Establishment of safety management systems for wellness devices and digital-based medical devices

Seongjun Lim

The Graduate School
Yonsei University
Department of Medical Device Engineering
and Management

Establishment of safety management systems for wellness devices and digital-based medical devices

Directed by Professor: Sun K. Yoo

A Dissertation submitted to the graduate program of
Department of Medical Device Engineering
and Management and the graduate school of
Yonsei University in partial fulfillment of the requirements
for the degree of Doctor of Department
of Medical Device Engineering and Management.

Seongjun Lim

December 2023

This certifies that the dissertation of
Seongjun Lim is approved.

_____
Thesis Supervisor: Sun K. Yoo

_____
Thesis Committee Member: Jong-Chul Park

_____
Thesis Committee Member: Byeong-Ju Kwon

_____
Thesis Committee Member: Byung-Chae Lee

_____
Thesis Committee Member: Yonghyeon Yun

The Graduate School
Yonsei University
December 2023

Table of Contents

List of Table

List of Figures

Abstract

Establishment of safety management systems for wellness devices and digital-based medical devices

Seongjun, Lim

Graduate Program of Department of Medical Device Engineering and Management

The Graduate School

Yonsei University

This paper proposes a new management method and system for the rational classification of personal health care devices (hereinafter referred to as "wellness devices") in Korea and the establishment of a safety management system. In addition, with the rapid development of digital technology, new types of medical devices and convergence types of drugs that do not conform to the existing management (or regulation) system are emerging. Accordingly, by presenting a new management system that can reflect the development of advanced digital technology, we intend to establish a management system specialized for medical devices with digital technology that continues to develop throughout the Total Product Life Cycle and to accommodate the innovation of digital technology to help create a preemptive and predictable regulatory and support environment for medical devices with various digital technologies.

To this end, we conducted surveys on related systems and policies in countries around the world, including the United States, Europe, Japan, and Korea, and investigations on industry perceptions of domestic stakeholders. Based on the findings, we would like to suggest methods and systems for establishing a safety

management system for personal wellness devices and digital technology-based medical devices. In addition, by defining the concept of "digital medical products," we would like to emphasize the need to clearly classify and manage wellness devices and medical devices applied with digital technology.

Keywords : Wellness devices, Software as Medical Devices, SaMD, DTx, Digital Therapeutics

Chapter 1

Introduction

1.1 Motivation

1.1.1 The need for global harmonization

As we experience the COVID-19 pandemic, the medical environment around the world is facing rapid changes. As the development of digital technologies such as artificial intelligence and wearables accelerates, global interest in digital health is also increasing, but the current legal management system suitable for traditional medical devices has limitations in accommodating innovations in 'digital technologies' such as wellness devices, software medical devices, and data. In addition, there are limitations in efficient safety and effectiveness evaluation of medical devices that combine wellness devices and digital technology, and as various convergent medical devices are born and utilized, public demand for reliability improvement and safety regulation support is also increasing. In addition to these parts, items that fall under a different classification system from foreign countries are having difficulty in exporting them because they do not meet the regulatory requirements of the country when exporting to foreign countries. For example, ophthalmic lubricants are classified as pharmaceuticals in Korea, but are classified as medical devices in some foreign countries. For this reason, licensing, GMP certification, and follow-up management are separately managed. Accordingly, to improve the reliability of wellness devices and digital technology-based medical devices, support safety regulations, and promote exports and industries of domestic companies, global harmonization of items classified and managed on a standard that is inconsistent with the international classification

system is required.

1.1.2 An aging society and the wellness industry

According to the National Statistical Office's "2019 Domestic and Foreign Population Outlook Reflecting Future Population Trends: 2017-2040" the number of Koreans excluding foreigners reached 50.5 million as of July 2020, and then the continuous decline is expected (49.92 million in 2025 and 49.8 million in 2030). Although the population is declining, the proportion of the elderly to the population is rapidly increasing as the baby boomers (born in 55~63) with a high proportion of the population enter the elderly population. The elderly population (65 years of age or older) in Korea is expected to exceed 10 million in 2025 and 15 million in 2036. In addition, as shown in Figure 1, the proportion of the elderly population is expected to exceed 16.1% in 2020 and 20% in 2025 and exceed 30% in 2035. The United Nations divides the proportion of the population aged 65 or older into an aging early society if it accounts for 7% or more of the total population, an aging society if it is 14% or more, and a super-aged society if it exceeds 20%.

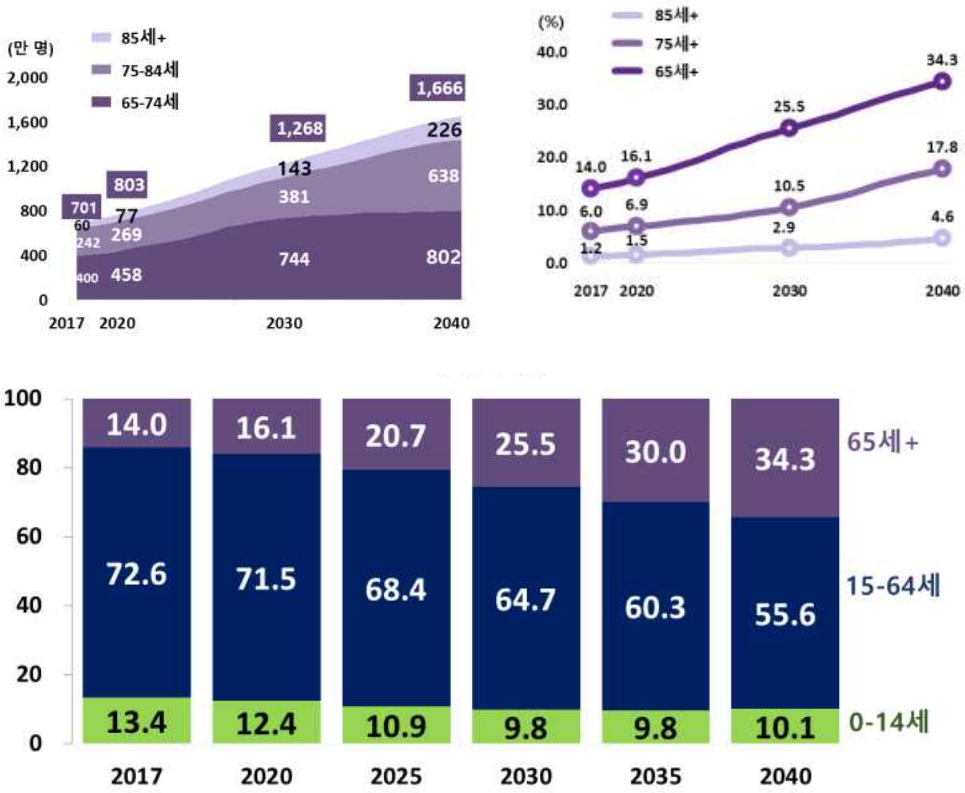


Figure 1 Population composition ratio by the elderly population (upper) and age group in Korea from 2017 to 2040[1]

As the elderly population increases, it is a combination of "well-being" and "happiness" that pursues a comfortable and balanced life in mental, health, and environment Wellness is starting to boom. This demand for wellness is leading the growth of related industries, and accordingly, the growth of the digital healthcare industry that measures and collects various biometric information is emerging. It is expected to grow more than 17.4% annually between 2021 and 2027. In addition, the rapid use of wireless and mobile health services and the increasing use of mHealth apps are impacting the growth of the digital healthcare market as it accelerates market growth and increases awareness of innovative and advanced applications of medical devices. The COVID-19 virus has disrupted all major sectors around the world, but the digital healthcare sector has seen a surge in use under these circumstances, which has had a positive impact on industrial growth. For example, various governments in developed and developing countries have revised regulations related to the use of digital technology for medical purposes.

1.1.3 Classification of wellness device

Wellness devices similar to medical devices have been continuously developed to claim medical purposes, but currently, medical devices and wellness devices are not clearly distinguished due to ambiguous standards and causes. Accordingly, devices with low risk are classified as wellness devices, so the general public can use them without any restrictions. Wellness devices are currently classified as industrial products, not medical devices. Industrial products managed under the Quality Management and Industrial Products Safety Management Act are managed as "electric products and household goods" under the "Electrical Products and Household Products Safety Management Act" as they are integrated with the "Electrical Products and Household Products Safety Management Act", and most wellness devices are managed as "Safety Certification Target Products" under the Act.

Table 1. Act on the Safety Management of Electrical Appliances and Household Appliances[3]

<Act on the Safety Management of Electrical Appliances and Household Appliances> Article 2 (Definitions)
10. The term "product subject to safety certification" means the following electrical appliances and household goods.
(a) Electrical appliances subject to safety certification: Electrical appliances recognized as highly likely to cause harm such as fire, electric shock, etc. due to structure or method of use, etc., and are recognized as being able to prevent such harm through safety certification
(b) Household goods subject to safety certification: Household goods that are recognized to be highly concerned about damage to the life and body of consumers due to structure, material, or method of use, property damage or damage to the natural environment, and are recognized to be prevented through safety certification
11. The term "product subject to safety verification" means the following electrical appliances and household goods.

(a) Electrical appliances subject to safety verification: Electrical appliances that are likely to cause damage such as fire, electric shock, etc. due to structure or method of use, etc., and are recognized as being able to prevent such damage through product testing by an institution designated by the Minister of Trade, Industry and Energy and prescribed by Ordinance of the Ministry of Trade, and Industry

(b) Household goods subject to safety verification: Household goods that are feared to cause damage to the life and body of consumers due to structure, material or method of use, property damage or damage to the natural environment, and are recognized to be prevented through product testing by an institution designated by the Minister of Trade, Industry and Energy

12. The term "product subject to supplier conformity verification" means electrical appliances and household goods falling under the following items.

(a) Electrical appliances subject to supplier conformity verification: Electrical appliances that are likely to cause damage such as fire, electric shock, etc. due to structure or method of use, etc., and are recognized as being able to prevent such damage through product tests conducted directly by manufacturers or importers or by commissioning them to third parties, and are prescribed by Ordinance of the Ministry of Trade, Industry and Energy

(b) Household goods subject to supplier suitability verification: Household goods that are likely to cause an accident or cause harm in handling, use, transportation, etc., or are difficult for consumers to distinguish components, performance, standards, etc., and are recognized to prevent such harm through product tests conducted directly by manufacturers or importers or by requesting third parties

13. The term "household goods subject to safety standards" means household goods that are unlikely to cause accidents or harm in the process of handling, using, transporting, etc., but are difficult for consumers to distinguish components, performance, standards, etc., and are recognized by manufacturers or importers to prevent such harm by complying with safety standards.

However, despite the absence of a safety verification method, blind spots for safety management are occurring due to different ministries in charge of verification. Side effects such as retinal damage and conjunctivitis caused by LED

masks, which are industrial products, are occurring ('17 (1 case), '18 (23 cases), '19 (39 cases)', and even if the risk is lowered by reducing performance or SPAC, repeated and continuous use can lead to anatomical and physiological changes in the human body.

Wellness devices classified as industrial products are excluded from the management of medical devices, and there is no need to comply with mandatory regulations applied to medical devices such as pre-licensing screening, manufacturing of medical devices, and quality control standards (GMP), and low-cost products such as Chinese products are also classified as industrial products and do not require permission, making it virtually impossible to follow-up management according to side effects on the human body. Because of measurement errors or malfunctions, there is a risk of missing proper treatment or prevention opportunities, and there are concerns about unlicensed medical practices by non-medical personnel, such as first aid guidance through mobile applications and breathing training for patients with panic disorder.

