Establishing a Reasonable Regulatory Framework for Personalized Medical Devices in Korea: Integrating Global Best Practices for Custom-Made and Patient-Matched Medical Devices

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ABSTRACT

Establishing a Reasonable Regulatory Framework for Personalized Medical Devices in Korea: Integrating Global Best Practices for Custom-Made and Patient-Matched Medical Devices

Advancements in cutting-edge technologies, including Artificial Intelligence (AI) and 3D printing, are driving innovative transformations within the medical technology sector. These innovations facilitate more precise patient diagnoses and enable the development of Personalized Medical Devices (PMDs) tailored to individual patient anatomical, physiological, and pathological characteristics, thereby allowing for precision treatment. The rapid progress in medical device manufacturing technologies, such as 3D printing, has also created an environment conducive to the faster production and supply of PMDs to patients.

However, Korea's current marketing authorization system faces limitations in adequately accommodating the unique characteristics of PMDs, which are products

manufactured and supplied to reflect specific patient conditions. This is primarily due to its operational model, which mandates obtaining authorization with detailed specifications (e.g., form, structure, dimensions) prior to manufacture and supply. Although a 'Custom Made Device (CMD)' management system exists for specific patients in cases where no alternative treatment is available domestically, its application remains highly restrictive. A significant deficiency in current Korean regulations is the absence of clear definitions for various types of PMDs, such as Patient-Matched Medical Devices (PMMDs). This definitional gap results in an underdeveloped marketing authorization management system for diverse PMD types, often leading to products that should be classified as PMMDs being managed as CMDs, thereby obscuring the regulatory pathway.

This study aimed to analyze the current PMD management system within the Korean Ministry of Food and Drug Safety (MFDS) and to derive implications for establishing a rational regulatory framework for PMDs in Korea. This was achieved through a comparative analysis of PMD-related regulations (CMDs and PMMDs) from the United States (FDA), Europe (EU MDR), and the International Medical Device Regulators Forum (IMDRF).

The research findings indicate that despite the rapid growth of the PMDs market, Korea's current regulatory framework does not adequately reflect these changes. Consequently, to promote international regulatory harmonization and advance the domestic industry, this study proposes the establishment of clear definitions for Custom-Made Medical Devices (CMDs) and Patient-Matched Medical Devices (PMMDs), alongside the development of a differentiated marketing authorization management system that specifically reflects the characteristics of each type.

1. Clarification of CMD and PMMD Definition Regulations

It is proposed to establish clear definitions for CMDs and PMMDs, benchmarking international definitions from organizations such as the IMDRF, EU, and FDA, adapted to the Korean context. This is essential because the current lack of clear distinction between CMDs and PMMDs in Korea leads to ambiguity in regulatory application. The proposed CMD definition reflects the core elements of IMDRF N49 and EU MDR Article 2(3), emphasizing the leading role and responsibility of medical professionals in design, exclusivity for specific patients, and use limited to cases where alternatives are not available. This explicitly excludes PMMDs to prevent conceptual confusion. The proposed PMMD definition fundamentally reflects the PMMD concept of IMDRF N49 and MDCG 2021-3. Its most important characteristics are that personalization is performed within a 'design envelope' pre-established and verified by the manufacturer, and that the manufacturer bears full responsibility for the design and quality of the final product. The introduction of this clear definitional concept is a prerequisite for the effective management of personalized medical devices.

2. Proposed CMD Regulatory Framework

Instead of the current Korean management method, which only exempts variation marketing authorization (including certification), it is proposed to adopt an approach similar to the EU MDR's Annex XIII or the FDA's

Custom Device Exemption (CDE) system, covering exemptions for both new and modified CMDs from standard pre-market marketing authorization, product certification, or notification requirements. This exemption would be contingent upon strict conditions that ensure patient safety, device effectiveness, and robust post-market safety management. These conditions include: a written request and design responsibility from a qualified medical professional for a specific patient, a demonstration of the device's irreplaceability and necessity, and the manufacturer's declaration of conformity with applicable General Safety and Performance Requirements (GSPRs).

Furthermore, to ensure that users (patients and medical professionals) clearly recognize that the medical device is a CMD specifically manufactured for a particular patient and has not undergone the general marketing authorization process, it is proposed to amend the medical device labeling regulations to mandate the display of the statement 'This product is a Custom Made Device' on the container, packaging, or accompanying documents. In addition to this, CMD labeling must include patient identification information, the name and affiliated institution of the prescribing medical professional, the trade name and address of the manufacturer, manufacturing date or expiration date (if applicable), sterilization status (if applicable), precautions for storage or handling, and other information necessary for the safe and effective use of the CMD.

Considering their uniqueness and extremely small production volume, CMDs are proposed to be excluded from the mandatory application of the standardized Unique Device Identification (UDI) system (affixing to containers / packaging and information registration) that applies to general medical devices. However, to address the potential traceability gap resulting from the UDI exemption, it is proposed to impose stringent obligations on manufacturers for establishing and operating a robust patient tracking management system. This includes maintaining detailed records (e.g., patient identification information, prescriber details, design specifications, raw materials, manufacturing/supply/use dates) and providing relevant information promptly upon request or in the event of safety concerns.

Additionally, a system is proposed to review the necessity of transitioning products with repeated CMD reporting to PMMD management. If such products are identified, it is proposed that the marketing authorization management system be operated in a way that requires manufacturers to obtain authorization or variation authorization (or consider authorization updates using re-evaluation or product renewal systems) based on Real-World Data/Evidence and mandatory CMD records, thereby resolving potential risks arising from past regulatory ambiguities.

3. Proposed PMMD Regulatory Framework

PMMDs refer to a group of products manufactured under the manufacturer's responsibility within a pre-verified 'design envelope' to match the anatomical structure of individual patients, which is fundamentally different from CMDs manufactured on a one-off basis according to specific medical professional instructions. Therefore, it is necessary to establish rational marketing authorization and management systems that consider the characteristics of PMMDs, with 'design envelope' management being crucial.

Manufacturers are required to clearly define all relevant design variables for the PMMD and their allowable ranges, and provide a robust scientific rationale for the establishment of this design envelope. Crucially, manufacturers must submit verification and validation (V&V) data demonstrating that all PMMDs produced within the defined design envelope are consistently safe and effective. This typically involves methodologies such as worst-case scenario testing, representative sampling testing, computer modeling and simulation, and manufacturing process validation.

4. Proposed Reorganization of the Medical Device Product License Management System (in Korea)

For the rational and efficient marketing authorization management of

medical devices with various potential modifications depending on the patient's condition, such as PMMDs among PMDs, a fundamental review and reorganization of the current Korean medical device product marketing authorization certificate management system is necessary. The current management method, which focuses on listing detailed physical specifications like shape, structure, and raw materials on the marketing authorization certificate, is proposed to transition to a system that manages based on essential elements such as the device's core mechanism of action, intended use, and the essential safety and performance requirements to be achieved (e.g., FDA's GSPRs). This change would enable manufacturers to produce and supply various patient-specific variations within an authorized design envelope without requiring separate additional change authorizations, thereby facilitating rapid market entry and reducing administrative burden.

These proposed regulatory improvements are anticipated to significantly contribute to enhancing patient safety, promoting innovation within the medical device industry, and advancing Korean PMD-related regulations through harmonization with international standards.

Key words : personalized medical devices, custom made device, patient-matched medical device, adaptable medical device;

I. INTRODUCTION

1. Background

The medical technology field is experiencing innovative transformations due to the remarkable advancements in cutting-edge technologies, including Artificial Intelligence (AI) and 3D printing. These technologies are fundamentally changing the design, manufacturing, and delivery methods of medical devices, enabling the development of personalized medical solutions tailored to individual patients, which was previously impossible.

In particular, AI plays a pivotal role in enhancing diagnostic accuracy, optimizing treatment plans, and improving the efficiency of healthcare services[1][2][3], Simultaneously, 3D printing technology has begun to contribute to providing customized treatments that meet the individual needs of patients by enabling the precise fabrication of medical devices[4][5].

AI technology is demonstrating remarkable achievements in fields such as medical image analysis and disease prediction modeling. For example, deep learning algorithms exhibit high accuracy in detecting cancer cells in radiological images[1][2], significantly improving early diagnosis and treatment success rates. Furthermore, AI-based prediction models enable the proactive identification of disease occurrence possibilities by analyzing

patients' genetic information and lifestyle data, and facilitate the provision of preventive strategies[3].

3D printing technology is revolutionizing the design and manufacturing methods of medical devices. In particular, the fabrication of customized implants and prostheses based on patients' anatomical structures has become possible, significantly enhancing the accuracy of surgical outcomes and patient satisfaction. This technology is already commercialized in various fields, including orthopedics, dentistry, and cardiovascular surgery, and is expected to continue to advance[4][6][7]].

In conclusion, the innovative changes in medical technology fields, including AI and 3D printing, are accelerating the development of patient-centric personalized medical solutions, and accordingly, the need for rational regulatory measures for the supply of personalized medical devices (PMDs) is also increasing.

The European Medicines Agency(EMA) also recognizes the innovative potential of 3D printing technology in the medical device manufacturing sector and emphasizes the need for regulatory frameworks to adapt to these technological advancements. The EMA highly values the potential of medical devices manufactured through 3D printing to provide personalized medical solutions and is developing new regulatory approaches to utilize this technology in a manner that ensures safety and efficacy[8][9][10].

To ensure the safety and efficacy of 3D-printed medical devices, major regulatory agencies, including the EMA, are strengthening Good

Manufacturing Practice (GMP) audit guidelines. These audit guidelines serve as essential elements for ensuring the quality control of medical devices and the consistency of production processes, and are considered to play a crucial role, particularly in the fabrication of personalized medical devices tailored to individual patients[10][11]. For example, regulatory frameworks are being improved to ensure that 3D-printed medical devices can reflect new technological characteristics while maintaining conformity and consistency with existing product classifications[12].

Furthermore, the EMA notes that 3D printing technology is suitable not only for the mass production of medical devices but also for small-batch production, and anticipates that this will enable the provision of personalized medical services. However, it is also recognized that achieving these innovative healthcare services requires addressing challenges such as high costs, a shortage of trained professionals, and current stringent regulations(guidelines)[9][12]. Therefore, to address these issues, the EMA is pursuing international collaboration and standardization, and striving to adopt a balanced approach that promotes innovative technological advancements while ensuring safety[11][12].

In conclusion, 3D printing has established itself as a powerful tool for realizing personalized treatment in the medical device manufacturing sector, and regulatory agencies such as the EMA are continuously striving to establish future-oriented regulatory frameworks to support the changes brought about by these technological advancements[8][9][12].

2. Purpose

As such, PMDs have unique characteristics in that they are custom-designed and manufactured considering the individual's unique physiological and pathological traits, necessitating a regulatory management framework distinct from the regulations for conventional mass-produced medical devices. The existing regulatory framework is inevitably limited in regulating Personalized Medical Devices (PMDs - Custom Made Devices or Patient-Matched Medical Devices) with unique characteristics such as small-batch production, rapid design changes, and the need for prompt supply. In particular, if PMDs with individualized designs are managed solely through pre-approval procedures, their introduction into the market will be hindered. This not only impedes innovation but also raises the issue of limiting patient accessibility, which should be of paramount importance. Considering the characteristics of continuously evolving personalized medical devices, such as software updates or AI algorithm changes, the lack of flexibility in current change management regulations is deemed a critical challenge that must be overcome[13].

Therefore, the current regulatory paradigm needs to be improved to promote market entry of innovative medical technologies, considering the unique characteristics of PMDs, and to provide benefits to individual patients.

Accordingly, this study aims to analyze the current Korean regulatory framework for PMDs and the management system for marketing authorization, focusing on the relevant regulations managed by the Ministry of Food and Drug Safety (MFDS); to examine regulatory considerations for various manufacturing models, including marketing authorization(change) procedures, post-market management systems through GMP management, and collaborative manufacturing between medical institutions and manufacturers; and furthermore, to derive implications for domestic regulatory improvements by comparatively analyzing medical device regulations of the FDA and the EU MDR.

3. Method

This study comprehensively utilized various academic and policy-oriented approaches to explore rational regulatory measures for PMDs. Initially, to conduct an in-depth analysis of the current management system for domestic PMDs, a wide range of literature, including medical device-related laws, enforcement decrees, enforcement regulations, Ministry of Food and Drug Safety(MFDS) notices, and guidelines, was reviewed. Throughout this process, the focus was placed on identifying the characteristics and limitations of the existing regulatory framework.

Subsequently, to comparatively analyze regulatory cases of PMDs in major overseas countries, relevant regulations and guidelines of the United States FDA and the EU MDR, as well as documents from the International Medical Device Regulators Forum (IMDRF), were investigated. In particular, the classification and management systems for PMDs, including the FDA's Custom Device Exemption and Patient-Matched Medical Device, and the EU MDR's Custom-Made Devices, Patient-Matched Medical Device, and Adaptable Medical Device, were intensively examined, and implications were derived by comparing them with the domestic regulatory framework.

