death or an irreversible deterioration of a person's state of health,"is not the method of diagnosis but the method of prognosis.

2. A person's state regarding serious incidents

As demonstrated in the Rule 11 of MDR, new regulations of serious incidents are mentioned compared to MDD. For instance, the death of a patient and irreversible or serious deterioration of a patient's state of health are stipulated in the Rule 11 of MDR. However, there are no regulations regarding a person's state regarding serious incidents in the classification rules of MDD. In addition, although the regulation of serious incident is stipulated in the Article 10(1a) of MDD, the explanation would be unclear to understand the scope of serious incidents. However, the definition of serious incident is clearly stipulated in the Article 2(65) of MDR.

3. Introduction of SaMD

As demonstrated in the Rule 11 of MDR, the introduction of new Rule 11 related to SaMD helps software medical products fall under the scope of a medical device even though they may not be qualified as a medical device under MDD. Even though additional software applications are categorized in the scope of the medical device, various changes shall be only applied to standalone software excluding software embedded in the part of system. Before issuing new Rule 11 of MDR, most standalone medical software has been categorized in a lower risk product classified as class I. After issuing new Rule 11 of MDR, most standalone medical software is categorized in a higher risk product classified as class II or class III.

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