Due to the various concerns mentioned above, it is urgent to prepare a safety management strategy to prevent the occurrence of harm, and it is necessary to prepare rational and systematic safety management measures for wellness devices to improve the quality of public health and pay attention to the lives and safety of the people.

1.2 A method of research

This study was studied through various literature surveys, as well as briefing sessions and surveys on stakeholders' perceptions of the industry.

Chapter 2

Definition of Wellness Device, Software as Medical Device, etc.

2.1 Definition of Wellness Device

As shown in Figure 2, the Ministry of Food and Drug Safety states that medical devices and wellness devices are judged according to the purpose and risk of use for wellness devices with ambiguous distinction from medical devices, and this judgment is required to be judged by the manufacturer.

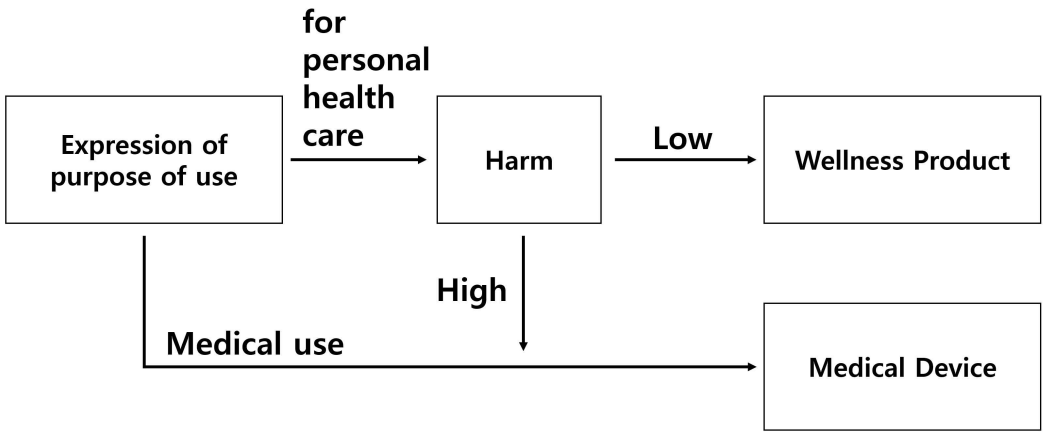


Figure 2. Flow of classification according to the purpose of use of medical devices and personal health care products[4]

The specific judgment criteria for using the manufacturer's objective intentions provided by manufacturer and information provided by manufacturer, documentation, and information of the production criteria provided by manufacturer.

Table 2. Specific criteria for determining the risk[5]

<Specific criteria for determining the risk>

1) Hazard Judgment Factors

A) Whether it causes biocompatibility issues

B) whether it is invasive

C) Whether injuries or diseases occur to users if they do not operate as intended for use

D) Whether an emergency is detected

E) Whether the functions or characteristics of the device are controlled or changed

2) High Hazard

If the product causes biocompatibility problems, invasive, invasive, user injury or disease when it does not work as intended, products that detect emergency situations, and control or change functions or characteristics of devices are considered high-level, so they are not considered personal health care products. Therefore, products that apply energy that can affect the human body or invasive products can harm the safety of users, so they are considered high-risk.

3) Low Hazard

If the product does not fall under the high level, that is, if the degree of harm to the user's safety is low, it is considered a low risk.

As such, wellness devices are not, in principle, judged as medical devices, and there are two types of wellness devices that do not correspond to medical devices: 'products for daily health management' and 'products for self-management of chronic diseases'. Products for daily health management are 'for measuring and analyzing biological phenomena', 'for improving physical function', 'for providing medical information for daily health management', and 'for exercise and leisure'. Products for self-management of chronically ill patients are 'for chronic disease phenomenon management' and 'for providing medical information for chronic diseases'.

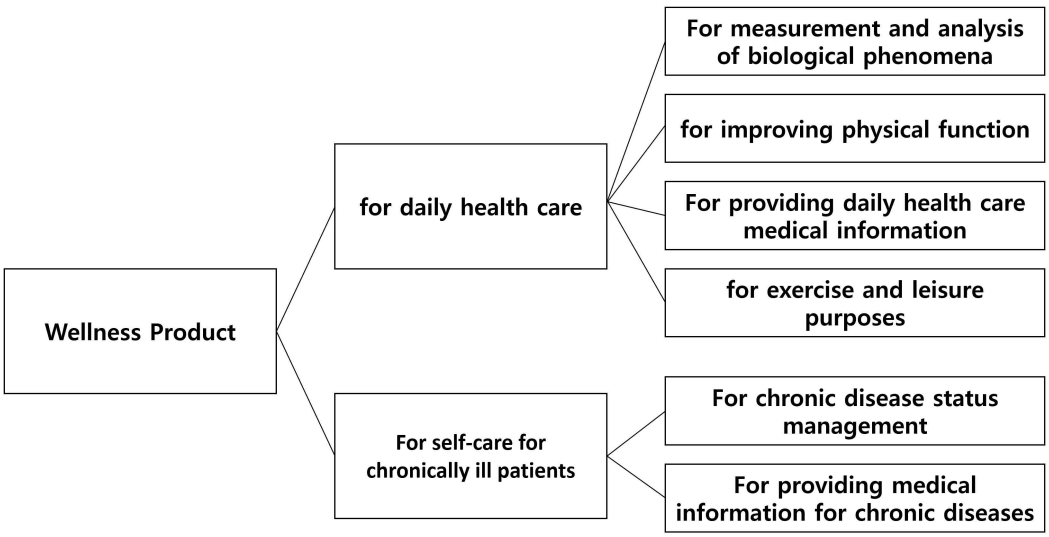


Figure 3. Classification of Wellness Product[6]

2.2 Definition of Software as Medical Device(SaMD)

Software as Medical devices are developed in the form of software, and it is divided into the form of software, and independent type of software. Software as Medical devices are drawing attention as a key technology related to medical paradigm, and various types of software medical paradigm, and various types of software as medical devices are continuously developed.As a standalone software form, there are AI and digital treatment systems and digital treatment systems. AI, AI and medical data-based software medical devices provide customized treatment methods based on the machine learning (machinery learning) method and provide customized treatment methods. Software Medical devices with these artificial intelligence (AI) and data technology is used to analyze medical video, and treatment based on the type of data technology and treatment. Digital therapy refers to medical devices that manage patients' diseases and perform therapeutic interventions in the form of software such as smartphone apps and programs.

Software as medical devices themselves cannot replace doctors, but software medical devices support better treatment of patients, such as diagnosis, treatment, and management of diseases, based on the latest technology. Software as medical devices can easily, quickly, and continuously collect a variety of valuable data, thereby providing essential or meaningful information for medical treatment and support for users. Software medical devices can enhance the functionality of existing medical devices through software solutions that are faster and easier to update than hardware, and companies that commercialize or develop software medical devices can increase product functionality and shorten the market launch period through quick feedback from users.

Table 3. Comparison of Software as Medical Device and traditional medical device characteristics

Category	Software as Medical Device	Medical Device
Form	Intangible	Tangible
Human danger level	Relatively low	Relatively high
Manufacturing facilities	Unnecessary	Necessary
Product Change	Occasional (version upgrade)	Required for a period of time (more than 1 year)
Quality Management	Scope, criterion ambiguous	scope, criteria clear
Product Shipment	Distribute online	Shipment from warehouse
Display material	Displaying the screen	Container and Packaging

2.3 Characteristics of Software as Medical Device

The biggest feature of software as medical devices is that they are intangible medical devices that have no physical form. There are updates, ease of reproduction and distribution caused by the nature of the lack of form, and the possibility that a third party can install updates provided by software medical device organizations. software as medical devices run on general computers, smart devices, and cloud multipurpose devices and are used in various environments, and are used by being connected to other systems or databases through a communication network or the Internet. Accordingly, there is a possibility that new risk factors may occur because the hardware base using the software is different for each user. Unlike medical devices that change products every few months or years, software as medical devices have a very short design and development period and frequent product changes due to the nature of product changes based on actual use performance and user feedback every few weeks or months. Changes that do not seem to be significant can cause unexpected serious problems elsewhere than software programs. Unlike hardware defects, software defects occur without prior warning, and software development processes must be sufficiently planned, managed, and documented to detect and correct unexpected consequences of software changes. Unlike general medical devices, the boundaries of production stage and development steps to replace the software development stage and development steps to replace software developing software development through software development tools. Software cannot be considered as a factor, but it is always considered in order to contribute to the situation of software as medical devices, and the risk management of software as medical devices. The software must be complete and systematically verified by software and accurate,

and documentized development process should be performed in order to ensure comprehensive validity.software as medical devices products are quickly handled by quickly and efficiently processing the patient behavior, and provides opportunities such as helping patients in non-critical environment, and provide opportunities such as support of patients. The problem of design or execution of software as medical devices may contribute to the wrong selection or decision-making steps, and this can affect patients. Therefore, in order to develop a safe software medical device, measures to identify risk factors and give reliability that certain risk factors are acceptable must be accompanied, and to improve the safety of software medical devices, the standards of risk management, quality management, systematic and systematic system engineering* must be harmonized. These standards should be considered in various aspects such as social technology environment, technology and system environment, and safety-related information security.

2.4 Etc.

In the case of a combination of pharmaceuticals and medical devices, which is one of the new concept medical devices to which digital technology is applied in addition to wellness products and software medical devices, it is impossible to evaluate and manage various types of convergence products as it is currently managed as one of the medical devices and pharmaceuticals. According to Article 31 (7) of the Pharmaceutical Affairs Act in 2011, "When a product or item is a combination of medicines, etc. and medical devices, or a product approved or reported under the Medical Devices Act because its main function is a medical device, is deemed to have obtained an item permission or reported pursuant to paragraphs (2) through (4), the legal basis for convergence medical products was established for the first time." The Medical Devices Act was also newly established in accordance with Article 6 (6) of the 2011 (Production Permission, etc.) and was partially revised in 2015, and it is deemed that "medicine or non-medical products and medical devices are combined or combined, and their main function is to be a drug or non-medical product, and when a manufacturing product is already approved or certified or reported pursuant to Article 31 (2) of the Pharmaceutical Affairs Act, it is deemed to have obtained manufacturing approval or manufacturing certification pursuant to paragraph (2)."

Chapter 3

Investigation of domestic and international institutions

3.1 Wellness Device management status in KOREA

The Ministry of Food and Drug Safety and Drug Safety and medical medical medical devices are used to secure the consistency of the Ministry of Food and Drug Safety and Drug Safety is used as a public health management (wellness).According to Article 2 of the Medical Device Act, a method of determining the product used as a mechanism, mechanical, or treatment, or methods used to treat diseases, treatment, treatment, or prevent diseases.According to Article 3 of the Dong Act, the Ministry of Food and Drug Safety and Drug Safety's safety treatment on the human body and use of medical devices.