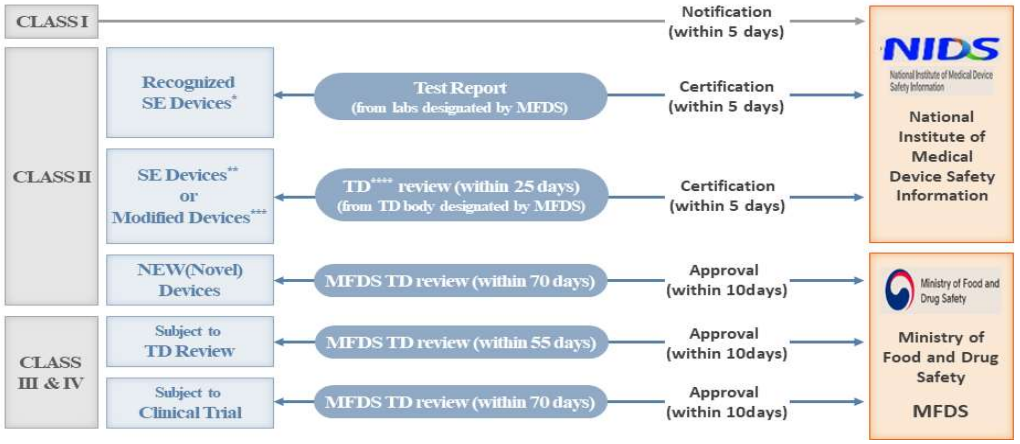
Based on this, this study aimed to propose rational regulatory measures for PMDs, including the necessity of establishing definition regulations for each classification by classifying PMDs according to international classification criteria, and proposing the revision or establishment of regulatory frameworks for each classification(CMDs and PMMDs).

Furthermore, to enhance the comprehensiveness of this study, it suggests additional research topics for establishing a more precise PMDs management system that considers the regulatory environment of Korea.

II. METHODOLOGY

1. Analysis of the Current Management System and Problems of Personalized Medical Devices (PMDs) in Korea

The Korean medical device regulatory framework fundamentally operates by classifying medical devices according to their risk level, applying corresponding approval, certification, and notification pathways for each grade, as illustrated in Figure 1.



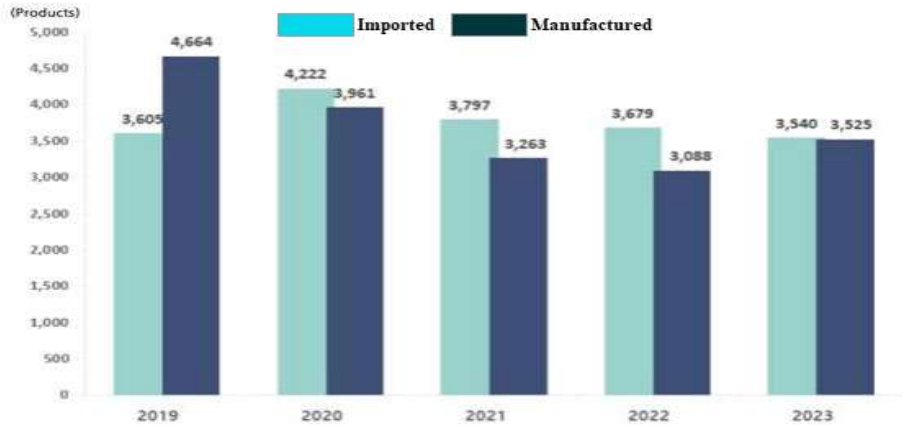
* "Recognized SE Devices" is a recognized medical device that is equivalent in the purpose of use, working mechanism, and so on defined by MFDS

** "SE Devices" is a medical device that is equivalent in the purpose of use, working mechanism, raw materials(limited to medical supplies), performance, test specifications and instructions for use with the already approved medical device.

*** "Modified Devices" is a medical device that is equivalent in the purpose of use, working mechanism, raw materials(limited to medical supplies) with the already approved medical device, but not equivalent in performance, test specifications and instructions for use, etc.

**** "TD" is Technical Document.

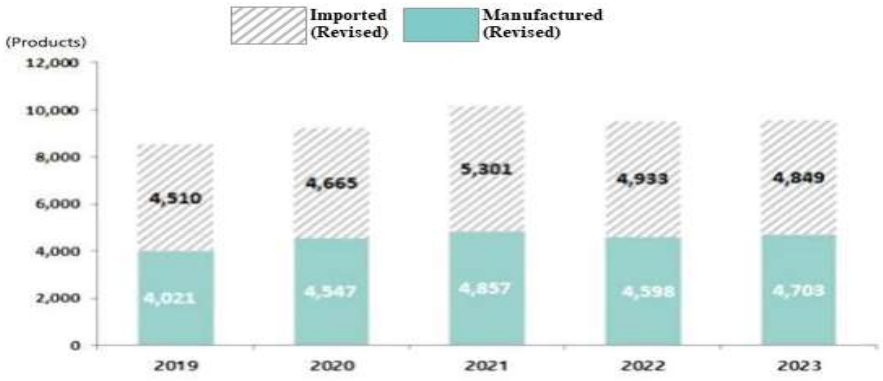
Figure 1. Medical Device Approval Procedure and Processing Time (MFDS, NIDS)



(Unit: No. of products)

Category	2019	2020	2021	2022	2023
Imported	3,605 (43.6%)	4,222 (51.6%)	3,797 (53.8%)	3,679 (54.4%)	3,540 (50.1%)
Manufactured	4,664 (56.4%)	3,961 (48.4%)	3,263 (46.2%)	3,088 (45.6%)	3,525 (49.9%)
Total	**8,269**	**8,183**	**7,060**	**6,767**	**7,065**

Figure 2. Status of Medical Device Approvals (including Certifications)



(Unit: No. of products)

Category	2019	2020	2021	2022	2023	Total
Manufactured [Year-on-year (%)]	4,021 (△0.3%)	4,547 (13.1%)	4,857 (6.8%)	4,598 (△5.3%)	4,703 (2.3%)	22,726
Imported [Year-on-year (%)]	4,510 (4.5%)	4,665 (3.4%)	5,301 (13.6%)	4,933 (△7.0%)	4,849 (△1.7%)	24,258
Total	**8,531**	**9,212**	**10,158**	**9,531**	**9,552**	**46,984**

Figure 3. Status of Medical Device Revised Approvals (including Certifications)

Furthermore, all medical devices are subject to pre-market authorization (approval or certification) or notification prior to manufacture or import. Any modifications to the approved, certified, or notified details necessitate amended authorization, amended certification, or amended notification. As depicted in Figures 2 and 3, manufacturers and importers annually undertake thousands of new authorizations, certifications, or their amendments to supply the market with necessary medical devices.

As evident from this general medical device pre-market regulatory framework and the volume of authorizations (including amendments), managing Personalized Medical Devices (PMDs), which are tailored to individual patient characteristics, under the existing regulatory system designed for mass-produced devices poses challenges in adequately addressing their unique attributes. Recognizing this issue, the Ministry of Food and Drug Safety (MFDS) has been proactively exploring distinct management strategies, initially focusing on Custom-Made Devices (CMDs), defined under Article 19, Paragraph 9 of the 'Regulations on Approval, Notification, and Review of Medical Devices(MFDS Notice)'.

An examination of the regulatory trends for PMDs in Korea reveals ongoing efforts to improve the CMDs system. In September 2016, the 'Regulations on Approval, Notification, and Review of Medical Devices' were amended (Article 19) to define CMDs as medical devices manufactured using 3D printers, under the responsibility of a physician, for use in patients with unique physiological or pathological characteristics and

for whom there are no alternative medical devices or treatments. These CMDs are manufactured upon request for modifications to shape and structure from the attending physician. The amendment introduced a management system allowing the supply of these CMDs without obtaining variation marketing authorization (certification) or submitting a notification. Subsequently, in 2021, as shown in Table 1, the scope of CMDs management was expanded through amendments to the same regulations to include not only 3D-printed medical devices but also medical devices classified under the 'orthopedic devices' and 'human tissue or function replacement' subcategories.

Table 1. Comparison of Former and Current Regulations of Article 19, Paragraph 9 of the 'Regulations on Approval, Notification, and Review of Medical Devices'

Former Regulations	Current Regulations (April 2021 – Present)
⑨ Medical device manufacturers or importers who manufacture medical devices **using 3D printers**, under the responsibility of a physician, for the purpose of using in patients with unique physiological or pathological characteristics for whom there are no alternative medical devices or treatments, upon request from the attending physician with the following documents, to modify the shape and structure (hereinafter referred to as 'patient-tailored medical devices'), may supply such devices without obtaining variation marketing authorization (certification) or	⑨ Medical devices manufactured or imported **using previously authorized 3D printers, or medical devices classified under the 'orthopedic devices' or 'human tissue or function replacement' subcategories**, which medical device manufacturers or importers manufacture or import upon request for modifications to shape and structure from the attending physician, and which satisfy all of the following requirements (hereinafter referred to as 'patient-tailored medical devices'), may be supplied without obtaining variation marketing authorization (certification) or submitting

Former Regulations	Current Regulations (April 2021 – Present)
submitting a notification. In this case, the number of devices is limited to 5 per year per authorized (certified) or notified product. **1. Physician's statement on the appropriateness of applying the patient-tailored medical device** **2. Patient consent for the use of the patient-tailored medical device** **3. Consent from at least 5 physicians in the relevant field**	a notification. In this case, the number of devices is limited to 5 per year per authorized (certified) or notified product. **1. Medical devices manufactured, imported, or designed to meet the unique physiological or pathological characteristics of the patient** **2. Medical devices manufactured or imported upon written request from the attending physician with the following documents:** **a. The attending physician's request and statement on the appropriateness of applying the patient-tailored medical device** **b. Patient consent for the use of the patient-tailored medical device** **3. Medical devices used for patients for whom there are no alternative medical devices or treatment options available on the market** **4. Medical devices manufactured, imported, and used under the joint responsibility of the manufacturer/importer and the attending physician (requestor)** **5. Medical devices manufactured or imported in compliance with the procedures for recording/managing documents and quality inspections related to the receipt and delivery of raw materials/finished products, manufacturing processes, and quality control, in accordance with Enforcement Rules Articles 27 and 33**

* Here, 'patient-tailored medical devices' refers to 'Custom Made Devices'.

However, it is evident from the above regulations that the current CMDs management system is a management system for patients with specific diseases for whom there are no alternative medical devices or treatments, and it operates similarly to the management system for medical devices required for rare and urgent introduction. For reference, the difference between the two systems lies in whether the product has obtained authorization in Korea. If there is a product that has obtained authorization in Korea, the product can be manufactured (imported) and supplied under the CMDs management system. If there is no product that has obtained authorization in Korea, it can be imported and supplied under the management system for medical devices required for rare and urgent introduction.

In fact, the current CMDs management system can be more accurately described as the 'CMDs management system for urgent introduction.' To utilize this system, the medical device must be manufactured, imported, or designed to meet the unique physiological and pathological characteristics of the patient, and a written request from the attending physician is mandatory. Furthermore, it must be used for patients for whom there are no alternative medical devices available on the market or no other treatment options, and it must be manufactured, imported, and used under the joint responsibility of the manufacturer/importer and the attending physician. Such use is not permitted indefinitely and is limited to 5 times per year per authorized, certified, or notified product.

Moreover, even if it is a medical device that can be used without prior variation authorization in this manner, the relevant regulations require compliance with procedures such as recording and managing documents and quality inspections related to the receipt and delivery of raw materials and finished products, the manufacturing process, and quality control, to ensure the safety and effectiveness of the medical device. After supplying such a CMDs, the manufacturer/importer who has modified the shape and structure of the authorized, certified, or notified medical device is required to submit to the MFDS, within 15 days from the supply date, the attending physician's request and statement of appropriateness for application, patient consent, and materials that can verify the joint responsibility of the manufacturer/importer and the attending physician.

The aforementioned is stipulated in Article 19, Paragraph 10 of the Regulations on Approval, Notification, and Review of Medical Devices:

> Manufacturers or importers who have modified the shape and structure of the authorized or certified, or notified product in accordance with Paragraph 9 shall report to the head of the MFDS with the 'Patient-Tailored Medical Device* Usage Report' according to Form No. 1-2, within 15 days from the date of use of the medical device, attaching the following documents:
> 1. Documents according to each item of subparagraph 2 of Paragraph 9.
> 2. Materials that can verify the joint responsibility of the manufacturer (importer) and the attending physician according to subparagraph 4 of Paragraph 9 (e.g., materials demonstrating the physician's proficiency and clinical experience, and measures for patient protection and compensation in case of manufacturing technology issues or adverse events, etc., through consultation with the manufacturer (importer)).

* Here, 'patient-tailored medical devices' refers to 'Custom Made Devices'.

Thus, despite the considerable efforts of regulatory authorities, the Korea management system for CMDs has limitations in that it operates in a highly restrictive manner. Since the regulatory focus is limited to cases requiring urgent use, it is primarily tailored to medical devices manufactured with 3D printers, orthopedic devices such as stents, and human tissue and function replacement products such as artificial blood vessels. Consequently, it is somewhat inadequate as a regulatory measure in preparation for the emergence of other types of personalized medical devices utilizing AI or other advanced technologies (e.g., Patient-Matched Medical Devices), the prevalence of which is anticipated in the future. Furthermore, while the current CMDs management system contributes to meeting urgent patient needs, there may be inherent limitations in securing safety and effectiveness due to its reliance on a post-use reporting system. Limiting the supply to only 5 units per year per authorized, certified, or notified product also raises concerns that it may hinder accessibility if more patients require personalized medical devices. Considering these points, it is judged that it would be difficult to effectively accommodate these requirements with the existing marketing authorization or variation marketing authorization management system.