It is very important to distinguish whether products for health care, including convergence products using ICT, are medical or non-medical devices. This is because medical devices intended for diagnostic treatment are exposed to various regulations, such as obtaining permission to manufacture medical devices under Article 6 of the Medical Device Act before making such products. However, products developed for health care without the purpose of diagnosis or treatment can immediately enter the healthcare market. Since mid-2014, as the convergence of ICT and medical care has intensified, the number of inquiries about whether the product to be developed by the Ministry of Food and Drug Safety is a medical device has increased, and the movement that this phenomenon needs a guide-level approach rather than a simple individual complaint appeared at the same time as Samsung Electronics launched its Galaxy series, and discussions

began in the United States and Korea, the target countries for the release, on whether the heart rate measuring app installed in it is a medical device. Samsung Electronics asked the Ministry of Food and Drug Safety whether it was a medical device when it launched the world's first heart rate measurement smartphone in March 2014, and the Ministry of Food and Drug Safety determined that it was a medical device. Samsung Electronics released it without installing a heart rate measurement app on the Galaxy S5 for commercial use in Korea. A heart rate measurement app was installed and released on the Galaxy S5 for foreign commercial use, which does not have these related regulations. As convergence and new concept products using ICT are developed and sold, the distinction between medical devices and personal health care products, which are medical devices and non-medical devices, becomes unclear in order to solve the problem that the distinction between medical devices and personal health care products, is a preemptive response to establish judgment standards for wellness products by the Ministry of Food and Drug Safety from March to June 2015, and based on this, a public hearing was held on June 22, 2015, collecting opinions from all walks of life, and then the medical device committee deliberated on July 7 to confirm the wellness product judgment criteria on July 10. However, many opinions were expressed against the wellness product judgment standards established during a public hearing on the wellness product judgment standards implemented from the end of June. In particular, the Korean Medical Association and the medical device industry strongly opposed the establishment of wellness product judgment standards without sufficient collection of opinions while enacting guidelines on issues directly related to public health. Despite these objections, the Ministry of Food and Drug Safety's wellness product judgment standards were set and implemented in the form of business guidelines that support the work of public officials, and the core standard is that the distinction between medical

devices and personal health care products is determined according to the purpose of use and risk. Medical products aimed at diagnosing and treating diseases are judged as medical devices, and personal health care products aimed at using personal health care in daily life are largely classified as non-medical devices. Personal health care products are used alone or in combination with humans, as devices, devices, materials, software, and apps, and refer to products with low risk to user safety. Medical devices and personal health care products are classified based on risk, and medical devices are classified into four grades according to their potential risk to the human body. In the distinction between medical devices and personal health care products, the purpose of use shall be classified through a comprehensive judgment based on the objective intention of the manufacturer, such as standards, instructions, information, etc., indicating and advertising the purpose of use, oral or written expressions, product structure and form, indicated purpose of use and effectiveness, propagation or explanation when selling.

The specific criteria for determining the risk are ① high risk in cases of causing biocompatibility problems, ② invasive cases, ③ user injury or disease when it does not work as intended by the user, ④ in cases of emergency situation detection, ⑤ special materials used in wearable devices such as device functions, characteristics control or change, etc., which are feared to cause problems such as skin diseases. On the other hand, in the case of low-risk, it refers to portable products that monitor the user's heart rate during exercise or hiking with a low degree of risk to user safety. Regardless of the purpose of use, if the principles of action, such as human insertion, energy transfer, and structural change, are harmful to the human body, they are managed as medical devices. Personal health care products other than medical devices are used for the purpose of maintaining and improving health conditions or healthy activities, and for 'self-management of chronically ill' products used to reduce the risk of chronic

diseases by inducing a healthy lifestyle. Products for Daily Health Management include biological phenomenon measurement and analysis, physical function improvement, exercise and leisure, and daily health care medical information, while Products for Self-Management of Chronic Diseases include chronic disease phenomenon management and chronic disease medical information. Table 4 is an example of these products.

Table 4. Distinguish between medical devices and wellness products

no	Name of the product	Wellness Device	Medical Device
1	Electrocardiogram	An instrument that measures an electrocardiogram to help provide food recipes that fit your body condition	An instrument that measures an electrocardiogram in a medical institution for the purpose of diagnosis and treatment of a disease, etc
2	Sleep evaluation device	A device that measures movement heart rate during sleep for simple sleep management at home	A device that records bio-signals recorded during sleep and is used to evaluate sleep disorders (insomnia, snoring, etc.)
3	Pneumatometer	an instrument that simply measures self-respiratory volume (lung capacity)	A lung function measurement tool that measures the amount of gas coming out and entering the patient's lungs
4	Instrument for internal function inspection	An app that receives, displays, stores, and analyzes measured data from various medical devices for self-health management	Patient monitoring devices that acquire bio-signals for diagnostic and therapeutic purposes
5	Personal blood glucose measuring system	Blood glucose meters and test papers used by themselves for the purpose of managing diabetes, which is a chronic disease	Instruments and testers used in medical institutions for medical purposes, such as diagnosis and treatment of diabetes (reagent)
6	Sphygmomanometer	A blood pressure gauge used by itself for the purpose of managing hypertension, a chronic disease	Blood pressure gauges used in medical institutions for medical purposes, such as diagnosis and treatment of hypertension

The Medical Device and Personal Health Management (Wellness) Product Judgment Standards are guidelines for public officials, and they present detailed standards or procedures for administrative affairs internally in order to unify administrative affairs, and since they do not have legal effect externally, they have limitations that can only be used as reference despite the technical method of the text (such as "to be done"). Guidelines for public officials differ in nature from ordinary administrative rules. Administrative rules are defined as "general and abstract rules issued within an administrative organization or by a higher administrative agency to a lower administrative agency regarding its organization, business processing, procedures, standards, etc." The definition of the "administrative rules" is not separately stipulated in laws and regulations, but Article 24-3 (1) of the "Regulations on the Operation of Legal Affairs" (Presidential Decree) abbreviates regulations, rules, instructions, guidelines, and notifications issued directly in connection with the enforcement of laws and regulations as "instructions, regulations, etc." Article 2 (1) of the "Regulations on the Issuance and Management of Orders, Regulations, etc." (Presidential Decree) abbreviates orders, regulations, notifications, regulations, rules, guidelines, etc. issued in connection with the enforcement of laws or administrative affairs, regardless of their name, as "instructions, regulations, regulations, regulations, regulations, guidelines, etc." and this is called administrative rules in practice or in academic terms.

Regarding the legal nature of administrative rules, academia has a non-legal theory that it has one-sided and one-sided binding force only within the administrative organization but does not have a direct effect on the people, a quasi-legal theory that discretionary rules among administrative rules indirectly have legal effect on the people through constitutional equality principles, and a legal theory that administrative power has an independent regulatory power within

the scope of its authority. In the case of courts, in principle, there is no legal regulation for administrative rules to guide and supervise the exercise of its authority within an administrative organization through precedents. On the other hand, the legal nature of administrative rules may vary depending on the type of administrative rules. Accordingly, administrative rules are divided into types and their legal nature is explained. As an important type of administrative rules, there are statutory supplementary rules (law supplementary administrative rules) that supplement the contents of the laws and regulations according to the delegation of higher laws. Legal effect is recognized for these statutory supplementary rules (law supplementary administrative rules). This includes directives and notices that determine the matter of delegation according to the delegation of laws and regulations, and it is very important in administrative practice because the legal effect is recognized.

The criteria for determining the health management system is not equipped with the law, and the administrative rules to map and supervise the administrative organization, and the administrative organization is also judged that there is no legal principles

It is true that administrative rules have a significant impact on people's lives today in a situation where administrative dependence on people's lives is increasing and administrative discretion is widely recognized in each field. In particular, in the absence of legal criteria, the criteria for judgment for the handling of work of public officials in charge will have a significant impact on companies that manufacture or sell health care products and consumers who use health care products. Even if it is an administrative rule for internal guidance and management, complete denial of the legal nature of the administrative rule will result in a loss of concrete validity, given the practical function and the need for judicial control. The 「Framework Act on Administrative Regulations」, which

stipulates basic matters related to administrative regulation, stipulates that regulations that should be based on the law can also be determined by public notice, etc., if the scope of the matter is specifically determined and delegated due to the nature of the work as professional and technical or minor matters. This criterion does not correspond to administrative rules in form, but it is very similar to the administrative rules issued by higher administrative agencies to rationalize administration by unifying the interpretation of laws and regulations, especially when applying the concept of uncertainty in laws and regulations.

As described above, in order to inform the relevant industries and the general public (consumers) of the relevant matters in the absence of standards for judgment on general health care products under the law, the current form of guidelines for public officials is not appropriate. At least, it is necessary to officially notify the general public of the safety of health care products by changing them to administrative rules (instructions, regulations, notices, etc.) that are recognized as legal regulations, and to promote the convenience of the industry. The term "notice" or administrative rules means a document for determining legal matters to supplement the contents of laws and regulations as delegated by laws and regulations, or for informing the general public of certain matters as prescribed by laws and regulations. A notification is an administrative rule only when the contents of the notification are general or abstract rules, and if the contents of the notification are simple notification of facts, it is difficult to regard it as an administrative rule. On the other hand, when a notification has a general or specific nature, it is a general disposition. In addition, a notification of the type of supplementary rules of laws and regulations according to the delegation of laws and regulations shall have the effect of a legal order. On the other hand, as a general or abstract rule, a notice corresponding to the administrative rule shall be registered in the legal information system (Government

Legislative Support Center) in accordance with Article 24-3 of the Legislative Business Operation Regulations, and even if a notice or a certain matter is notified to a large number of unspecified persons, it is desirable to register it in the legal information system (Government Legislative Support Center) to provide services to the public. Various notices such as "notice on detailed standards for virtual advertisements" and "notice on harmful media (publications) for juveniles" are used as examples of stipulating matters that are harmful to the general public in the form of notices. In order to enact the current judgment standards as a notice, it is necessary to examine the requirements and contents of the legislating entity. Since there is no special restriction on the person who has the right to issue administrative rules, an administrative agency with the status of an administrative agency may issue administrative rules. Article 24-3 (1) of the Presidential Decree, "Regulations on the Operation of Legal Affairs", stipulates the subject as "administrative agencies of each level". At this time, administrative agencies at each level will include not only central administrative agencies but also agencies affiliated with each central administrative agency. The administrative agencies that use the names of various committees, including the Fair Trade Commission, Financial Services Commission, Anti-Corruption and Civil Rights Commission, the National Human Rights Commission, the National Human Rights Commission, and the Nuclear Safety Commission, the presidential agencies such as the Board of Audit and Inspection and the National Intelligence Service, the constitutional agencies such as the National Election Commission, and some other committees such as the Korea Video Promotion Commission. The administrative rules that must be registered in the Government Legislative Support Center pursuant to Article 24-3 (2) of the "Regulations on the Operation of Legal Affairs" are administrative rules issued by the heads of each central administrative agency, and the administrative rules stipulated in Articles 3 and 9 (3) of the "Regulations on

the Issuance and Management of Directives and Regulations" (Presidential Decree No. 394) are not subject to registration. Content requirements are as follows. Unlike administrative rules in their original sense, which regulate organizations and activities within an administrative organization and the scope that does not affect the general public, supplementary administrative rules that affect not only the inside but also the outside of the administrative organization perform the same function as laws and regulations in that they affect the rights and obligations of the people. Therefore, only those within the scope specifically delegated by the statute should be prescribed, not contrary to the contents of the higher statute, and the regulatory contents set by the higher statute should not be strengthened. When determining matters concerning the enforcement of higher statutes, only supplementary matters necessary for the enforcement of the higher statutes should be determined, legal stability and predictability should be guaranteed, there should be no contradiction and overlap between regulations, and the expression should be clear.

3.2 Wellness Device International management status

3.2.1 The United States of America

The Food and Drug Administration(FDA) is an agency under the U.S. Department of Health and Human Services, which is similar to Korea's Ministry of Food and Drug Safety, responsible for protecting and promoting public safety by managing and supervising the safety of food, cigarettes, dairy products, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation devices (ERED), cosmetics, animal food, and feed. As a sub-organization, the Center for Devices and Radiological Health (CDRH) is an organization responsible for overseeing most medical devices in the FDA, including all departments of the Medical Device Safety Administration, an organization within the Korean Ministry of Food and Drug Safety.

The FDA CDRH has enacted and is utilizing the "General Wellness: Policy for Low Risk Devices Guide for Industry and Food and Drug Administration Staff" to ensure consistency of work and use it as an internal administrative guideline. With the development of the ICT and smartphone markets, various innovative products that help manage health are being developed, the distinction and predictability of medical devices and wellness products is becoming an increasingly important issue for manufacturers or developers. If a product is a medical device, it must be incorporated into a specific classification system and meet corresponding legal requirements in accordance with FDA regulations, but since general wellness products are FDA-exempted items, they can be released on the market without the explicit requirements of Article 510(k) of the Federal Food, Drug, and Cosmetics Act (FD&C Act) or the pre-market approval required for Class III medical devices. In addition, general wellness products do not have to

fulfill the annual registration and fee payments required of all medical device manufacturers. In addition, there is no need to register products in the registration and listing database.[2]

The U.S. FDA has prepared guidelines for judging low-risk wellness products through guidelines for industry and Food and Drug Administration officials titled General Wellness: Policy for Low Risk Devices. This guideline was first published on January 20, 2015, revised on September 27, 2019, and makes it clear that it is a non-binding recommendation as an administrative rule. The guide currently expresses the FDA's view and does not create any rights or impose any obligations, and stakeholders can take a different approach than the guide. This corresponds to the same format of internal business guidelines for administrative agencies as Korea's judgment standards.

The certification system that can be applied to various kinds of wellness products varies widely depending on the item. This is especially the case in the United States, where industrial products are not subject to special regulations unless they are medical devices. Here, we look at possible certification by considering the 'wearable heart rate monitoring device' as an item example.

(FCC-CoC) Daytime and international communication through radio, television, wired, satellite and cable in the United States is regulated, and all electrical and electronic and wired communication devices and wired and wireless communication devices that generate electromagnetic waves must meet FCC regulations. Conformity must be proved through a certification (CoC) procedure according to product classification. The regulatory body is the Federal Communications Commission (Federal Communications Commission), and certification can be granted through five certification bodies.[1)]

---

1) Information on the FCC-CoC certification authority in the United States can be searched at https://apps.fcc.gov/oetcf/tcb/reports/TCBSearch.cfm .

(FCC-SDoC) All electrical and electronic devices and wired and wireless communication devices that generate electromagnetic waves must meet FCC regulations. According to the product classification, conformity must be proved through the Supplier's Declaration of Conformity (SDoC) procedure. The relevant legislation is 47 CFR (Title 47 of the Code of Federal Regulations) - Telecommunication, and the regulatory body is the Federal Communications Commission (FCC). There are no designated certification bodies or test qualification standards. The certification process is carried out in the order of 1) checking which FCC rules the product falls under, 2) going through the conformity satisfaction process according to the regulations, 3) product test, 4) issuing SDC (Supiler's Declaration of Conformity), and 5) marking the FCC.

(Nationally Recognized Testing Laboratory (NRTL)) The Occupational Safety & Health Administration (OHSA) in the United States designates private laboratories in the United States as NRTLs, requiring them to be tested and certified by the NRTL for specified items. Each NRTL has a range of recognized test standards, and each NRTL uses its own registered certification mark to specify product conformity to that product safety test standard. After certification of the product, the NRTL authorizes the manufacturer to apply the certification mark registered on the product, and if certification is performed under the NRTL program, this indication indicates that the product has been tested and certified by the NRTL and that the product has complied with the requirements of one or more appropriate product safety testing standards. NRTL certification is not a mandatory approval requirement by the U.S. federal government, but in some places it is compulsory under non-rigid standards or state law for each state. The relevant legislation is 29 CFR (Title 29 of the Code of Federal Regulations) 1910.7 - Definition and requirements for an nationally registered testing lab, and the regulator is the U.S. Department of Labor, OSHA.

(Prop 65) A certification that requires an enterprise to provide warnings to Californians about serious exposure to chemicals that cause cancer, birth defects or other reproductive disorders. These chemicals may be in products purchased by Californians, in their homes, at work, or released into the environment, and by requiring the provision of this information, Prop 65 allows Californians to make informed decisions about exposure to these chemicals. The relevant statute is the Safe Drinking Water and Toxic Enforcement Act of 1986, and the regulator is the California Office of Environmental Hazard Assessment (OEHHA). This certification does not obtain a separate certification authority approval, and no separate testing agency is established in the form of labeling by the manufacturer depending on the analysis results.

The certification process consists of 1) evaluating chemical content and exposure, and 2) attaching a Proposition 65 warning label to the product, if applicable. The label should list the name of the chemical contained in the product and the damage caused by exposure. Items subject to certification are all consumer products sold or distributed in the state of California.

(US-FDA) Overseas companies and distributors in the United States that manufacture medical devices sold in the United States are required to register and obtain licenses under the U.S. Federal Food and Drugs and Cosmetics Act (FD&C Act) before or during importation of products into U.S. territory. This certification applies only to medical devices. Medical devices that are not licensed by the FDA cannot be distributed and sold in the United States, and even products on sale may be subject to penalties for correction, recall, product seizure or disposal, and criminal disposition if they are found to be unsatisfied with the regulations in the FDA's follow-up management. All medical devices exported into the United States are classified into grades 1, 2, and 3, accordingly, the level of regulation and required data are different. 510K (Premarket Notification) is required for grade 1

and 2 medical devices. The FDA implements this certification system to monitor reports on side effects and other problems of medical devices and, if necessary, to ensure proper use of devices and health and safety of patients to medical experts and the public. The certification body is the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA's) and, in the case of electrical tests, the ISO/IEC 17025 testing body in Korea can receive them.

Table 5. U.S. Certification of Wearable Heart Rate Measuring Devices

Certification name	Content	Certification mark
FCC-CoC	Daytime and international communication through radio, television, wired, satellite and cable in the United States is regulated. All electrical and electronic devices and wired and wireless communication devices that generate electromagnetic waves must meet FCC regulations. Conformity must be demonstrated through a certification (CoC) procedure according to product classification	none
FCC-SDoC	Daytime and international communication through radio, television, wired, satellite and cable in the United States is regulated, and all electrical and electronic devices and wired and wireless communication devices that generate electromagnetic waves must meet FCC regulations. Compatibility must be demonstrated through the Supplier's Declaration of Conformity (SDoC) procedure according to product classification	FC
NRTL	The U.S. Office of Occupational Safety and Health (OHSA) designated private testing labs in the U.S. as NRTLs, requiring them to undergo product testing and certification in the NRTLs	Using the Certification Authority's

	for the specified items. Each NRTL has a range of recognized test standards, and each NRTL uses its own registered certification mark to specify product conformity to the applicable product safety test standards. After certification of the product, the NRTL authorizes the manufacturer to apply the certification mark registered in the product. If certification is carried out in accordance with the NRTL program, this indication indicates that the product has been tested and certified by the NRTL and that the product complies with the requirements of one or more appropriate product safety test standards	Logo
Prop 65	Requires businesses to provide warnings to Californians about serious exposure to chemicals that cause cancer, birth defects, or other reproductive disorders. These chemicals may be in products purchased by Californians, in their homes, at work, or in products released into the environment. By requiring this information to be provided, Proposition 65 allows Californians to make informed decisions about exposure to these chemicals	none
US-FDA	Overseas companies manufacturing medical devices sold in the United States and distributors in the United States need to register and obtain licenses under the U.S. Federal Food and Drugs and Cosmetics Act (FD&C Act) before or during the import of products into the U.S. Medical devices that have not been approved by the FDA cannot be distributed and sold in the United States, and even products on sale may be subject to penalties for correction, recall, product seizure or disposal, and criminal punishment if they are found not satisfied with the regulations in the FDA's follow-up management	none

3.2.2 Europe

European health care products are first defined under the judgment of whether or not they are medical devices, and medical device regulations are based on the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), and the European Commission manages the health authorities of each country, and countries in Europe apply their laws so that CE-certified products can be distributed in Europe according to the above regulations. In addition, a third-party body (NB) licensed by national health authorities in Europe qualifies for CE certification in Europe for products from manufacturers and importers.

The European Union does not separately define or regulate health care products, so even if it is concomitant with disease prevention and health, it is not regulated as a medical device if the manufacturer does not intend to use it for medical purposes. In the case of medical devices, in order to be released on the EU market, they must be CE certified with safety and functional requirements, and go through risk management procedures and clinical evaluation, so in practice, the distinction between health care products and medical devices is becoming an important issue.

The division of medical devices and health care products in the UK is handled by the UK Medicines and Healthcare Products Regulatory Agency (MHRA). MHRA enacted and utilized the "Guidance on Regulatory Borderline Legislation Guide for Medical Devices and Other Products in the UK on the 2002 UK Medical Device Guidelines". "Guidance on Regulation Borders with medical devices and other products in the UK for the 2002 UK Medical Device Guidelines, Guide on Regulations 2002[7] (SI 2002 No 618, as approved) is a legislative guide that represents the MHRA's current views on the interpretation of borderline products

and related medical device laws. This is a general guide and should not be considered an authoritative statement of the law or considered to have legal consequences. (State not to rely solely on this guide - it corresponds to the same format of internal administrative guidelines as in Korea.)

Table 6. Guidance on legislation Borderlines with medical devices and other products in Great Britain In relation to the UK Medical Device Regulations 2002

「Guidance on legislation Borderlines with medical devices and other products in Great Britain In relation to the UK Medical Device Regulations 2002 (SI 2002 No 618, as amended」

A) Definition of health care products (wellness products)

General equipment that can be used by all people is regarded as an 'assisted tool for daily life' rather than a medical device. In general, sports or leisure products are not medical devices, but in some cases, it is stipulated that products targeting sportspeople can be regarded as medical devices. In other words, if there are specific claims about the treatment of pain or injury in general and the product acts in a physical way, it is likely to be a medical device.

B) Key types and examples

This document presents whether medical devices are applicable for specific products related to.

· Medical devices and in vitro diagnostics
· Pharmaceuticals including medical devices and advanced medical drugs (ATMP)
· Medical devices and biological agents
· Medical devices and human-derived materials

· Medical devices and cosmetics

· Medical devices and food

· Medical devices and personal protective equipment

· Medical devices and general consumer goods

· Other medical devices

Assistive devices for everyday life are not medical devices (such as sound signals from traffic lights, bathtubs with doors, handle rails (exits, stairs, etc.), personal alarm systems/home alarm systems, special faucets, disabled/senior toilet equipment (e.g., toilet seats, shower seats, toilet seats, etc.) 2) Equipment for mitigation or compensation of disabilities may or may not be medical devices. A determinant is whether there is a direct association with a specific individual in relation to the calibration function of the equipment, which is determined based on the main purpose of use of the product as defined by the manufacturer. It is entirely up to the manufacturer's claim for each product. In the case of software, if a particular software, including standalone software, is used with the device depending on the manufacturer's diagnostic/treatment purpose, the software is considered a medical device. Therefore, simple patient management systems and record storage systems are not medical devices.