This is not to say that previous efforts have been insufficient. Although not actively discussed, research such as the National Institute of Medical Device Safety Information's '2020 Patient Matched (3D Printing) Medical Device Regulatory Response Strategy Research[14]' which analyzes global regulatory trends and explores domestic response strategies, should be continuously conducted. It is believed that these studies will lead Korea to become a nation that proactively establishes rational regulatory measures for personalized medical devices and, furthermore, will enable it to lead the global market for personalized medical devices.

2. Comparative Analysis of Regulatory Cases of Personalized Medical Devices in Major Overseas Countries

A. FDA

1) FDA Custom Device Exemption

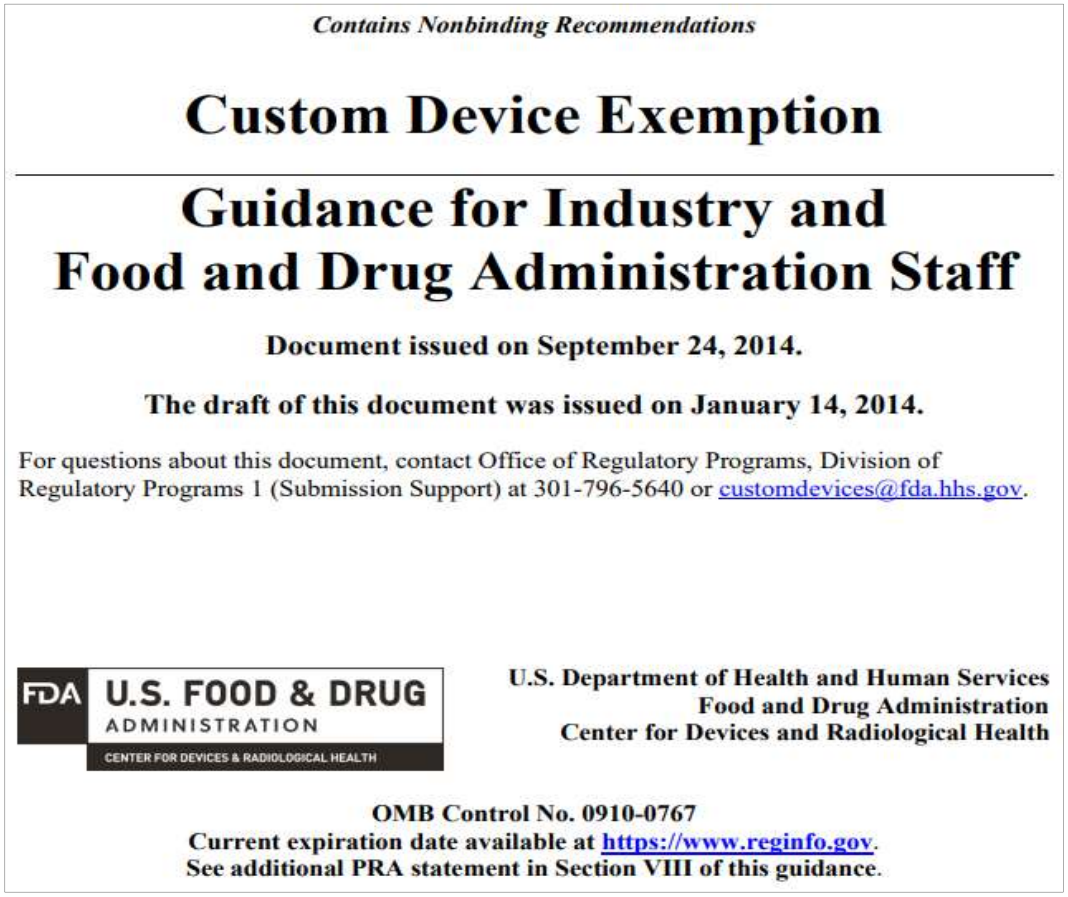
Similar to Korea, the United States Food and Drug Administration (FDA) generally requires premarket approval or clearance for medical devices before they can be marketed. This is a critical procedure to ensure the safety and effectiveness of medical devices. However, the United States also exempts certain medical devices from premarket approval or clearance under specific circumstances, similar to Korea's management system for patient-tailored medical devices(Custom Made Devices, CMDs), and this is referred to as the 'Custom Device Exemption,' a special exemption provision[15]. This is based on Section 520(b) of the Federal Food, Drug, and Cosmetic Act, and exempts medical devices that meet specific conditions from premarket notification (510(k)) and premarket approval (PMA) procedures. This exemption regulation applies to devices manufactured according to the order of an individual physician or dentist, and when the device must be manufactured deviating from the performance standards or requirements of previously granted approval or clearance. These products cannot be generally sold within the United States for

commercial distribution through labeling or advertising by the manufacturer, importer, or distributor. Furthermore, the device must be intended to treat a unique pathological or physiological condition that cannot be treated with other approved (including authorized or certified, or notified) products, and must be manufactured to meet the specific requirements of the ordering physician or dentist or for use by a specific patient named in the order.

The main limitations of the Custom Device Exemption (hereinafter 'CDE') include that the medical device must be used solely for the purpose of treating a sufficiently rare condition, and that production is limited to no more than 5 units per year for a particular device type, similar to Korea. (It is understood that the Korean regulations for patient-tailored medical devices(CMDs) were improved by benchmarking the U.S. regulations.) Manufacturers are obligated to submit an annual report to the FDA on the custom made medical devices supplied, and the FDA issues guidance documents on custom made medical devices, providing definitions of relevant terms and interpretations of devices that may be eligible for exemption. Importantly, devices that are simply modified for a patient or personalized devices (e.g., dental abutments, 3D-printed orthopedic devices) are not considered CDE devices. These devices generally require premarket approval or clearance. Even CDE medical devices are required to comply with Good Manufacturing Practices (GMP) under the FDA's Quality System Regulation (QSR).

2) Definition and Requirements of FDA Custom Device Exemption

CDE medical devices are defined according to Section 520(b) of the United States Federal Food, Drug, and Cosmetic (FD&C) Act.



Contains Nonbinding Recommendations

Custom Device Exemption

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 24, 2014.

The draft of this document was issued on January 14, 2014.

For questions about this document, contact Office of Regulatory Programs, Division of Regulatory Programs 1 (Submission Support) at 301-796-5640 or customdevices@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

OMB Control No. 0910-0767
Current expiration date available at https://www.reginfo.gov.
See additional PRA statement in Section VIII of this guidance.

Figure 4. FDA Custom Device Exemption (Guidance for Industry and FDA Staff)

The FDA recognizes a medical device as a CDE medical device only if it meets all of the following requirements[16]:

Section 520(b) of the FD&C Act, as amended by section 617 of FDASIA, changed some of the criteria to qualify for the custom device exemption, which is different from the criteria currently described in the regulations. The amendment to section 520(b) of the FD&C Act states that a device will qualify as a "custom device" by meeting new enumerated statutory requirements, including, among others, the following for each device: **(1) Is created or modified in order to comply with the order of an individual physician or dentist (or other specially qualified person); (2) necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515 of the FD&C Act; (3) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution; (4) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat; (5) either (a) is intended to meet the special needs of such physician or dentist in the course of the professional practice of such physician or dentist (or other specially qualified person as designated) in the course of their professional practice or (b) is intended for use by an individual patient named in the order of a physician or dentist (or other specially qualified person as designated); (6) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals, physician, or dentist; and (7) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices** (21 U.S.C. 360j(b)).

The new provisions for the custom device exemption also include the following limitations: **(1) The device is for the purpose of treating a "sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;" (2) the production of the device must be "limited to no more than five units per year of a particular device type"; and (3) a manufacturer is required to submit an annual report to FDA on the custom devices it supplied**

① It must be created or modified according to the request of a physician or dentist (or other specially qualified person), not simply a modification of existing products, and ② it must deviate from the applicable standards under Section 514 (Performance Standards) or requirements under Section 515 (Approval Requirements) of the FD&C Act. ③ The manufacturer, importer, or distributor must not supply the product in finished form within the United States by labeling or advertising it for commercial distribution, and ④ it must be designed to treat a unique pathological or physiological condition that cannot be treated with other available medical devices in the United States. ⑤ It must either be intended to meet the special needs of a

physician or dentist in the course of their professional practice or be intended for use by a specific patient designated by a physician or dentist (or other specially qualified person), and ⑥ it must be assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of physicians, dentists, or patients. ⑦ Lastly, it specifies the legal requirement that it can have common, standardized design characteristics, chemical and material compositions, and manufacturing processes like commercially distributed medical devices.

When the relevant regulations were amended in 2016, the following requirements were added: ① The medical device must be intended for use in treating a sufficiently rare condition to the extent that conducting clinical trials is practically impossible, ② production must be limited to a maximum of 5 units per year of a particular device type, and ③ the manufacturer must submit an annual report to the FDA on the supply status of custom-made devices.

Upon reviewing the above requirements, it can be observed that some are similar to the Korea Korea regulations for patient-tailored medical devices(CMDs) management, while others are different.

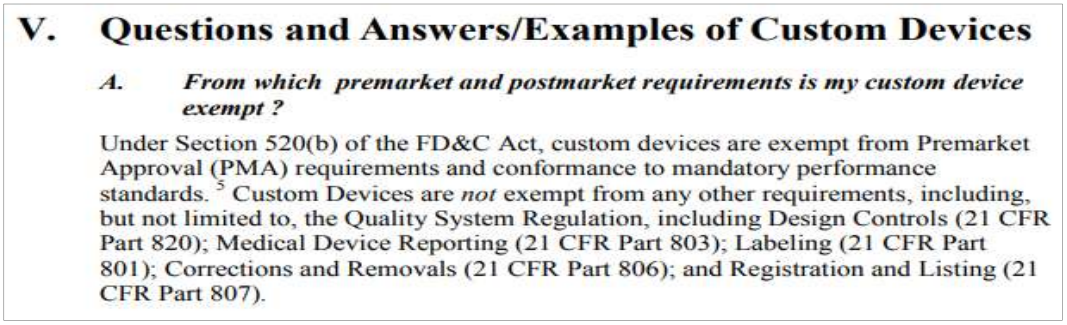
Firstly, it is judged that there is a difference in that it considers not only patient-centric CDE medical devices (Patient Centric Need), which only consider the unique pathological or physiological conditions of the patient, but also physician-centric CDE medical devices (Physician Centric Need), which consider the special needs that may arise in the course of physicians' or dentists' professional practice. Patient-centric CDE medical devices (Patient Centric Need), similar to Korea, are designed to treat the unique pathological or physiological

conditions of a specific patient, such as a custom-sized artificial hip joint that deviates from the standard size. In contrast, physician-centric CDE medical devices (Physician Centric Need) are manufactured to meet the special needs that arise in the course of physicians' or dentists' professional practice, such as when a medical professional requires a special handle on a surgical instrument due to a permanent hand injury. Furthermore, physician-centric CDE medical devices not only consider the medical professional's condition but can also be manufactured to reflect the specific requirements necessary for the medical staff's capabilities to perform procedures on unique patient conditions more safely and effectively. Therefore, it is understood that they provide broader and more flexible regulations compared to the Korea regulations for patient-tailored medical devices(CMDs in Korea).

The requirement that it must be a newly manufactured or modified product that deviates from the standards to meet specific needs is similar to the U.S. requirement, considering that Korea also has the obligation to submit a 'physician's request and statement on the appropriateness of applying the patient-tailored medical device,' which can be interpreted as manufacturing a medical device that deviates from the authorized scope under specific requirements. Regarding the requirement to prohibit commercial distribution, there are no explicit regulations prohibiting commercial distribution in the Korea regulations. However, considering that exemptions are granted under highly restrictive conditions, that exemptions, etc., are limited to 5 times per year, and that reporting to the regulatory authority is required, it can be inferred that commercial distribution is also prohibited in Korea. The requirement that it must be designed to treat a unique pathological or

physiological condition that cannot be treated with other available medical devices is also stipulated in the Korea regulations. The limitation of 5 units per year for a specific device type and the obligation to submit an annual report to the FDA on the supplied custom-made devices are the same as the Korea regulations. In conclusion, although there are some differences in the definition of custom-made medical devices between the U.S. and Korea, it can be observed that they have established and operate a fairly similar management system, particularly for patient-centric custom made medical devices.