C) Criteria for determining risk

No risk criteria for determining wellness products were presented separately within this document.

3.2.3 Japan

On November 25, 2014, the Pharmaceutical Affairs Act was revised to partially revise the law, and at the same time, the name of the law was also revised to the Act on Securing the Quality, Effectiveness, and Safety of Drugs and Medical Devices. In general, it is abbreviated as the "Pharmaceutical-Medical Device" or sometimes referred to as the "Pharmaceutical-Medical Device". As the name suggests, this Act stipulates in detail manufacturing, labeling, sales, distribution, advertising, etc. in order to secure the quality, effectiveness, and safety of products such as pharmaceuticals, non-medical products, cosmetics, medical devices, and regenerative medicine (hereinafter referred to as "medicine, etc."), and it is the law that the relationship must come when manufacturing, selling, or advertising drugs, etc. Businesses handling medicines, non-medical products, cosmetics, etc. must follow the drug techniques. In addition, it is necessary to ensure that businesses handling health foods, supplements, health and beauty products, etc. do not violate this Act. Among the drug techniques, products such as pharmaceuticals, non-medical products, cosmetics, medical devices, and regenerative medicine are defined and rules respectively.

Table 7. Article 1 of the Pharmaceutical-Medical Device

Article 1 of the Pharmaceutical-Medical Device
Article 1 The purpose of this Act is to improve health and hygiene by taking necessary measures to ensure the quality, effectiveness, and safety of products such as medicines, cosmetics, medical devices, and regenerative medicine (hereinafter referred to as pharmaceuticals), to prevent the occurrence and

expansion of health and hygiene risks caused by their use, and to promote research and development of products such as medicines, medical devices, and regenerative medicine that are particularly necessary for medical purposes.

Pharmaceutical-Medical Device are regulated by a total of five products, including pharmaceuticals, non-medical products, cosmetics, medical devices, and regenerative medicine, and each definition is described in Article 2 of the Pharmaceutical-Medical Device. Since health foods, supplements, health-related products, beauty devices, etc. do not fall under these five categories, there are no direct restrictions by law. However, expressions that violate drug techniques, such as appeal for effects such as medical products, are prohibited by law.

Health-related devices and beauty devices do not fall within the scope of the regulation of the pharmaceutical technique, such as health foods and supplements, but if an expression such as mistaking it for a drug is made, it violates the pharmaceutical technique. Health and beauty miscellaneous goods include, for example, compression stockings, muscle exercise aids, and hair loss devices. These are miscellaneous goods to the fullest, and it is forbidden to appeal for effectiveness.

Japan's Ministry of Economy, Trade and Industry has established the "Healthcare Service Guideline Method" as a guideline for the guideline certification system established by industry organizations of businesses that provide healthcare products/services in order to promote environmental improvement that enables continuous quality evaluation while urging policies on voluntary quality evaluation standards related to each industry. In accordance with this guideline, there are cases in which a business operator directly provides products/services through securing the quality of healthcare and wellness products/services by industry, improving the reliability of business operators, and securing trust from

intermediaries and users, and in order to make it easier to understand the value enjoyed by intermediaries or users. In this guideline, the term "healthcare (wellness) products/services" means the production, sale, or provision of products that contribute to the extension of healthy life through maintenance and promotion of health, care, and prevention. (excluding products or services that require permission under individual laws), as a distribution structure of healthcare products/services, there are cases in which a business operator directly provides products/services to users (BtoC) and cases in which health care products/services are provided to users through intermediaries (BtoBtoC). Considering the above health care industry phenomenon, it is necessary to establish a desirable distribution structure, especially between groups, business operators and intermediaries (BtoB). This guideline is a guideline for matters to be based on when an industry organization to which a business belongs establishes industry independent guidelines, etc., and it is expected that the use of quality-guaranteed health care products/services will be promoted and contribute to the development of a healthy health care industry as medical services based on industry independent guidelines based on these guidelines maintain an environment selected by intermediaries and users. As a structure for securing the quality of health care services, there are two types of industry independent guidelines based on this guideline. As shown in Table 8 and Table 9, it is a mechanism to secure quality by voluntarily securing quality according to the standards set by industry organizations, and by introducing a certification system to replace certification by industry organizations, third-party certification, and self-declaration.

Table 8. Classification of certification systems based on industry frequent guidelines

no	Way	Kind	Content
1	Certification system	Third-party authentication	Since it is an examination and certification by a transparent and neutral third party, fairness and objectivity are easily guaranteed and the most reliable method. On the other hand, there are tasks or costs for establishing and operating an examination certification agency, maintenance of manuals according to the examination, and establishment of an examiner or examination committee.
2		Industry group certification	Since it is not reviewed and certified by a transparent and neutral third party, it lacks reliability in terms of fairness and objectivity compared to third-party authentication, but the work and cost related to the operation of the certification system are relatively small compared to third-party authentication, so it is considered an easy way for industry organizations to respond independently.

Table 9. Self-declaration and Accession criteria for industry organizations

no	Way	Content
1	Self-declaration	It is a method of independently declaring that individual business operators strictly comply with the guidelines as an alternative to certification in accordance with the "Industry Independent Guidelines" discussed in a transparent and neutral place. When an individual business operator self-declares about the reliability of his or her service, it may be understood that fairness, objectivity, and reliability are insufficient because it has not been reviewed by a neutral third party or industry organization. There is also a method for a neutral third party or industry organization to check the contents of the self-declared business operator after the fact. In addition, it is necessary to review measures to ensure the reliability of a neutral third party or industry organization in case the content of the self-declaration is deemed not to comply with the "Industry Independent Guidelines".
2	Accession criteria for industry organizations	This is a method based on each item of the "Industry Independence Guidelines" established after discussions in a transparent and neutral chapter. If it is regarded as a response to motivation to comply with industry independence guidelines, but is not properly observed, fairness or objectivity is inferior to third-party or industry group certification if appropriate measures are not taken by industry groups.

Health care products fall under the primary prevention stage, so relevant regulations or laws under the drug technology do not apply. Currently, there are no primary prevention evaluation agencies or laws. However, various health products, foods, and services that correspond to the primary prevention are being released, making it difficult for consumers to know about the products, and accidents occur. Therefore, it is required to issue a common license mark (certification mark) to products, services, and systems that have cleared certain standards with an emphasis on health care prevention, create a system that allows consumers to "buy and use good things at an appropriate price," and to issue a certification mark (certification) for the provision of products or services that respond to consumer needs through this basis. The certification business focuses on preventing health care and issues a common license mark (certification mark) to products, services, and systems that meet certain standards, and aims to 'create a system where consumers can buy good things at an appropriate price and use them properly to gain joy'. It is a business that issues certification marks (certificates) for the provision of products or services in response to consumer needs through the creation of such a foundation. It is considering not only the certification business of corporate healthcare products and services, but also holding seminars and events, or obtaining healthcare product meister qualifications for general consumers. A monitor group by support members is formed to evaluate products or to provide services at a member price.

Massager, a representative health care product in Korea, corresponds to a management medical device that considers risks to the human body in Japan. Medical devices are classified into three categories, such as altitude management medical device, management medical device, general medical device, and massager is classified as a medical device corresponding to Class 2 among the four global classes, and permission and reporting are set according to the Pharmaceutical

Medical Device Act (Medical Technology on November 25, 2015). In other words, it is a medical device that advocates the "massage effect" with electricity, and "toy (goods)" that vibrates with a motor is treated as miscellaneous goods (industrial products) that do not correspond to the medicine technique. Except for electricity, simple acupressure devices (severe pressure devices, foot health devices) should also be treated as miscellaneous goods that do not correspond to the medicine technique.[8] Management medical devices are classified as having a risk of affecting human life and health due to side effects or dysfunction. Blood pressure gauges, hearing aids, and home massage chairs are also management medical devices in a large category. Home massage chairs, which are classified in more detail, correspond to managed medical devices (home management medical devices) other than specific managed medical devices. Home care medical devices can be sold only with a formal report, not permission, so they can be sold by reporting the sale to the local public health center. Where you can check whether you have a formal report or not, you can refer it to the Kanagawa Prefectural Health and Welfare Center.[9]

Table 10. Certification Authority Comparison[10], [11]

	Japan Healthcare Product Evaluation Organization (Specified Non-Profit Activities Corporation)	Japan Home Health Devices Association (General Corporation)
Year of establishment	2013	1972
Business contents	- Healthcare product evaluation certification business, new business creation business - Entrustment of administrative agencies, etc - Promoting other healthcare-related businesses	- Home health device certification project - Health promotion device certification project - Establish appropriate sales and advertising guidelines for home health devices - Promoting other healthcare-related businesses
Legal basis	- Compliance with relevant laws and regulations for each target product - Non-medical devices: PSE-related laws and third-party certification (private) - Medical device - PMDA approval	- Compliance with relevant laws and regulations for each target product - Non-medical devices: PSE-related laws and third-party certification (private) - Medical device - PMDA approval
Guidelines Basic Policy Application	X	O
Advertising guidelines or not	X	O

Authorization for certification	certification committee	an evaluation committee
Evaluation criteria	Calculate the evaluation score of the user and the certification commissioner	Calculation of the evaluation score of the member of the evaluation deliberation committee
certification target product	- Clothes - Living health - Structural system facilities (health care equipment) - Electrical IT Product Services, Others	- Home medical equipment (maskers, infrared therapy devices, etc.) - Health care equipment (blood pressure gauge, body fat meter, etc.) - Home beauty equipment (cleaning machine, moisturizing accelerator, etc.) - Health promotion devices (home devices for improving human health and beauty promotion QOL)
After authentication, follow-up management	Unable to investigate related information in detail	There is no detailed investigation information, but there is a follow-up management implementation
a major member company	Unable to investigate related information in detail	About 400 companies such as medical companies, IT companies, IT companies
certification cost	Unable to investigate related information in detail	- Certification examination cost: 580,000 yen (approximately 527,000 million won) - Update fee: 35,000 yen (about 318,000 won)

certification mark		- The external evaluation committee confirms the validity of the evaluation results and marks them as marks, and certifies products and services above a certain score		Association Mark, Association Member Company
				Health promoting device marks given to products and services that have passed the Association certification standards
Homepage	https://jao-hcb.org/		https://www.hapi.or.jp	

Table 11. Comparison of the status of wellness equipment certification by country (excluding beauty equipment)

	Korea	US	Japan	EU
Certification system	electrical appliances	electrical appliances	electrical appliances	electrical appliances
Authenticat-ion status	KC	FCC, UL	PSE, Separate certification	CE
Wellness Device Guidelines	O Medical devices and personal health care products (wellness) criteria	O General Wellness: Policy for Low Risk Devices	O Health care products / Basic Policy of Service Guidelines	X
Regulatory authorities	Government	Government(UL)	Government / Separate certification	NB(commissioned by the government)

Table 12 Comparison of the status of massager certification by country among wellness products

	Korea		US		Japan		EU	
Purpose of use	medical use	non-medical use	medical use	non-medical use	medical use	non-medical use	medical use	non-medical use
Certification system	medical devuce	electrical applian-ces	medical devuce	electrical applian-ces	medical devuce	electrical equipm-ent	medical devuce	electrical applian-ces
Authentic-ation status	MFDS	KC	FDA	FCC, UL	PMDA	PSE	CE (MDR)	CE (EMC, Safety)
Regulatory authorities	MFDS	Ministry of Industry	FDA	FCC	PMDA	Ministry of Economy	NB	NB

3.2.4 Implications for Korea's Management System

The Korean government's efforts to determine wellness products are basically in line with regulatory trends in major overseas countries in that it is a move to secure regulatory clarity in response to uncertainties arising from the development of wellness products, promote market growth, and minimize side effects, but a closer look at this reveals some major differences. First of all, in the case of the United States, rather than voices of concern for consumer safety, the direction for industrial promotion, investment, and development within the industry seems to be firm. Concerns such as consumer safety, environmental issues, and harmful substances are managed through existing industrial products laws and certification systems, and the United States promotes the industry by quickly developing and launching products without burdening medical device-related approval through FDA's general wellness product guidelines to secure market data and attract investment. In Europe, efforts are being made to establish a continuous and efficient legal system to ensure that the safety and utility of products are guaranteed at a high level in common without hindering technological innovation and innovative products from being released on the market and applied to users within the medical device regulatory system. The EU and its member countries, Germany and the United Kingdom, have only enacted a manual that presents a few cases of borderline products classified by medical device items, and the EU seems to be taking a considerably more cautious approach than the United States or Korea, where the competent department has set relatively clear criteria for judgment in the form of public officials' work guidelines for industrial promotion.

The most interesting country among major overseas countries is Japan. In the case of Japan, it is implementing policies that place more weight on manufacturing, such as domestic manufacturing and exports, rather than domestic

sales of wellness products (when imported from China and sold in Korea). Companies that manufacture and produce wellness products in Japan are establishing independent guidelines that are consistent with laws and government policy directions to secure quality on their own and establish a system that consumers can trust. In addition, the certification system according to these independent guidelines is autonomously implemented by business organizations, and the government is providing policy and financial support for the establishment and activation of these systems. This has the most characteristic implications among the foreign countries examined in that the state does not actively lead regulations or industrial promotion, but rather supports the successful establishment of a virtuous cycle structure that encourages the independent movement of the industry as much as possible.

Overall, Korea's current criteria for judgment need to be continuously revised in that the United States has established guidelines related to wellness products and is constantly revising the guidelines by collecting opinions from the industry and consumers. As mentioned above, the current "Medical devices and personal health care product judgment standards" are business guidelines of public officials within administrative agencies, which are not externally binding, and only a few cases are presented, which is insufficient to help the industry and the general public understand sufficiently. In addition, the opinions of various stakeholders are reflected during the revision process, and the criteria for determining harm are subject to confusion due to different risks and requirements of medical devices. It is necessary to review ways to safely launch and utilize health care products to maintain and promote the health of the people by upgrading the current judgment standards to the level of administrative rules (notices or guidelines) that the industry and the general public can more easily access and trust. Furthermore, it is necessary to review whether it is necessary to re-establish the standards for

risk by revising the guidance of the Medical Device Act and the "Medical Device and Personal Health Care (Wellness) Judgment Standards". Products that come into contact with the human body for a long time or have strong electromagnetic waves that affect the human body need to be incorporated into an appropriate location within the existing medical device classification system. In the case of health functional foods, it is necessary to revise the Medical Device Act or review whether separate legislation is necessary, referring to the case of enacting the "Health Functional Food Act", which stipulates standards, standards for the manufacture of health functional foods, and penalties for violations, in order to evaluate the safety and functional foods manufactured and sold in our society and manage the distribution order. It is necessary to consider whether a separate legislation is necessary or not, referring to the case of the enactment of the "Health Functional Food Act", which stipulates standards, standards for the manufacture of health functional foods, etc., is necessary. For health management products that are the most basic field in health management prevention medicine, it is difficult to cope with the side effects, so it is necessary to consider introducing a certification system voluntarily in the related industry for personal health care products excluded from the Medical Device Act, as in Japan's case. In addition, industry policy and financial support measures and measures to raise public awareness necessary to promote the establishment and use of the certification system should be sought together.

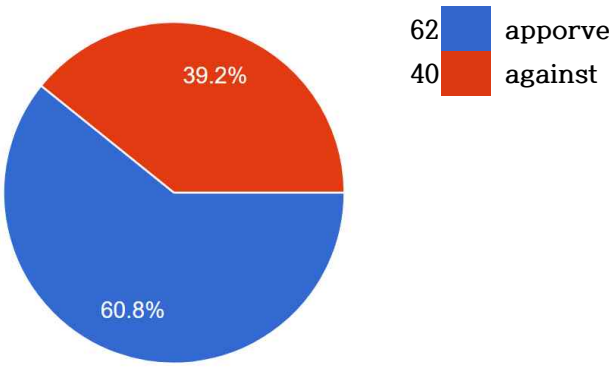
Chapter 4. A Study on Industry Awareness for the Establishment of Safety Management System

According to a survey of 102 industry officials, including companies producing wellness products in Korea and software medical device companies, the majority (60.8%) agreed to the introduction of a group standard and certification system for wellness products, but some (39.2%) opposed it. The main reason for approval was securing product reliability through certification at 48.4%, followed by blocking low-cost products such as Chinese products at 19.4%. For the opposite reason, 50% of the respondents said that the system would be a starting point for strengthening another regulation in the future, with 20% of the increase in certification costs and 15% of the burden on the new certification system. The results of these surveys show that they expect the certification system to act as a means of securing the reliability of the product as well as a marketing tool, and expect domestic companies to revitalize and develop industries by blocking the offensive of low-cost products from China. Contrary to the intention of this system, opposition was concerned that new regulations would arise in the future and become stricter, and it can be seen that the burden of certification costs and new procedures is at play due to the nature of domestic companies with many small businesses.

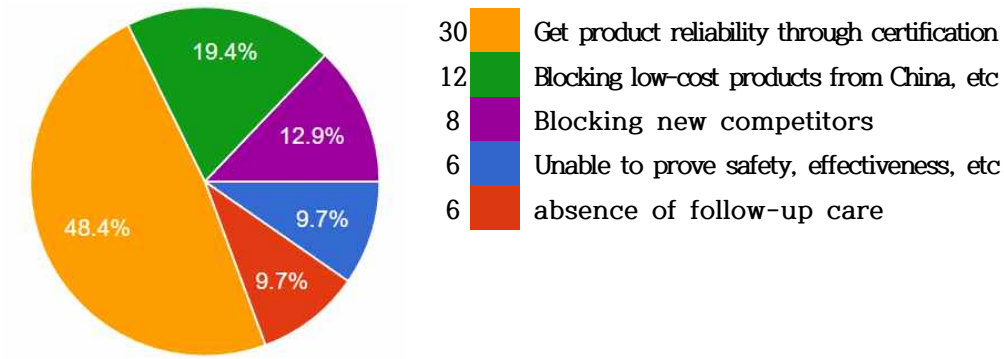
On the other hand, the majority (70.6%) agreed to the incorporation of digital technology into the new classification system, such as software and medical devices, and the main reason for their approval was the expectation of reflecting the characteristics of medical products with digital technology (58.3%) and the increase in new types of medical devices that do not conform to the existing regulatory system (30.6%). This seems to reflect the practical difficulties that the

current Medical Device Act does not contain the characteristics of medical devices to which digital technology is applied. However, for some opponents (29.4%), there were concerns that the classification system would lead to another strengthening of regulations (40%) and that adaptation to the new regulatory system would be a burden (26.7%). This shows that new bills and systems are perceived as strengthening regulations by companies, and this may be natural in a way due to the structure of the domestic medical device industry, where the majority of small companies are located. In the case of introducing a new legal regulation or classification system in areas where there were no existing regulations, it is necessary to comprehensively examine whether the regulatory method is appropriate to achieve legislative purposes and whether there is any concern that it may hinder industrial autonomy.

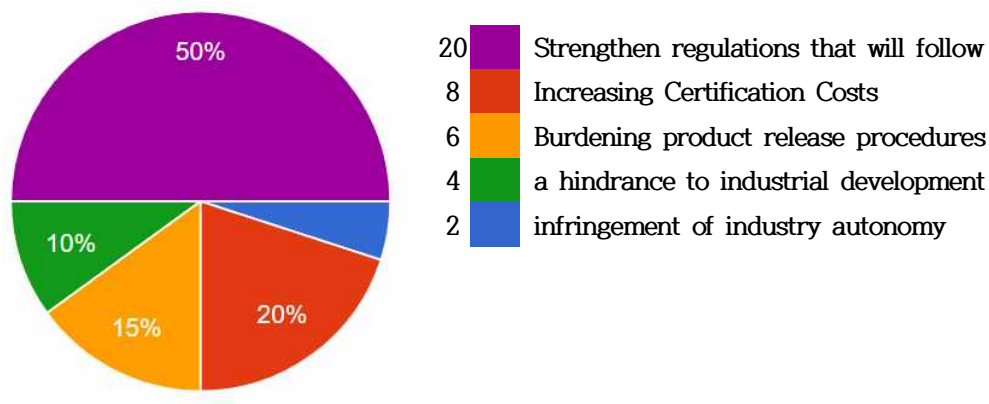
1-1. What do you think about shifting wellness products from current industrial products to a new framework of digital medical products and introducing collective standards and certification systems?



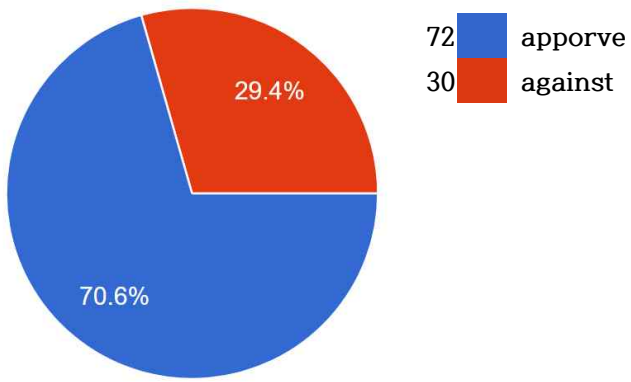
1-2. Please choose a reason for your approval.



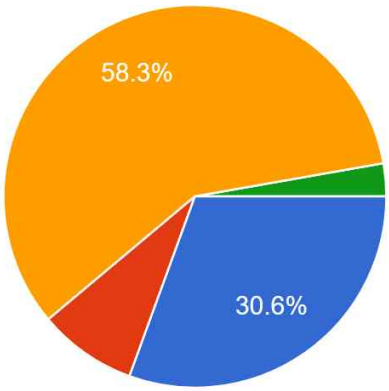
1-3. Please choose a reason to oppose it.



2-1. What do you think about incorporating digital technology-applied medical devices such as software medical devices into a new classification system called the Digital Medical Products Act from the existing Medical Devices Act?

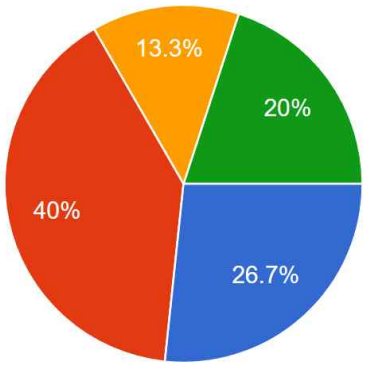


2-2. Please choose a reason for your approval.