3) FDA Custom Device Exemption QMS Obligations



V. Questions and Answers/Examples of Custom Devices

A. From which premarket and postmarket requirements is my custom device exempt ?

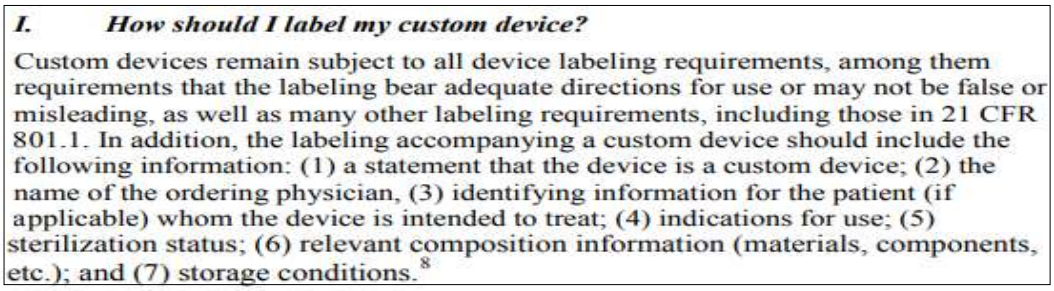
Under Section 520(b) of the FD&C Act, custom devices are exempt from Premarket Approval (PMA) requirements and conformance to mandatory performance standards. [5] Custom Devices are *not* exempt from any other requirements, including, but not limited to, the Quality System Regulation, including Design Controls (21 CFR Part 820); Medical Device Reporting (21 CFR Part 803); Labeling (21 CFR Part 801); Corrections and Removals (21 CFR Part 806); and Registration and Listing (21 CFR Part 807).

Figure 5. Requirements of Custom Device Exemption (Guidance for Industry and Food and Drug Administration Staff) September 24, 2014

CDE medical devices are exempt from 510(k) and PMA if they meet specific criteria. However, despite these exemptions, custom-made medical device manufacturers must still comply with several regulatory requirements. Most importantly, compliance with the Quality System Regulation (QSR) (21 CFR Part 820) is mandatory, as it is not exempt. The quality control that must be adhered to includes GMP requirements

such as design controls. Additionally, manufacturers must comply with other regulations such as Medical Device Reporting (MDR) (21 CFR Part 803), labeling that includes appropriate use instructions and is not false or misleading (21 CFR Part 801), Corrections and Removals (21 CFR Part 806), and Registration and Listing (21 CFR Part 807). Similarly, Korean regulations also require manufacturers and importers of patient-tailored medical devices to comply with procedures such as recording and managing documents and quality inspections related to the receipt and delivery of raw materials and finished products, manufacturing processes, and quality control. Therefore, it can be stated that there is a fairly similar management system in this regard as well.

4) FDA Custom Device Exemption Labeling


I. How should I label my custom device?

Custom devices remain subject to all device labeling requirements, among them requirements that the labeling bear adequate directions for use or may not be false or misleading, as well as many other labeling requirements, including those in 21 CFR 801.1. In addition, the labeling accompanying a custom device should include the following information: (1) a statement that the device is a custom device; (2) the name of the ordering physician, (3) identifying information for the patient (if applicable) whom the device is intended to treat; (4) indications for use; (5) sterilization status; (6) relevant composition information (materials, components, etc.); and (7) storage conditions.[8]

Figure 6. Labeling of Custom Device Exemption (Guidance for Industry and Food and Drug Administration Staff) September 24, 2014

The labeling of CDE medical devices must include an indication that the device is a custom-made device, the name of the ordering physician, patient identification information (if applicable), the intended use, sterilization status, relevant component information, and storage conditions. The Korea regulations do not have labeling requirements like those in the United States.

5) FDA Custom Device Exemption Annual Reporting

Manufacturers who have supplied medical devices under the CDE exemption regulations must submit an annual report to the FDA by March 31st of each year for devices issued in the preceding year (January 1st to December 31st). This report serves to explain and justify how each device meets the legal requirements for custom-made medical devices. The report must be a printed document written in English and submitted via email to the designated FDA address[17].

Patient-centric CDE medical device reports must include justification for meeting the exemption criteria, a device description, patient and physician information, and manufacturing details. Physician-centric CDE medical device reports include justification for meeting the exemption criteria, a device description, physician information, and manufacturing details[18]. The report must clearly justify how each device meets the legal requirements for CDE medical devices[17]. The FDA may confirm receipt of the report and take follow-up actions if there are questions or concerns, and the FDA may take action if a device distributed under the exemption does not meet the requirements.

Tables 2 and 3 provide a summary of the key requirements and regulatory obligations for the FDA Custom Device Exemption, detailed in points 1) through 5).

Table 2. Key Requirements of FDA Custom Device Exemption

Key criteria	Requirements
Written Request	Must be manufactured based on a written request from a physician or dentist.
Not Generally Available	The device must not be generally available in the U.S. in finished form.
Patient-Centric Need	Designed to treat a unique pathology or physiological condition of a specific patient.
Physician-Centric Need	Intended to meet the special needs of a physician or dentist in their professional practice.
Case-by-Case Basis	Produced on an individual basis to accommodate the unique needs.
Necessarily Deviates	Should be sufficiently unique that clinical investigations would be impractical.
Limited Production Volume (≤ 5 per year)	Production of the device must be limited to no more than five units per year of a particular device type.
Sufficiently Rare Condition	The device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations would be impractical.

Table 3. FDA Custom Device Exemption Regulatory Obligations

Item	Regulatory Obligations
Premarket Approval (PMA)	Exempt if criteria are met.
510(k) Premarket Notification	Exempt if criteria are met.
Quality Systems Regulation (QSR)	NOT exempt (21 CFR Part 820).
Medical Device Reporting (MDR)	Required (21 CFR Part 803) for adverse event reporting.
Labeling	Required (21 CFR Part 801) with specific requirements for custom devices.
Corrections and Removals	Required (21 CFR Part 806).
Registration and Listing	Required (21 CFR Part 807).
Prohibition of Marketing to General Public	Custom devices may not be marketed to the general public.
Annual Reporting	Required by March 31st for devices issued the prior calendar year.

6) FDA Patient-Matched Medical Device

Patient-Matched medical devices are designed based on patient image data or anatomical structures and refer to medical devices manufactured to match an individual's anatomical structure according to specific design parameters (e.g., size, shape). These devices are typically manufactured in batches, and verification and reproducibility of the product must be ensured[19][20].

※ For reference, if all the criteria of Section 520(b) of the FD&C Act are not met, it is not considered a CDE medical device.

Table 4. Comparison of Custom Made Deivces and Patient-Matched Medical Devices

CDE	PMMD
Uniquely fabricated for a specific individual when there are no alternative devices available in the market	Designed within a predefined specification range and often mass-produced, thus distinguished from custom-made devices[21]

Patient-Matched medical devices, like general medical devices, are managed under the FDA's risk-based classification system (Class I, II, III). They are authorized and managed through the commonly known premarket notification (510(k)) pathway or the premarket approval (PMA) pathway. New types of Class I or II devices without a predicate device may also be managed through the De Novo pathway.

The difference from general medical devices in terms of marketing authorization management is that it must include the design process, patient image requirements if applicable, the definition of Patient-Matched characteristics, and the design envelope. It must be demonstrated through Verification and Validation, based on QMS procedures, that it is used as intended by the user and for its intended purpose within the specified design envelope, and clear documentation of the design process, including medical professional consent, is mandatory[22].

Here, the concept of the 'Design Envelope' is crucial. This is equivalent to the manufacturer predefining the 'maximum' and 'minimum' allowable variations when creating Patient-Matched medical devices and obtaining FDA approval for them.

By clearly defining and verifying the 'Design Envelope,' the FDA can utilize this range as a 'standard' to leverage the existing review framework. This is considered a core concept that acknowledges the diversity of Patient-Matched medical devices while simultaneously securing efficient regulation by the FDA and convenience for manufacturers.

B. EU MDR

1) EU MDR Custom-Made Device

The European Union Medical Device Regulation (EU MDR, Regulation (EU) 2017/745) aims to enhance the regulatory framework for medical devices to ensure patient safety and product performance[23]. Within this regulation, Custom-Made Devices (hereinafter CMDs) are products uniquely designed and manufactured to meet the individual conditions and needs of specific patients, and follow different regulatory pathways than general mass-produced medical devices. While explicit requirements for CMDs were relatively limited under the previous Medical Device Directive (MDD/AIMDD), the MDR has introduced clearer and more stringent requirements for CMDs as well, to increase transparency and strengthen safety[24].

Although CMDs receive certain exemptions, they must comply with important regulatory obligations to ensure patient safety and performance. These obligations include compliance with General Safety and Performance Requirements (GSPR), establishment of a Quality Management System (QMS), and documentation and reporting requirements.

Regarding these CMD regulations, this study reviewed the definition and requirements of CMDs, conformity assessment procedures, manufacturer obligations, labeling, post-market surveillance, and reporting obligations, based on MDR-related provisions and guidelines issued by the Medical Device Coordination Group (MDCG).

2) EU MDR Custom-Made Device Definition and Requirements

2-1) MDR Article 2(3) Definition

EU MDR Article 2(3) clearly defines 'Custom-Made Device' as follows[25]:

'Custom-Made Device' means a device exclusively intended for use by a particular patient, prepared in accordance with a written prescription from a person authorized by national law by virtue of their professional qualifications, under whose responsibility specific design characteristics are established, and is intended to be used exclusively for a particular patient, to meet their individual condition and needs. However, mass-produced devices that need to be adapted to meet the specific requirements of a professional user, and devices mass-produced through industrial manufacturing processes in accordance with the written prescription of an authorized person, are not considered custom-made medical devices.

Table 5. Key Requirements of EU MDR Custom Made Device

Key criteria	Requirements
Written prescription	It must be specifically manufactured according to a written prescription issued by an authorized person with professional qualifications (e.g., physician, dentist, etc.).

Key criteria	Requirements
Specific design characteristics under prescriber's responsibility	The prescriber must specify the specific design characteristics of the device under their responsibility. This refers to a design unique to the patient's anatomical and physiological features, and may include models, molds, dental impressions, etc. The authority to prescribe is determined by the individual laws of each member state.
Use exclusively for a particular patient	The device must be intended for use exclusively for a single, specific patient.
Meeting individual conditions & needs	It must be intended to meet the individual conditions and needs of the patient. This generally applies when there are clinical needs that cannot be met by mass-produced devices.

* The following are **cases where they are not considered CMDs** (exclusion clauses):

- Mass-produced devices that are adapted to meet the specific requirements of a professional.
- Devices mass-produced through industrial manufacturing processes in accordance with the written prescription of an authorized person. For example, contact lenses with specified diopters according to a prescription are not CMDs because they are mass-produced.

2-2) Distinction from Adaptable Medical Devices and Patient-Matched Medical Devices[26]

To clarify the definition of CMDs, the MDCG published guideline MDCG 2021-3, which explains the concepts of Adaptable Medical Devices and Patient-Matched Medical Devices, which are similar to CMDs but distinct in terms of regulation. Although these are personalized medical devices, they are not considered CMDs according to MDR Article 2(3).

Table 6. Comparison of Adaptable and Patient-Matched Medical Device

Adaptable	Patient-Matched
Mass-produced devices that are fitted, adjusted, or assembled by a professional (mainly a medical professional) according to the patient's specific anatomical and physiological characteristics, following the manufacturer's instructions at the point of use.	Patient-Matched Medical Devices" are devices produced in batches using industrial or continuous manufacturing processes based on the patient's anatomical structure within a specified design range. These devices are generally designed under the manufacturer's responsibility, and while consultation with medical professionals is possible, they do not require a written prescription from an authorized person specifying particular design characteristics under their own responsibility.

This distinction is important because the regulatory pathway differs. CMDs meet the unique needs of patients with the prescriber responsible for specific design characteristics, while adaptable/patient-matched devices, even if tailored to the patient, are primarily designed under the manufacturer's responsibility and are often mass-produced or batch-produced through industrial processes.

Therefore, manufacturers cannot classify a device as 'custom-made' simply because it is tailored to an individual. If it falls under adaptable or patient-matched devices, it must follow stricter standard pathways, including CE marking.