42 Expectation of reflecting the characteristics of medical products with digital technology
22 Increasing number of new forms of medical devices that do not conform to existing regulatory frameworks
6 International Leading Role through New Classification System
2 Expectation of industrial development through digitalization promotion

2-3. Please choose a reason to oppose it.



12 Tightening regulations
8 The burden of adaptation to the new regulatory framework
6 A shortage of manpower
4 Burden of additional costs and licensing due to the new classification system

Chapter 5. Policy Suggestions for the Establishment of Safety System

5.1 A new classification system

With the rapid development of digital technology, new types of medical devices or convergence drugs that do not conform to the existing regulatory system are emerging, and it is necessary to clearly classify and manage these new products by defining the concept of "digital medical products". The new comprehensive concept of digital medical products that encompass wellness products for health management purposes, "medical devices" applied with digital technology, and related "software" is currently classified as industrial products in the case of wellness products, and the "Electric Household Goods Safety Act" and "Software Promotion Act" are sometimes applied in the process of approval and approval depending on the characteristics of individual products, and the current law does not separately define and manage digital medical and health support devices. The Ministry of Food and Drug Safety establishes "Medical devices and personal health care products (wellness products)" as guidelines to define the criteria for distinguishing them from medical devices and the types of products, but the guidelines are intended to clarify that "personal health care products do not correspond to medical devices," and do not have regulations to evaluate the performance of related products or to prove safety and effectiveness. It is difficult to prepare a management system for digital medical and health support devices based on this. In the case of "medical devices" and related "software" applied with digital technology, the Medical Device Act, which has a general legal characteristic of medical devices, is currently applied, and the In vitro Diagnostic Medical Device Act and the Medical Device Industry Promotion and Innovative Medical Device

Support Act are sometimes applied depending on the characteristics of individual medical devices. However, despite the need for management, problems such as "authorization and examination of artificial intelligence medical devices," "operation of software medical device manufacturing centers" and "cybersecurity of medical devices" related to digital medical products have no relevant grounds under the current law or are unclear whether they are applied, and the Ministry of Food and Drug Safety has prepared related guidelines and provided them as guides for civil petitioners, but there is a problem that there is no clear legal basis even though the guidelines can actually be regulatory as they stipulate approval, examination and classification standards. Although digital technology has been applied, the Pharmaceutical Affairs Act and the Act on the Safety and Support of Advanced Regenerative Medicine and Advanced Biopharmaceuticals are applied to products whose main functions are drugs, and in the case of convergence products with medical devices, the Ministry of Food and Drug Safety's regulations, "Regulations on the Coordination and Processing of Complaints for Convergence Medical Products" and "Regulations on the Processing of Complaints for Complex and Combination Items" can be applied, but there are no current regulations that apply separately to "combination products of medicines, digital medical and health support devices." Digital medical products have different characteristics from existing medical devices and pharmaceuticals as the speed of technology development based on software, convergence between areas actively takes place, and cybersecurity problems caused by network connection can occur. Accordingly, it is proposed through this paper to clearly classify and manage these new products by unifying wellness products, software medical devices, and digital therapeutics applied with digital technology into the concept of digital medical products as follows. Since digital medical devices and digital convergence drugs are medical devices, it is expected that in the big frame, procedures such as

licensing should be followed in the same way as the existing medical device law, and only areas that do not comply with the regulations of traditional medical devices should be prepared through future enforcement ordinances and enforcement regulations. However, in the case of wellness products, we would like to suggest new measures for areas that may be harmful to the human body due to user carelessness, such as LED masks and massagers.

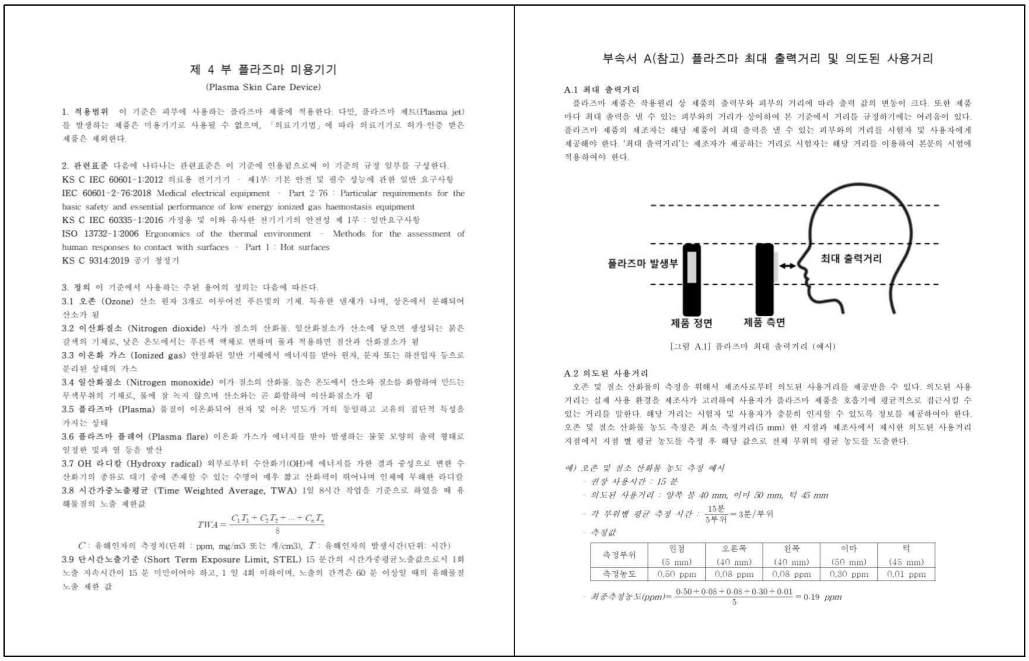
Table 13 Digital Healthcare Product Classification System

major category	middle classification	Definition
Digital medical products	Wellness Products	Devices, machinery, devices, software, or similar products to which digital technology is applied, but used for monitoring, measuring, collecting, and analyzing bio-signals for the purpose of medical support or maintaining and improving health
	Digital medical device	Medical devices referred to in Article 2 (1) of the Medical Devices Act to which digital technology is applied and used for the purpose of diagnosis, treatment, follow-up observation of diseases, prediction of treatment outcomes, assistance of diagnosis and rehabilitation, etc. including software constituting digital medical devices or corresponding to digital medical devices themselves
	Digital Convergence Drugs	A combination of medicines (including advanced biopharmaceuticals) and digital medical devices or digital medical and health support devices under subparagraph 4 of Article 2 of the Pharmaceutical Affairs Act, whose main function corresponds to pharmaceuticals

5.2 Introduction of a wellness product certification system

5.2.1 Establish association standard

Health care products that are not for medical purposes such as diagnosis, treatment, and prevention are currently classified as industrial products under domestic law and are managed by the Ministry of Industry. It is managed as "Electrical Products and Household Products" under the Electrical Products and Household Products Safety Management Act, which is managed by the Ministry of Industry, and most health care products are classified as "products subject to safety certification" in the relevant law, focusing on protecting the safety of the product itself that protects users from electric shock when using the product. As there are no separate regulations or guidelines to verify the effectiveness of human safety and performance that affect the user's human body, separate regulations or guidelines are required. As an example, the National Institute of Technology and Standards cited the 'Guidelines for License Review for Plasma Generated Medical Devices used on the Skin' provided by the Ministry of Food and Drug Safety as a safety test for industrial product certification for plasma beauty devices that are not licensed under the Medical Device Act. As a result, there is a case of enacting the 'Safety Standards for Household Products Subject to Safety Verification (Annex 74 Home Beauty Devices)' as shown in Figure 4 (implemented on 22.3.22).



제 4 부 플라즈마 미용기기

(Plasma Skin Care Device)

1. **적용범위** 이 기준은 피부에 사용하는 플라즈마 제품에 적용한다. 다만, 플라즈마 제트(Plasma jet)를 발생하는 제품은 미용기기로 사용될 수 없으며, 「의료기기법」에 따라 의료기기로 허가·인증 받은 제품은 제외한다.

2. **관련표준** 다음에 나타나는 관련표준은 이 기준에 인용됨으로써 이 기준의 규정 일부를 구성한다.
KS C IEC 60601-1:2012 의료용 전기기기 - 제1부: 기본 안전 및 필수 성능에 관한 일반 요구사항
IEC 60601-2-76:2018 Medical electrical equipment - Part 2-76 : Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment
KS C IEC 60335-1:2016 가정용 및 이와 유사한 전기기기의 안전성 제 1부 : 일반요구사항
ISO 13732-1:2006 Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1 : Hot surfaces
KS C 9314:2019 공기 청정기

3. **정의** 이 기준에서 사용하는 주된 용어의 정의는 다음에 따른다.
3.1 **오존 (Ozone)** 산소 원자 3개로 이루어진 푸른빛의 기체. 특유한 냄새가 나며, 상온에서 분해되어 산소가 됨
3.2 **이산화질소 (Nitrogen dioxide)** 사가 질소의 산화물, 일산화질소가 산소에 닿으면 생성되는 붉은 갈색의 기체로, 낮은 온도에서는 푸른색 액체로 변하며 물과 작용하면 질산과 산화질소가 됨
3.3 **이온화 가스 (Ionized gas)** 안정화된 일반 기체에서 에너지를 받아 원자, 분자 또는 하전입자 등으로 분리된 상태의 가스
3.4 **일산화질소 (Nitrogen monoxide)** 이가 질소의 산화물. 높은 온도에서 산소와 질소를 화합하여 만드는 무색무취의 기체로, 물에 잘 녹지 않으며 산소와는 곧 화합하여 이산화질소가 됨
3.5 **플라즈마 (Plasma)** 물질이 이온화되어 전자 및 이온 밀도가 거의 동일하고 고유의 집단적 특성을 가지는 상태
3.6 **플라즈마 플레어 (Plasma flare)** 이온화 가스가 에너지를 받아 발생하는 불꽃 모양의 출력 형태로 일정한 빛과 열 등을 발산
3.7 **OH 라디칼 (Hydroxy radical)** 외부로부터 수산화기(OH)에 에너지를 가한 결과 중성으로 변한 수산화기의 종류로 대기 중에 존재할 수 있는 수명이 매우 짧고 산화력이 뛰어나며 인체에 무해한 라디칼
3.8 **시간가중노출평균 (Time Weighted Average, TWA)** 1일 8시간 작업을 기준으로 하였을 때 유해물질의 노출 제한값

$$TWA = \frac{C_1T_1 + C_2T_2 + \cdots + C_nT_n}{8}$$

C : 유해인자의 측정치(단위 : ppm, mg/m3 또는 개/cm3), T : 유해인자의 발생시간(단위: 시간)
3.9 **단시간노출기준 (Short Term Exposure Limit, STEL)** 15 분간의 시간가중평균노출값으로서 1회 노출 지속시간이 15 분 미만이어야 하고, 1 일 4회 이하이며, 노출의 간격은 60 분 이상일 때의 유해물질 노출 제한 값

부속서 A(참고) 플라즈마 최대 출력거리 및 의도된 사용거리

A.1 **최대 출력거리**
플라즈마 제품은 작용원리 상 제품의 출력부와 피부의 거리에 따라 출력 값의 변동이 크다. 또한 제품마다 최대 출력을 낼 수 있는 피부와의 거리가 상이하여 본 기준에서 거리를 규정하기에는 어려움이 있다. 플라즈마 제품의 제조자는 해당 제품이 최대 출력을 낼 수 있는 피부와의 거리를 시험자 및 사용자에게 제공해야 한다. '최대 출력거리'는 제조자가 제공하는 거리로 시험자는 해당 거리를 이용하여 본문의 시험에 적용하여야 한다.