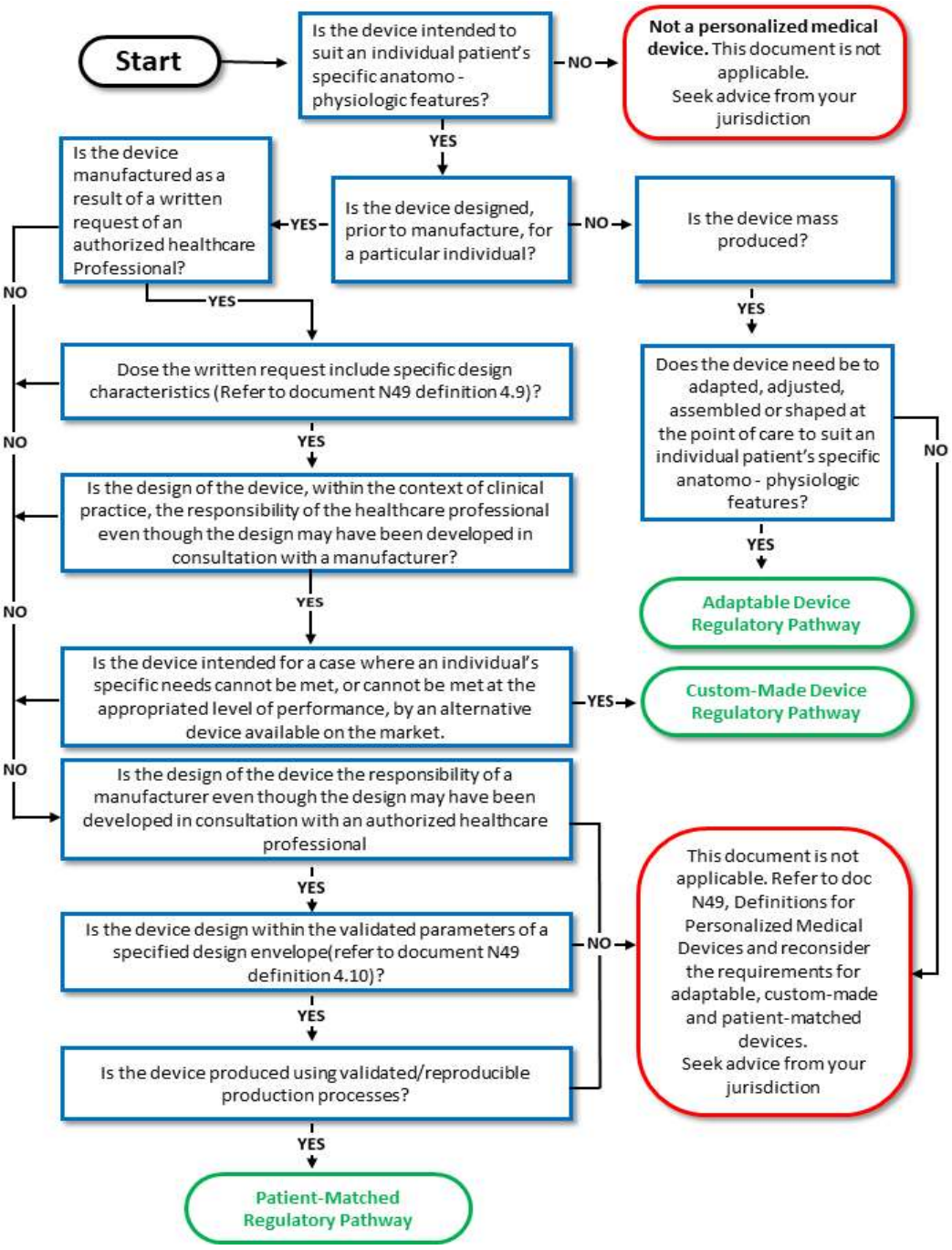


Figure 7. CMD, Adaptable Device, Patient-Matched Medical Device Decision Tree

2-3) CMD Eligibility Based on Manufacturing Technology, such as 3D Printing

The use of modern manufacturing technologies such as 3D printing or CAD/CAM does not automatically classify a device as a CMD[25]. MDCG 2021-3 clarifies this point. To be recognized as a CMD, all criteria of MDR Article 2(3) must be met, regardless of the manufacturing technology. That is, it must have unique design characteristics for a specific patient according to a written prescription from an authorized person and must not be mass-produced. Manufacturing technology is merely a manufacturing method and not a factor that determines regulatory classification.

3) EU MDR Custom-Made Device Exemptions from Conformity Assessment, etc.

CMDs follow specific conformity assessment procedures that differ from those for general medical devices. The MDR details the procedures for CMDs in Annex XIII. These procedures replace the standard conformity assessment pathways that generally require the involvement of a Notified Body (e.g., Annex IX, X, XI) (except for Class III implantable CMDs). The key elements of Annex XIII are that the manufacturer prepares a statement including specific information (Section 1) and maintains the relevant documentation (Section 2).

CMDs are exempt from certain regulatory requirements. This is a measure that considers the unique characteristics of CMDs (single patient use, non-mass production). However, this exemption does not mean that they are exempt from all regulations.

The following Tables 7 and 8 summarize the exemptions for CMDs under the EU MDR and provide a comparison of the requirements for general medical devices versus CMDs.

Table 7. Exemptions for CMDs under the EU MDR

Item	Exemption & Requirements
CE marking	CMDs do not bear the CE mark (MDR Article 21(1)). Since the CE mark is an indication that standard conformity assessment procedures have been completed, it does not apply to CMDs that follow a separate procedure under Annex XIII. In other words, CE conformity assessment is exempt.
UDI	CMDs are excluded from the scope of the UDI system. Therefore, there is no obligation to assign a UDI, affix a label, or register in EUDAMED (MDR Article 27). This reflects the characteristic that each device is unique and difficult to track. However, traceability is still important and is secured through other means (e.g., internal code systems, patient identification information in the Annex XIII statement).
EUDAMED Actor Registration	Manufacturers who only manufacture CMDs are exempt from the initial obligation to register as an actor in EUDAMED before placing devices on the market (MDR Article 31, MDCG 2021-13)[24]. However, this is not a complete exemption. If specific information provision obligations arise later, such as post-market surveillance activities (e.g., reporting of serious incidents) or registration of certificates for Class III implantable CMDs, registration in EUDAMED is required at that time.
EU DOC	Instead of preparing a standard EU Declaration of Conformity, CMD manufacturers must prepare a 'statement' that includes the specific information specified in Annex XIII Section 1.
Technical Documentation	Instead of the comprehensive Technical Documentation detailed in MDR Annex II and III, CMDs must prepare and maintain specific documentation according to Annex XIII Section 2 (to enable understanding of the device's design, manufacture, performance, etc.).

Table 8. Comparison of Requirements: General Medical Devices vs. CMD

Item	General Medical Device	CMD
CE marking	Mandatory (Article 20)	**Exempt** (Article 21(1))
Conformity Assessment	Annex IX, X or XI	**Annex XIII 절차** (Class I/IIa/IIb NB Not required, Class III (Implantable) NB mandatory)
EU DOC	Mandatory (Article 19)	**Not required** (using Annex XIII statement)
Technical Documentation	Annex II & III	**Annex XIII, Section 2**
UDI	Mandatory (Article 27, 29)	**Exempt**
EUDAMED Actor Registration	Mandatory before placing on the market (Article 31)	Initial registration exempt (required later for surveillance/Class III certification)
Labeling	Standard requirements + CE mark + UDI	Standard requirements + **"Custom-Made Device" statement** (no CE mark/UDI)

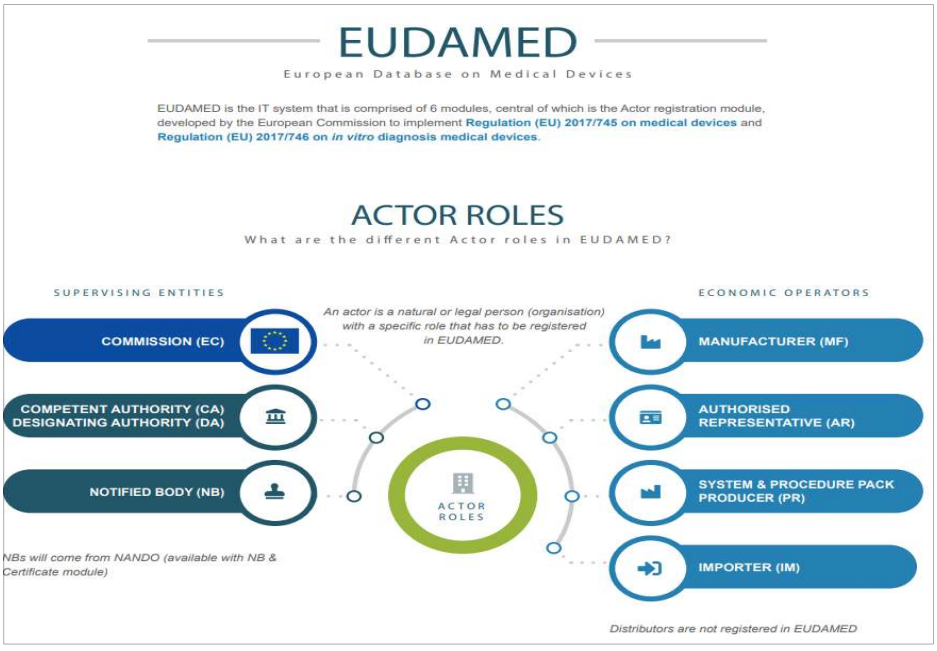


Figure 8. EUDAMED ACTOR ROLES[27]

4) EU MDR Custom-Made Device Manufacturer Obligations

Despite specific exemptions, CMD manufacturers must comply with comprehensive obligations under the MDR. This is to ensure that CMDs are safe for patients and perform as intended.

4-1) Obligation to Comply with General Safety and Performance Requirements (GSPR – Annex I)

Like all medical devices, CMDs must also meet the applicable General Safety and Performance Requirements (GSPRs) specified in MDR Annex I. GSPRs are broad safety and performance requirements covering risk management, chemical, physical, and biological properties, infection and microbial contamination, radiation protection, usability, etc.

Annex XIII requires that GSPR compliance be specified, and if specific GSPRs cannot be fully met due to the custom-made nature of the device, the reasons must be clearly stated and justified. Justification for 'non-compliance' with GSPRs should be interpreted very restrictively. That is, a clear causal relationship must be demonstrated, proving that full compliance with the relevant GSPR provision is impossible due to the specific custom design specified by the prescriber. This does not imply a comprehensive exemption from GSPRs, and manufacturers must still fulfill the requirements to the greatest extent possible, considering

the device's intended purpose, and document detailed justifications for any non-compliance. Key safety-related requirements such as risk management (Annex I, Section 3), post-market surveillance (Article 83), and corrective and preventive actions (CAPA, Article 10(12)) are mandatory regardless of whether the device is custom-made.

4-2) Obligation to Establish and Maintain a Quality Management System (Article 10(9))

CMD manufacturers must establish, document, implement, maintain, keep up to date, and continually improve a Quality Management System (QMS) in accordance with MDR Article 10(9). This QMS must ensure compliance with the MDR and must operate most effectively in a manner proportionate to the risk class and type of device. ISO 13485 is the only harmonized QMS standard with the EU MDR. The QMS shall address at least the aspects presented in Table 9 below[28]:

QMS requirements also apply comprehensively to CMD manufacturers. QMS elements are not omitted, but rather the scale and complexity of implementation can be adjusted to suit the characteristics of the device. For example, small-scale CMD manufacturers may have streamlined procedures compared to large multinational corporations, but core processes such as risk management, PMS, and CAPA must still be robustly established. The regulatory exemptions for CMDs do not exempt them from QMS requirements; management must be tailored to their specific characteristics.

Table 9. Key QMS Aspects for CMDs

QMS Aspect to Address	ISO13485
Regulatory compliance strategy (including conformity assessment procedures and change management)	Clause 4 (Quality management system), Clause 5 (Management responsibility) for ensuring compliance, and Clause 7 (Product realization) regarding design and development changes and regulatory requirements
Identification of applicable GSPRs and exploration of solutions	Clause 4 (Quality management system) - General Requirements, and Clause 7 (Product realization) - Design and development input (regulatory requirements)
Management responsibility	Clause 5 (Management responsibility)
Resource management (including selection and management of suppliers and subcontractors)	Clause 6 (Resource management) and Clause 7 (Product realization) regarding purchasing
Risk management (Annex I Section 3)	Clause 7 (Product realization) - Design and development, Clause 4 (Quality management system) regarding process control. ISO 14971 is the specific standard for risk management for medical devices, which ISO 13485 references
Clinical evaluation (including Post-Market Clinical Follow-up (PMCF), Annex XIV)	Design and development, and Clause 8 (Measurement, analysis and improvement) for post-market data.
Product realization (including planning, design, development, production, and service provision)	Clause 7 (Product realization)
UDI system (MDR article 27(3), 29 / Not applicable to CMDs)	Clause 7 (Product realization) - Identification and traceability, although the specific UDI requirements are more detailed in the MDR itself
Post-market surveillance (PMS) system (MDR article 83)	Clause 8 (Measurement, analysis and improvement) - Feedback, complaint handling, and reporting, with links to Clause 7 (Product realization) for design changes based on PMS
Communication with authorities, economic operators, and customers	Clause 5 (Management responsibility) - Customer focus and communication, Clause 8 (Measurement, analysis and improvement) - Feedback and reporting
Processes for reporting serious incidents and taking field safety corrective actions	Clause 8 (Measurement, analysis and improvement) - Complaint handling and regulatory reporting, and nonconformity control
Management and effectiveness verification of corrective and preventive actions (CAPA)	Clause 8 (Measurement, analysis and improvement) - Corrective and preventive action
Monitoring and measurement of outputs, data analysis, and processes for product improvement	Clause 8 (Measurement, analysis and improvement)

4-3) MDR Annex XIII Statement and Documentation Requirements

Before placing a device on the market, CMD manufacturers must prepare a statement that includes all the information specified in Annex XIII, Section 1. This statement must be made available with the device and must be made available to the specific patient or user identified by name, abbreviation or numerical code (Article 21(2)). Table 10 below summarizes the required information that must be included in the statement and the requirements for other documents that need to be controlled.