[그림 A.1] 플라즈마 최대 출력거리 (예시)

A.2 **의도된 사용거리**
오존 및 질소 산화물의 측정을 위해서 제조사로부터 의도된 사용거리를 제공받을 수 있다. 의도된 사용거리는 실제 사용 환경을 제조사가 고려하여 사용자가 플라즈마 제품을 오즐기에 평균적으로 접근시킬 수 있는 거리를 말한다. 해당 거리는 시험자 및 사용자가 충분히 인지할 수 있도록 정보를 제공하여야 한다. 오존 및 질소 산화물 농도 측정은 최소 측정거리(5 mm) 한 지점과 제조사에서 제시한 의도된 사용거리 지점에서 지점 별 평균 농도를 측정 후 해당 값으로 전체 부위의 평균 농도를 도출한다.

예) 오존 및 질소 산화물 농도 측정 예시
- *권장 사용시간 : 15 분*
- *의도된 사용거리 : 앞쪽 面 40 mm, 이마 50 mm, 턱 45 mm*
- *각 부위별 평균 측정 시간 :* $\frac{15분}{5부위}$ *= 3분/부위*
- *측정값*

측정부위	턴점 (5 mm)	오른쪽 (40 mm)	왼쪽 (40 mm)	이마 (50 mm)	턱 (45 mm)
측정농도	0.50 ppm	0.08 ppm	0.08 ppm	0.30 ppm	0.01 ppm

- *최종측정농도(ppm)=* $\frac{0.50+0.08+0.08+0.30+0.01}{5} = 0.19$ *ppm*

Figure 4. "Safety Standards for Household Products Subject to Safety Verification (Annex 74 Home Beauty Equipment)"

There is currently no special licensing procedure in Korea for wellness products, which are the most basic fields in terms of health care prevention medicine. Therefore, it is difficult to deal with the side effects of personal wellness products due to the lack of safety verification methods and follow-up management. From the manufacturer's point of view, since it is excluded from the medical device management, it is not necessary to comply with the mandatory regulations applied to medical devices such as pre-license examination, medical device manufacturing, and quality control standards (GMP), and in particular, industrial products such as Chinese products do not need permission, making it impossible to follow-up management due to side effects on safety. In addition, as consumers are becoming more difficult to know about products, it is necessary to voluntarily introduce a certification system for wellness products excluded from the medical device law,

such as in Japan, to issue a common license mark (certification mark) to products, services, and systems that meet certain standards, and provide consumers with reliability that "you can purchase and use good things at an appropriate price." Accordingly, through close consultation with the Ministry of Food and Drug Safety and related ministries, a legal basis is established and announced through a medium such as public notice, and based on this basis, a separate independent agency develops standards or standards for human safety and performance effectiveness. First, as shown in Table 14 below, three classification systems for wellness products are newly established, and three group standards for each characteristic are developed accordingly, and companies are certified through this and release products.

Table 14 Wellness Product Classification System

no	Wellness Product Classification	Example
1	Electrically stimulated wellness products	Laser, LED, electrical stimulation, etc
2	Sensor-type wellness products	Collection of biometric signals, etc
3	Software-type wellness products	Telemedicine, health care, etc

5.2.2 The basis for a proposal

As mentioned earlier, there is currently no special licensing procedure in Korea for wellness products that are the most basic field in health care preventive medicine. Therefore, it is difficult to deal with the side effects of personal health care products due to safety verification methods and lack of follow-up management. However, if wellness products are placed under a strict legal regulatory system such as the Medical Device Act, the entry barrier will be very high for companies that manufacture wellness products, which will hinder the development of related industries, and only products centered on large or medium-sized companies with a lot of capital will be released. This is because the stricter the regulations, the higher the cost of licensing for product launch. Therefore, it seems that the most realistic and manageable system at this point is to lower the barriers to entry for manufacturers through collective standards rather than under strict regulatory systems such as the existing Medical Device Act, and to enable quality control (test inspection) on their own according to collective standards. Organizational standards refer to standards established by private organizations on symbols, terms, performances, procedures, and technologies in specific fields for public safety, consumer protection, and the convenience of members. Through such a collective standard and certification system, it is necessary to issue a common license mark (certification mark) to products, services, and systems that meet certain standards and provide consumers with reliability to "buy and use good things at a reasonable price."

5.2.3 Test and Evaluation System

As mentioned earlier, it is necessary to enable self-quality control (test inspection) according to group standards as shown in Table 23 below to provide consumers with reliability to "buy and use good things at the right price." In addition, the safety of wellness products due to side effects on safety can be secured by conducting self-inspection of certification organizations and follow-up management of group guidance and inspection once a year. Regarding the test evaluation, each standard should conduct a test evaluation only on the part that fits the characteristics of each wellness product so that it can be certified.

Table 15 Quality Management system and test evaluation system according to group standards

no	Group Standard Type	Quality Management system	Test evaluation system
1	Electrically stimulated wellness products	ISO 9001 (Quality Management System, QMS)	Test and Evaluation System for Electrical Stimulus
2	Sensor-type wellness products		Test and Evaluation System for Sensors
3	Software-type wellness products		software-related test and evaluation system

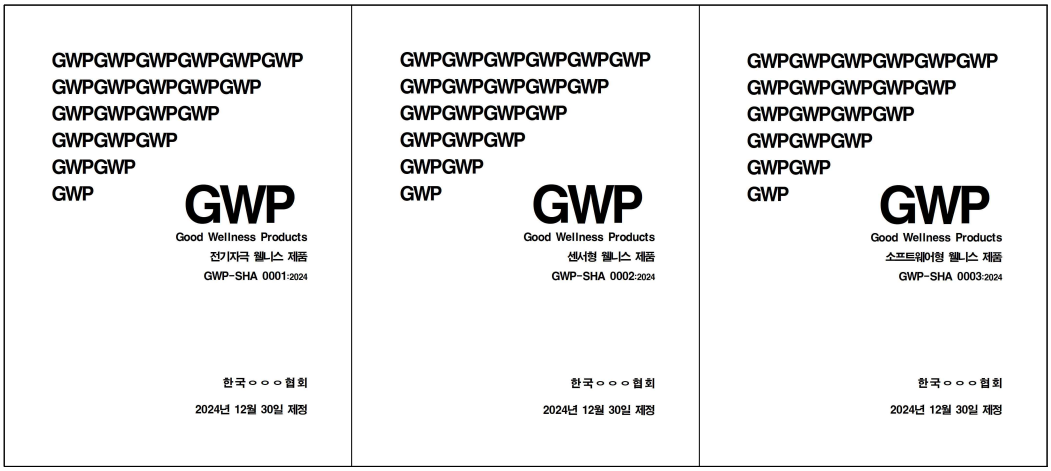


Figure 5. Example of the group standard

Chapter 6. Conclusion

Although wellness devices support daily health care and need to be managed, they are classified as industrial products, etc., without separate regulations under the current law, and are regulated differently according to the characteristics of individual products. As a result, there are no separate regulations or guidelines to verify the effectiveness of human safety and performance, and it is necessary to include them in the framework of digital medical products and establish and manage a certification system through group standards that take into account the reality of regulation and industry autonomy, as suggested in this paper. In that case, the relevant industry can voluntarily introduce a certification system to issue a common license mark (certification mark) to products, services, and systems that meet certain standards, and provide consumers with reliability to purchase and use good things at an appropriate price. In addition, since the existing medical device regulatory system has limitations in regulating and managing newly developed digital medical products, it is necessary to establish a new classification system separately, as suggested in this paper, to accommodate digital technological innovations in digital medical products that continue to develop throughout the development, use, and evaluation cycle, and to create a preemptive and predictable regulatory and support environment for various digital medical products. If a new legal regulation is to be introduced in areas where there was no previous regulation, it is necessary to comprehensively examine whether the regulatory method is appropriate to achieve legislative purposes and whether there is any concern that it will hinder industrial autonomy, and in the process, it is judged that the opinions of related companies should be heard. In this study, the opinions of related companies manufacturing wellness products and medical devices with

digital technology were heard, and through this, it was confirmed that a common perception that the regulatory system presented in this paper is necessary is established throughout the industry.

Bibliography

[1] Kim Soo Young, Ahn Eun Jin, Future Population Prospects for Domestic and Foreigners Reflecting Special Estimation of Population in 2019: 2017-2040, 2019; 1-7.

[2] 3L Kaitlyn Crobar, General Wellness v. Medical Device Considerations, APRIL 9, 2021, https://nysstlc.syr.edu/general-wellness-v-medical-device-considerations/

[3] MOTIE, Act on the Safety Management of Electrical Appliances and Household Appliances, 2023.

[4] MFDS, Criteria for determining medical devices and personal health care (wellness) products, 2020; 7.

[5] MFDS, Criteria for determining medical devices and personal health care (wellness) products, 2020; 8-10.

[6] MFDS, Criteria for determining medical devices and personal health care (wellness) products, 2020; 15.

[7] MHRA, Borderlines with medical devices and other products in Great Britain, 2023.

[8] https://www.assist001.co.jp/massage-chair-sell-6571.html

[9] http://www.pref.kanagawa.jp/div/1588

[10] Japan Healthcare Product Evaluation Organization, https://jao-hcb.org

[11] Japan Home Health Devices Association(General Corporation), https://www.hapi.or.jp

[12] National Institute of Technology and Standards Notice No. 2021-226, Safety standards for household goods subject to safety verification, 2022.

국문 초록

웰니스기기 및 디지털 기반 의료기기의 안전관리 시스템 구축

임 성 준
의료기기산업학과
연세대학교 일반대학원

본 논문에서는 국내 개인용 건강관리기기(이하 “웰니스 기기”)의 합리적인 분류 및 안전관리 시스템 구축을 위하여 새로운 관리 방법 및 제도를 제언하고자 한다. 또한 디지털 기술이 급속도로 발전하면서 기존의 관리(또는 규제) 체계에 부합되지 않는 새로운 형태의 의료기기 및 융복합 형태의 의약품 등이 등장하고 있다. 이에 첨단 디지털 기술의 발전을 반영할 수 있는 새로운 관리시스템을 제시하여 개발·사용·평가 전주기(Total Product Life Cycle)에 걸쳐 지속적으로 발전하는 디지털 기술이 적용된 의료기기에 특화된 관리시스템을 구축하고 디지털 기술의 혁신을 수용하여 다양한 디지털 기술이 적용된 의료기기에 대한 선제적이고 예측 가능한 규제·지원 환경을 조성하는데 일조하고자 한다.

이를 위해 미국, 유럽, 일본, 한국 등 세계 각 나라의 관련 제도 및 정책 조사, 국내 이해당사자들의 산업계 인식 조사 등을 진행하였으며 조사 결과를 토대로 개인용 웰니스 기기 및 디지털 기술 기반 의료기기의 안전관리 시스템 구축을 위한 방법 및 제도를 제언하고자 한다. 또한 새롭게 ‘디지털의료제품’이라는 개념을 정의하여 웰니스 기기 및 디지털 기술이 적용된 의료기기들을 명확히 분류하고 이를 통합적으로 관리할 필요성에 대해 역설하고자 한다.

키워드 : 웰니스 기기, 소프트웨어의료기기, SaMD, DTx, 디지털치료제