Table 10. Statement and Documentation Requirements for CMDs under the EU MDR

Item	Information or Requirements
Statement (Annex XIII, Section 1)[29]	• The manufacturer's name and address (and the name and address of all manufacturing sites) • The name and address of the authorized representative, if applicable • Data allowing identification of the device • A statement indicating that the device is intended for exclusive use for a specific patient or user, identified by name, abbreviation, or numerical code • The name of the person (and the name of the relevant medical institution, if applicable) who wrote the prescription and is authorized under national law by virtue of their professional qualifications • The specific characteristics of the product indicated in the prescription • A statement that the device complies with the general safety and performance requirements specified in Annex I, and, where applicable, a statement indicating the requirements that are not fully met and the grounds for this • Where applicable, an indication that the device incorporates or is constituted of tissues or cells of human origin, or medicinal substances of animal origin as referred to in Regulation (EU) No 722/2012

Item	Information or Requirements
Documentation (Annex XIII, Section 2)	CDM manufacturers have an obligation to provide the relevant national authorities with documentation that includes the following. They must prepare and maintain documentation that includes: • Indication of the manufacturing site(s) • Documentation enabling an understanding of the device's design, manufacture, and performance (including intended performance). This allows for the conformity assessment of MDR requirements. This includes GSPRs, risk management, and the Clinical Evaluation Report (CER, evidence of safety and performance)[29].
Documentation retention period	Relevant documentation, including the statement, must be kept for a minimum of 10 years after the device is placed on the market. For implantable devices, this period is a minimum of 15 years (Annex XIII, Section 4).
Manufacturing process	The manufacturer must take all necessary measures to ensure that the manufacturing process produces devices consistently with the documentation in Section 2 (Annex XIII, Section 3).

4-4) Obligation to Appoint a Person Responsible for Regulatory Compliance

CMD manufacturers must ensure that they have at least one Person Responsible for Regulatory Compliance (PRRC) within their organization (MDR Article 15).

While the PRRC qualification requirements typically include a university degree and relevant field experience or 4 years of professional experience (Article 15(1)), CMD manufacturers are allowed

alternative proof of qualification. They can demonstrate the required expertise through at least 2 years of professional experience in the relevant manufacturing field (MDR Article 15(1)).

The PRRC is responsible for ensuring compliance with conformity assessment procedures for devices, maintaining technical documentation/statements, fulfilling PMS obligations, and fulfilling reporting obligations (MDR Article 15(3)). The PRRC of a CMD manufacturer is not required to register in EUDAMED.

4-5) Obligation to Provide a List of Devices (MDR Article 21(2) / MDCG 2021-13)

Member States may require CMD manufacturers to submit a list of the devices available in their territory to the relevant authorities. Therefore, manufacturers must maintain records of the supplied devices (including patient/user identification information and the source of supply).

This is an important requirement to ensure traceability even in the absence of a UDI. Since CMDs do not have a UDI and are not registered in the EUDAMED device database, this obligation serves as a means for competent authorities to conduct market surveillance of CMD devices. Therefore, CMD manufacturers must have a clear tracking system linked to the patient identification information in the Annex XIII statement.

5) EU MDR Custom-Made Device Labeling

They follow specific labeling requirements that reflect the regulatory particularities of CMDs.

CMD labeling must comply with the general labeling requirements specified in the General Safety and Performance Requirements (GSPR) of MDR Annex I, Section 23. In addition to these, the specific information that must be included in CMD labeling is as follows:

Table 11. Requirements for the Label and Instructions for use (Section 23 of Annex I of the EU MDR)

subsections	Requirements
23.1	**General requirements regarding the information supplied by the manufacturer:** This covers the need for information to identify the device and its manufacturer, as well as relevant safety and performance information. It discusses where this information should appear (device, packaging, instructions for use, website), the format, legibility, and the use of symbols.
23.2	**Information on the label:** This details the specific particulars that must be present on the device label, such as the device name, manufacturer details, lot or serial number, UDI carrier, warnings, single-use indication, and **if it's a custom-made device. (23.2(p), the words 'custom-made device')**
23.3	**Information on the packaging which maintains the sterile condition of a device ('sterile packaging'):** This outlines the information required on the sterile packaging, such as an indication of sterility, sterilization method, manufacturer details, and warnings if the packaging is damaged.
23.4	**Information in the instructions for use:** This is a comprehensive list of information that must be included in the instructions for use, covering the device's intended purpose, performance characteristics, residual risks, instructions for use, reprocessing (if applicable), warnings, and information to be supplied to the patient with an implantable device, among other things.

6) EU MDR Custom-Made Device PMS & Reporting

CMD manufacturers have significant obligations to continuously monitor the safety and performance of devices after they are placed on the market and to report relevant information.

6-1) Post-Market Surveillance(PMS) System for CMDs

CMD manufacturers must establish and maintain a PMS system in accordance with MDR Article 83, which must be part of the QMS under Article 10(9). The PMS system is a systematic process of collecting and reviewing experience gained from devices placed on the market to identify and implement necessary corrective and preventive actions (CAPA).

Annex XIII, Section 5, explicitly requires CMD manufacturers to review and document experience gained in the post-production phase (including Post-Market Clinical Follow-up (PMCF)) and to implement necessary corrective actions.

6-2) Post-Market Clinical Follow-up (PMCF) for CMDs

Post-Market Clinical Follow-up (PMCF) is part of the PMS system according to Annex XIV, Part B. According to Annex XIII, Section 5,

CMD manufacturers must review and document experience gained in the post-production phase, including PMCF, and implement appropriate means to apply necessary corrective actions. In this regard, manufacturers must report any serious incidents or Field Safety Corrective Actions (FSCAs), or both, to the relevant competent authorities without delay in accordance with MDR Article 87(1).

6-3) Vigilance Reporting for CMDs

If specific safety events related to CMDs occur or if there is a trend of statistically significant increases in the frequency or severity of adverse events, manufacturers must report this promptly (MDR Articles 87, 88).

Table 12. Type of Reporting obligations and Reporting Requirements

Type	Requirements
Serious Incidents	CMD manufacturers must report any serious incidents involving their devices to the relevant competent authorities.
Field Safety Corrective Actions, FSCA	FSCAs taken to reduce the risk of death or serious deterioration in health must be reported. A Field Safety Notice (FSN) may be required if necessary.
Trend Reporting	If there is a statistically significant increase in the frequency or severity of non-serious incidents or anticipated undesirable side-effects that could have a significant impact on the benefit-risk analysis, this must be reported.
EUDAMED Reporting	If these vigilance reporting obligations (serious incidents, FSCA, trend reporting) arise, CMD manufacturers must register as actors in EUDAMED to submit the corresponding reports electronically.

6-4) Periodic Safety Update Report (PSUR) (Periodic Reporting Obligation)

PSURs (Periodic Safety Update Reports) are key safety reports that must be submitted regularly for CMDs of specific risk classes (MDR Article 86, MDCG 2021-3). The reporting obligations, including the applicable class and update frequency, are summarized in Table 13 below. MDR Article 86 clearly requires PSURs for Class IIa, IIb, and III devices, which is distinct from reporting (Articles 87/88) triggered by specific events or trends.

Table 13. EU MDR Periodic Safety Update Report (PSUR) for CMDs

Aspect	Class I (via PMSR)	Class IIa (via PSUR)	Class IIb & III (via PSUR)
Report Type	Post-Market Surveillance Report (PMSR, MDR Article 85)	Periodic Safety Update Report (PSUR)	
Contents	Simpler reporting via PMSR	PMS data analysis results, benefit-risk conclusions, key PMCF results, sales/usage estimates, CAPA rationale, etc.	
Update Frequency	As appropriate	At least every 2 years	At least annually
Documentation	Part of the documentation	Part of the documentation (Annex XIII Section 2)	
Submission	Provide to NB and competent authorities upon request	Provide to NB and competent authorities upon request (if relevant NB involved)	Submit via EUDAMED to the Notified Body (for ClassIII implantable, if applicable). Provide to NB and competent authorities upon request for others.

Table 14. EU MDR CMD Regulatory Obligations (summary of Requirements)

Obligations	Summary of Requirements
Device Qualification Requirements	Meets the definition of MDR Article 2(3); distinguished from adaptable/patient-matched devices
Conformity Assessment	Compliance with Annex XIII procedures
GSPR Compliance	Compliance with applicable General Safety and Performance Requirements
Quality Management System (QMS)	Establishment, implementation, maintenance, and continuous improvement of a compliant QMS (proportionate to risk/type)
Annex XIII statement	Preparation of a statement including essential information; provision to patient/user
Annex XIII Documentation	Preparation and maintenance of design, manufacturing, and performance-related documentation; retention for 10/15 years
Person Responsible for Regulatory Compliance (PRRC)	Appointment of a PRRC meeting qualification requirements (including 2-year experience option)
Labeling	Inclusion of "Custom-Made Device" statement and other essential information (no CE mark/UDI)
PMS	Implementation of a PMS system (including PMCF), review of experience, CAPA actions
Vigilance Reporting	Reporting of serious incidents (Article 87), FSCA (Article 87), and trends (Article 88) to authorities (EUDAMED registration may be required)
Periodic Reporting (PSUR/PMSR)	Preparation of PSUR (Class IIa+) or PMSR (Class I) based on PMS data; renewal annually/biennially (PSUR) or as needed (PMSR)
Class III Implantable Specifics	Conformity assessment (QMS/type examination) by a Notified Body (NB); NB registers the certificate in EUDAMED (manufacturer registers as an actor).

7) EU MDR Patient-Matched Medical Device

In Europe, Patient-Matched Medical Devices (PMMDs) are defined by several key characteristics[25].

These devices are manufactured within a specified design envelope, utilizing scaling based on anatomical references or complete anatomical features derived from patient imaging data to achieve a match with the individual patient's anatomical structure. Notably, PMMDs are generally produced in batches using processes that ensure verification and reproducibility. Their design and production fall under the sole responsibility of the manufacturer, although consultation with authorized medical professionals may occur during the design development phase. A significant distinction from Custom-Made Devices (CMDs) is that PMMDs do not necessarily require a written prescription from an authorized person.

Consequently, unlike CMDs, PMMDs must adhere to the standard Medical Device Regulation (MDR) regulatory pathway and necessitate CE marking. The process of obtaining authorization by defining the design range for PMMDs bears similarity to the FDA's approach to Patient-Matched Devices.

Furthermore, their Quality Management Systems (QMS) and technical documentation are subject to review by a Notified Body following standard procedures outlined in Annexes IX, X, or XI of the MDR.

Table 15. EU MDR CMD vs. PMMD

Feature	Custom Made Device	Patient-Matched
Written Prescription	Mandatory (authorized person specifies particular design characteristics)	Not required (consultation with medical professionals possible)
Production Method	Production for single patient only	Batch production (verifiable/reproducible process)
Design Responsibility	Prescriber and manufacturer (GSPR compliance)	Manufacturer (sole responsibility)
Application / Matching Location	During manufacturing process	Within design envelope
CE Marking	Not required (Annex XIII statement required)	Mandatory
UDI Requirements	Exempt	Mandatory
Conformity Assessment	Annex XIII	Standard MDR pathway (Article 52)

C. IMDRF (International Medical Deivce Regulators Forum)

1) IMDRF Personalized Medical Devices

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of regulatory authorities aiming to accelerate international harmonization and convergence of medical device regulations. While the IMDRF is not an organization that enacts legally binding regulations, it develops guidance and best practices that are widely recognized and adopted by regulatory authorities and industry worldwide.

Recent technological advancements, such as 3D printing, have driven innovation in the field of Personalized Medical Devices (PMDs), which are designed and manufactured to meet the individual needs of patients. These advancements have presented new challenges to regulatory authorities, and the IMDRF has actively participated in developing guidance in this area through its PMD Working Group.

The Korean Ministry of Food and Drug Safety (MFDS, Medical Device Review Department) also created and distributed a Korean version, the 'Guidelines for Classification and Definition of Personalized Medical Devices,' based on the IMDRF's 'Definitions for Personalized Medical Devices' guidelines discussed in October 2018.

Based on official documents, discussion papers, and working group outcomes published by the IMDRF, this study closely examined the IMDRF's recommendations, particularly regarding 'Custom-Made Medical Devices (CMDs)' among personalized medical devices (PMDs). It explored the IMDRF's position on CMD definitions and classification criteria, recommended regulatory pathways and exemptions, manufacturer obligations (quality management systems, documentation, compliance with essential principles, etc.), labeling requirements (including Unique Device Identification (UDI)), and post-market surveillance and reporting systems. Furthermore, it compared how IMDRF principles are reflected in actual regulations, such as those of the European MDR and the Australian Therapeutic Goods Administration (TGA).

2) Personalized Medical Devices Definition and Classification Criteria

The IMDRF aimed to establish harmonized definitions for Personalized Medical Devices (PMDs), including CMDs, Patient-Matched Medical Devices, and Adaptable Medical Devices, to lay the foundation for a consistent regulatory approach to PMDs. The key IMDRF documents related to this are IMDRF/PMD WG/N49 FINAL:2018/2019 and IMDRF/PMD WG/N58 FINAL:2023.

The key definition of CMDs specified in the IMDRF N49/N58 documents is a medical device that meets the following requirements:

Table 16. IMDRF Key Definition of CMDs

Requirement	Description/Detail
Intended Use	For the exclusive use of a specific individual (patient or healthcare professional).
Manufacturing Basis	Specifically manufactured according to a written request from an authorized healthcare professional legally qualified by law.
Design Specification	The request specifies particular design characteristics under the healthcare professional's responsibility (even if developed in consultation with the manufacturer).
Patient-Specific Need	Intended to address the specific anatomical-physiological characteristics or pathological condition of the individual for whom the device will be used.
Market Availability	Intended for cases where available alternative devices on the market cannot meet the individual's specific needs or cannot meet them with an appropriate level of performance.
Example	An acetabular cup implant (exceeding the manufacturer's verified design range) manufactured by a 3D printing implant manufacturer based on specific requirements from an orthopedic surgeon to reconstruct the acetabulum by connecting areas of acetabular bone loss using DICOM scan images.

Because distinguishing CMDs from other types of PMDs is crucial, IMDRF N49/N58 clearly differentiates between CMDs and Patient-Matched Medical Devices (PMMDs). PMMDs are classified as follows (PMMD characteristics):

Table 17. IMDRF Key Definition of PMMDs

Requirement	Description/Detail
Customization to Patient Anatomy	Adapted to the patient's anatomical structure, but within a "specified design envelope" defined by the manufacturer (e.g., device size adjustment based on imaging data).
Production Method	Generally manufactured in batches using validated and reproducible processes.
Design Responsibility	Ultimate design responsibility resides with the manufacturer, even if consultation with healthcare professionals occurs.
Written Request from Healthcare Professional	A written request or prescription from a healthcare professional is not mandatory.
Examples	• Mandibular implants produced by a 3D printing manufacturer based on patient imaging data. • External wearable cranial orthoses (helmet type) designed to correct or prevent infant plagiocephaly, based on 3D external imaging of the patient's head.

Similarly, CMDs are also distinguished from Adaptable Medical Devices (AMDs). Their characteristics are as follows:

Table 18. IMDRF Key Definition of AMDs

Requirement	Description/Detail
Production Method	Mass-produced.
Customization at Point of Care	Applied, adjusted, assembled, or shaped to the individual patient's characteristics at the point of care by a healthcare professional, in accordance with the manufacturer's validated and documented instructions for use.
Examples	Polymer surgical implants for cranial reconstruction (mass-produced; manufacturer provides comprehensive instructions for intraoperative heating and shaping to fit the patient's unique anatomy), supplied sterile for thermoforming procedures.

The key elements of the CMD definition are the 'written request' from a medical professional and the responsibility for 'specific design characteristics.' IMDRF N49 defines 'specific design characteristics' as 'unique design specifications based on an individual's specific anatomical-physiological characteristics and/or pathological condition, necessary for CMD production that the manufacturer cannot propose without the involvement of a medical professional.' This contrasts with PMMDs, where the manufacturer manages the design range. In other words, design leadership and ultimate responsibility for CMDs lie with the prescribing medical professional. For example, an orthopedic implant that an orthopedic surgeon requires to have specific rigidity/flexibility at a particular location due to a patient's unique pathological condition can be an example of a CMD.

These IMDRF definition principles are similarly reflected or applied with slight differences in several countries. For example, EU MDR Article 2(3) defines CMDs very similarly to the IMDRF definition, emphasizing the written prescription of a medical professional and specific design characteristics under their responsibility. Australian TGA regulations also use a similar definition but additionally specify the criterion that 'there is no equivalent medical device listed in the Australian Register of Therapeutic Goods (ARTG) or that such a device cannot adequately address the problem,' further emphasizing the exceptional nature of CMDs.

According to the ‘Guidelines for Classification and Definition of Personalized Medical Devices (October 2018)’ of the Medical Device Review Department of the Korean Ministry of Food and Drug Safety Evaluation, CMDs and other PMDs are defined as follows:

[Korean version]

4.2 주문 제작형 의료기기(custom-made medical device) - 최소한 다음의 요구사항을 충족하는 의료기기

- 특정 개인(환자 또는 의료인)의 전용 사용을 목적으로 함
- 전문 의료인의 서면 요청에 따라, 해당 전문 의료인의 책임 하에 구체적인 설계 특성을 부여하여 특수 제작됨
- 의도된 개인의 특정 인체구조·생리학적 특성 또는 병리학적 상태를 다루기 위함

※ 참고 1: 특정 환자용(patient-specific), 환자 적용형(adaptable) 또는 대량 생산형(mass-produced) 의료기기는 주문 제작형(custom-made) 의료기기로 간주되지 않는다.

※ 참고 2: 주문 제작형 의료기기는 한 개인의 특정 요구를 충족시키기 위한 경우를 목적으로 하거나, 시장에 유통 중인 대체 제품으로 적절한 성능 수준을 충족시킬 수 없는 경우를 목적으로 한다.

[English translation]

4.2 Custom-made medical device - A medical device that meets at least the following requirements:

- Intended for the exclusive use of a specific individual (patient or healthcare professional)
- Specifically manufactured under the responsibility of a qualified healthcare professional, according to their written request, with specific design characteristics assigned
- Intended to address the specific anatomical structure, physiological characteristics, or pathological condition of the intended individual

* Note 1: Patient-specific, adaptable, or mass-produced medical devices are not considered custom-made medical devices.
* Note 2: Custom-made medical devices are intended either to meet the specific needs of an individual or for cases where alternative products available on the market cannot provide an appropriate level of performance.

Figure 9. Custom Made Device (Korean and English version)

[Korean version]

4.3 특정 환자용 의료기기(patient-specific medical device) - 다음의 요구사항을 충족하는 의료기기

- 해부학적 자료를 기반으로 기기의 크기를 조정하는 등의 기술을 활용하거나 환자 영상의 전체적인 인체 특징을 활용함으로써 구체적인 설계 범위 내에서 환자의 인체에 맞출 수 있는 의료기기
- 일반적으로 유효성 검증 및 재생산이 가능한 공정을 통해 배치 생산됨
- 전문 의료인과 협의를 거쳐 설계가 마련될 수 있더라도 제조자의 책임 하에 설계되고 생산됨

※ 참고 1: 전문 의료인의 서면 요청이 요구될 수도 있고 요구되지 않을 수도 있다.
※ 참고 2: 설계 정보의 수와 유형은 전문 의료인과의 협의를 통해, 제조할 의료기기에 따라 달라질 수 있다.
※ 참고 3: 설계는 구체적인 설계 범위의 검증된 기준치 내에서 유지되어야 한다.

[English translation]

4.3 Patient-specific medical device - A medical device that meets the following requirements:

- A medical device that can be adapted to a patient's anatomy within a specific design range by utilizing techniques such as scaling based on anatomical data or utilizing the complete anatomical features of patient images.
- Generally batch-produced through processes that allow for validation and reproduction.
- Designed and produced under the responsibility of the manufacturer, even if the design may be developed in consultation with medical professionals.

* Note 1: A written request from a medical professional may or may not be required.
* Note 2: The number and type of design information may vary depending on the medical device to be manufactured through consultation with medical professionals.
* Note 3: The design must be maintained within the verified criteria of a specific design range.

Figure 10. Patient-Matched Medical Device (Korean and English version)

[Korean version]

4.4 환자 적용형 의료기기(adaptable medical device) - 아래의 요구사항을 충족하는 의료기기

- 대량 생산된 의료기기
- 사용 전, 개별 환자의 특정 인체구조·생리학적 특성에 맞추기 위해 제조자의 검증된 지시에 따라 치료 시점에 맞추고, 조정하고, 조립하거나 형태를 만드는 의료기기

[English translation]

4.4 Adaptable medical device - A medical device that meets the following requirements:

- Mass-produced medical device
- Medical device that is fitted, adjusted, assembled, or shaped at the point of care according to the manufacturer's verified instructions to match the specific anatomical structure and physiological characteristics of an individual patient before use

Figure 11. Adaptable Medical Device (Korean and English version)

Analyzing these definitions, it is understood that the decisive criterion for distinguishing CMDs from other PMDs is who bears the ultimate responsibility for the design characteristics. In the case of CMDs, medical professionals assume design responsibility, whereas manufacturers are responsible for the design (design range or application guidelines) in PMMDs and AMDs. Since this difference in responsibility directly affects the regulatory pathway applicable to the device, manufacturers must carefully evaluate the design input process and responsibility to correctly classify PMDs according to IMDRF principles. Incorrect classification can lead to regulatory non-compliance.

Furthermore, IMDRF guidelines consistently define CMDs as intended for 'special cases' where standard or PMMDs are unsuitable. Note 2 of IMDRF N49 specifies that CMDs are for needs without alternatives, and N58 mentions that historically, CMD exemption clauses were intended for these special cases and small-volume production. Accordingly, when classifying as a CMD, the specific request of the medical professional and the design responsibility requirements are important criteria for judgment. This contrasts with the requirements for PMMDs or AMDs, which include mass production elements or standardized design ranges/guidelines. Therefore, the IMDRF considers CMDs not as devices that can be produced within standardized or verified ranges, but as true exceptions. This means that regulatory authorities adopting IMDRF principles are likely to require evidence that a medical device claimed to be a CMD does not conform to PMMD or AMD, and therefore, it must be managed with clear documentation to demonstrate that it is a device that meets specific and unique patient needs identified by a medical professional.

3) IMDRF Custom Made Device Recommended Regulatory Pathways and Exemptions

The IMDRF/PMD WG/N58 FINAL:2023 (Personalized Medical Devices – Regulatory Pathways) document outlines recommended regulatory pathways based on PMD definitions and aims to present a harmonized approach. The

regulatory pathways recommended by the IMDRF for CMDs generally have the following characteristics. (The following general exemptions observed in guidance reflecting IMDRF principles related to CMDs are observed in the EU and TGA):

Table 19. Regulatory Exemptions for CMDs under IMDRF Guidelines

Aspect	Description
Exemption from Standard Premarket Review/Approval	Custom-Made Devices (CMDs) are generally exempt from the comprehensive premarket review, approval, or certification procedures required for mass-produced devices.
Exemption from CE Marking / ARTG Listing	As a result of these exemptions, CMDs typically do not bear the CE mark (EU) and are not listed on the Australian Register of Therapeutic Goods (ARTG).
Use of Specific Conformity Assessment Procedures	CMDs follow conformity assessment procedures specifically designed for custom-made devices, such as those outlined in EU MDR Annex XIII.
Exemption from Standard Technical Documentation	CMDs require specific documentation tailored for custom-made devices, rather than the standard technical documentation required for mass-produced devices.
Exemption from UDI	CMDs are generally exempt from Unique Device Identification (UDI) assignment and labeling requirements.
Exemption from Standard Database Registration	CMDs may be exempt from standard database registration obligations (e.g., EUDAMED), although registration may be required in certain cases (e.g., Class III CMD certification or vigilance reporting).

These exemptions reflect the unique characteristics of CMDs and features such as small-volume production. However, these exemptions do not mean that CMDs are exempt from all regulations. CMDs must still meet basic safety and performance requirements, and manufacturers must fulfill key regulatory obligations such as quality control, documentation, and post-market surveillance. IMDRF N58 outlines specific pathways and presents customized requirements, and N47 (Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices) emphasizes that essential principles apply to all devices. EU MDR Annex XIII, although different from Annexes II/III, still requires specific documentation and PMS activities. TGA exemptions in Australia are conditional on meeting other requirements such as notification, record keeping, statements, and annual reports. Therefore, the 'partial regulatory exemptions' for CMDs mean exemptions from specific and often burdensome procedures (such as marketing authorization procedures) in the regulations for mass-produced devices, but the obligation to comply with core regulations remains valid. Even though some regulations are exempt, manufacturers must comply with obligations related to QMS, documentation, demonstration of safety/performance, and post-market activities.

Table 20. Summary of IMDRF Recommendations / Principles on CMD Exemptions / Specific Procedures

Regulatory Aspect	IMDRF-Related Recommendations/Considerations	Key IMDRF Document Reference/Principle
Standard Premarket Approval/Review	High probability of exemption	N58 pathway, N49 definition (special cases)
CE Marking / ARTG Listing	Exemption is common	N58 pathway, N49 definition
Standard Technical Documentation	Replaced by specific CMD documentation	N58 pathway, Annex XIII concept (EU MDR example)
Application of Unique Device Identification (UDI)	Exemption is common	UDI guidance N7/N48 context ("custom-made" excluded)
Standard Database Registration (EUDAMED, etc.)	High probability of exemption (but specific conditional registration possible)	N58 pathway, EUDAMED registration-related MDCG guidance (MDCG 2021-13) context

4) IMDRF Custom Made Device Manufacturer Obligations

Even if CMDs are exempt from certain regulatory procedures, manufacturers still bear the fundamental obligations to ensure the safety and performance of the devices.

4-1) Quality Management System (QMS)

The IMDRF emphasizes the importance of all medical device manufacturers establishing and maintaining a QMS. Relevant GHTF/IMDRF

documents detail QMS principles and recommend alignment with the international standard ISO 13485. One of the core principles is 'proportionality,' where the QMS should be appropriate to the device type and risk class.

This is particularly important for CMD manufacturers. EU MDR Article 10(9) explicitly requires all manufacturers, including CMD manufacturers, to establish, document, implement, maintain, keep up to date, and continually improve a QMS that ensures compliance in a manner proportionate to the risk class and device type. This QMS must address, as a minimum, aspects such as regulatory compliance strategy, identification and resolution of essential safety and performance requirements (GSPRs), management responsibility, resource management (including supplier management), risk management, clinical evaluation, post-market surveillance (PMS), communication, incident reporting, and corrective and preventive actions (CAPA).

Since CMDs are inherently unique or produced in very small quantities, applying the full QMS burden designed for mass production may be unrealistic or result in excessive costs, hindering availability. Therefore, CMD manufacturers can establish a QMS that covers key elements such as risk management, design input management from medical professionals, production management, PMS, and CAPA, but adjust the complexity and level of documentation based on low production volume and specific risks. It is important to justify this proportional approach.

4-2) Documentation

While CMDs are exempt from standard technical documentation requirements (e.g., EU MDR Annex II/III), specific documentation is mandatory. Documentation based on harmonized principles can be found in examples such as EU MDR Annex XIII Section 2 and TGA's Written Statement and record-keeping requirements. The documentation information generally required is as follows:

Table 21. Documentation Requirements for CMDs

Document Type / Content Requirement	Description
Place(s) of Manufacture	Documents specifying the manufacturing site(s) for the custom-made device.
Design, Manufacture, and Performance Information	Information sufficient to understand the device's design, manufacturing process, and (intended) performance characteristics.
Conformity Assessment Information	Documentation demonstrating conformity with applicable regulations and/or essential principles.
Prescription/ Request Copies	Copies of the prescription or request from the prescribing healthcare professional.
Clinical Evaluation Data	Clinical evaluation data relevant to the CMD, which may be adapted or proportionate to the device's risk and intended use.
Post-Market Surveillance (PMS) Plans/Data/Reports	Post-market surveillance plans, data, and reports, applied proportionally to the risk and nature of the CMD.
TGA Written Statement Requirements (Australia-specific)	Includes: manufacturer details, device identification, patient identification, prescribing physician information, specific design characteristics, statement of compliance with essential principles (or justification for non-compliance), instructions for use, etc.

While standard technical documentation focuses on demonstrating the conformity of mass-produced device types, CMD documentation focuses on demonstrating the conformity and traceability of specific individual devices based on medical professional requests. This means that the documentation burden shifts from the type to the individual device. Therefore, CMD manufacturers must implement a robust system to capture and maintain device-specific information such as medical professional requests, design inputs, manufacturing records, conformity statements, and PMS data for each individual CMD.

4-3) Essential Principles of Safety and Performance / General Safety and Performance Requirements(GSPR)

It is a fundamental requirement that all medical devices, including CMDs, comply with the Essential Principles of Safety and Performance or equivalent GSPRs specified in IMDRF/GRRP WG/N47. The method of demonstrating conformity may vary due to the unique characteristics of CMDs. Statements related to CMDs (EU Annex XIII Section 1, TGA Written Statement) must include a declaration of compliance with GSPRs/essential principles or justification for deviations.

4-4) Record Retention

Manufacturers must retain CMD-related documents for a specific period. Harmonized regulations (often influenced by EU MDR) generally require a retention period of 10 years or 15 years (especially for implantable devices). The Australian TGA requires record retention of a minimum of 5 years for non-implantable devices and a minimum of 15 years for implantable devices.

5) IMDRF Custom Made Device Labeling

IMDRF/GRRP WG/N52 presents general labeling principles applicable to all medical devices, emphasizing the importance of device identification, safety information, and providing correct usage information.

Regarding CMDs, a common requirement in harmonized systems is to explicitly indicate on the label that it is a CMD. EU MDR Annex I Section 23.2(c) requires the statement 'custom-made device,' and TGA regulation 13.3 item 8 specifies that 'the labeling must include an indication that the device has been custom-made.' This serves as an important identifier for clearly distinguishing CMDs from standard devices. Clear identification is a core labeling principle, and since CMDs follow a different regulatory pathway with specific exemptions, it is important for users, patients, and regulatory authorities to immediately

distinguish CMDs from standard CE-marked/ARTG-listed devices. Therefore, requiring the explicit statement 'custom-made device' on the label is to achieve this identification purpose. This label is not simply a description but a regulatory indication of the specific pathway and exemptions applicable to the device.

In accordance with general labeling principles, CMD labels must also include other relevant information such as the manufacturer's name/address, device identification information, patient/user identification information (or identifiable connection information), etc.

5-1) Unique Device Identification (UDI)

IMDRF UDI guidelines (N7, N48) describe the goals and framework of a harmonized UDI system for improved traceability and safety. However, IMDRF guidelines acknowledge potential exemptions for CMDs, and countries that have implemented UDI systems generally exempt CMDs from UDI assignment and labeling requirements. EU MDR Recital 42 and Articles 27 and 29 explicitly exclude UDI requirements for CMDs. The reason for these exemptions is that the UDI system is designed to track standardized mass-produced devices, so applying the UDI system (especially UDI-DI registration) to unique, single-patient devices is impractical and inefficient.

5-2) Traceability without UDI

Despite the UDI exemption, traceability of CMDs remains important. For post-market safety, it must be possible to trace the device back to the patient who used it and the manufacturing details. This traceability is possible through other means such as serial numbers, component batch codes (if applicable), and mandatory statements that link the device to a specific patient/user and prescribing physician. Therefore, CMD manufacturers, while relieved of the burden of the standard UDI system, must have a documentation (e.g., Annex XIII statements/records) system to ensure robust traceability that connects each device to a specific patient, prescribing physician, design inputs, and manufacturing details.

6) IMDRF Custom Made Device PMS & Reporting

IMDRF/GHTF emphasizes the importance of proactive and systematic Post-Market Surveillance (PMS) for all medical devices to ensure continued safety and performance and to identify necessary actions. PMS is an essential part of the QMS.

6-1) Vigilance / Incident Reporting

The IMDRF has worked to develop harmonized adverse event terminology and reporting systems (AE WG N43, N85, GHTF SG2 documents). Event-based reporting, such as for serious incidents and Field Safety Corrective Actions (FSCAs), is considered a basic requirement for all medical devices, including CMDs. The NCAR exchange program for information exchange between regulatory authorities is also in operation.

6-2) Periodic Reporting

It is unclear whether IMDRF guidelines specifically recommend regular safety reporting (e.g., annual reports or Periodic Safety Update Reports (PSURs)) for CMDs. A review of available IMDRF/GHTF PMS/Vigilance documents indicates that the IMDRF's primary focus appears to be on event-based reporting (vigilance) and continuous PMS data collection/review as part of the manufacturer's QMS, rather than mandating specific periodic reports for CMDs across all jurisdictions. IMDRF PMS guidance (such as GHTF SG2) focuses on data collection/analysis and adverse event/FSCA reporting. No major IMDRF documents that mandate specific periodic summary report formats or frequencies for CMDs worldwide have been identified.

This contrasts with the requirements of specific countries. Under the European MDR, the applicability of the Periodic Safety Update Report (PSUR) to custom-made devices (CMDs) is somewhat ambiguous. Article 86 requires PSURs for Class IIa, IIb, and III devices, and Article 86.1 specifically states that, for CMDs, the PSUR forms part of the documentation required under Annex XIII, thereby implying a requirement. However, Article 86.2 stipulates that the obligation to submit the PSUR to EUDAMED applies to Class III and implantable devices, without explicit reference to CMDs. Furthermore, Article 86.3 provides that, for other devices, manufacturers must make the PSUR available to the notified body involved in the conformity assessment, as well as to competent authorities upon request. While some interpret these provisions as requiring PSURs for CMDs depending on their classification, others consider CMDs to be exempt or subject to differentiated reporting requirements, particularly in light of the phrase “except in the case of CMDs...” found in Article 86.1. The content of the PSUR is focused on summarizing the results of post-market surveillance (PMS) data analysis, conclusions of benefit-risk determinations, key findings from post-market clinical follow-up (PMCF), and corrective and preventive actions (CAPAs), among other elements.

In the case of the Australian TGA Annual Report, this requirement is a specific condition attached to the CMD exemption in Australia, obligating manufacturers and sponsors to submit an annual report (by October 1st)

detailing all custom-made devices manufactured or supplied during the previous financial year. The report must comprehensively list all CMDs produced or distributed within that reporting period. This requirement stands in contrast to the lack of explicit IMDRF recommendations regarding periodic summary reporting obligations for CMDs.

These differences appear to stem from selective application of regulations by individual countries to ensure ongoing oversight of CMDs. While IMDRF principles may focus on event reporting and general PMS data review, CMD manufacturers should be aware that specific countries may impose additional periodic reporting obligations, such as PSURs or annual reports, as part of their national CMD regulations. For regulatory compliance, it is necessary to verify local requirements and not rely solely on general IMDRF PMS principles.

6-3) Post-Market Clinical Follow-up(PMCF)

PMS includes PMCF where appropriate. PMCF for unique CMDs can be challenging and may require a customized approach.

Table 22. Summary of Obligations for CMD (Based on IMDRF Recommendations / Principles)

Regulatory Aspect	Key IMDRF Recommendation/Principle	Key IMDRF Document Reference
Definition Criteria	Medical professional design responsibility, sole use, meeting specific needs	N49/N58
Regulatory Pathway	Specific pathway, high probability of exemption	N58
QMS	Proportional QMS expected (ISO 13485 principle)	QMS WG / ISO 13485 principle
Documentation	Specific CMD documentation required (replaces standard technical documentation)	N58 / Annex XIII concept
Essential Principles / GSPR Compliance	Essential	N47
Labeling - Identification Statement	"Custom-made device“ labeling principle	N52
UDI	High probability of exemption	UDI N7/N48 context
PMS	Proactive PMS required	GHTF SG2 / AE WG
Periodic Reporting (PSUR/Annual)	Event-based reporting focus / No specific periodic reporting recommendation	GHTF SG2 / AE WG
Vigilance Reporting	Mandatory(serious incidents, FSCA)	GHTF SG2 / AE WG

3. Comparison of Regulations for Custom Made Devices and Patient-Matched Medical Devices among Countries

The advancement of medical technology and the increasing demand for personalized treatment have highlighted the importance of various forms of Personalized Medical Devices (PMDs), which are designed and manufactured to match the unique anatomical, physiological, or pathological characteristics of individual patients. PMDs offer the advantage of satisfying specific patient requirements that are difficult to meet with conventional mass-produced medical devices. However, management methods using existing marketing authorization and quality management systems may not guarantee patient accessibility, and unconditional exemption from regulatory application can lead to safety concerns. Therefore, regulatory agencies in various countries are establishing separate regulatory pathways for PMDs to balance patient accessibility and safety, and it is understood that they are continuously improving these pathways.

Based on the analysis of regulations and guidelines related to personalized medical devices from the Korean Ministry of Food and Drug Safety (MFDS), the United States Food and Drug Administration (FDA), the European Union Medical Device Regulation (EU MDR), and the International Medical Device Regulators Forum (IMDRF), this study compared and analyzed the regulatory requirements for CMDs and PMMDs.

A. Custom Made Device

1) Similarities of Custom Made Devices by Country

When comparing the regulation of custom-made devices (CMDs) across different countries, a key similarity is that all jurisdictions strictly limit their use by requiring a prescription or request from a qualified healthcare professional. While regulatory frameworks often lower entry barriers for CMDs — such as through exemptions from standard pre-market approval — they simultaneously impose robust responsibilities on manufacturers to ensure device safety and performance, maintain quality management systems, and uphold comprehensive post-market surveillance obligations. This approach ensures that, even after market entry, there are stringent systems in place to safeguard patient safety through rigorous post-market oversight.

Table 23. Key Similarities in Custom-Made Device (CMD) Regulation Across Jurisdictions

Aspect	Summary of Commonalities Across Major Regulatory Systems
Core Concept	All major national regulatory frameworks define CMDs as devices individually designed and manufactured to meet the unique requirements of specific patients, typically based on a medical professional's prescription or request.

Aspect	Summary of Commonalities Across Major Regulatory Systems
Regulatory Relaxation / Differentiation	All systems acknowledge the distinct nature of CMDs compared to standard mass-produced devices and apply exemptions or differentiated procedures to certain regulatory requirements (e.g., standard pre-market authorization, select QMS elements, UDI), though the extent varies by jurisdiction.
Manufacturer Responsibility	Despite regulatory exemptions, all frameworks require manufacturers to ensure device safety and performance, maintain an appropriate quality management system, prepare and retain relevant documentation, and conduct post-market surveillance and reporting.
Prescription / Request-Based	MFDS (CMD), FDA (CDE), and EU MDR explicitly require a prescription or request from a qualified medical professional as the basis for the production of a CMD.

2) Differences of Custom Made Devices by Country

The EU MDR and FDA provide relatively clear legal definitions and criteria (differences) for 'CMD (CDE) and Patient-Matched Medical Device (PMMD). In contrast, the MFDS has specific regulations only for the 'CMD' category and does not regulate the definition of PMMD. As a result, products that should be managed as PMMDs are being reported as 'CMDs,' which can obscure the regulatory pathway for CMDs.

MFDS CMDs and FDA CDEs may have a relatively narrow scope of application, including specific criteria such as 'rare conditions' and 'limit of 5 units per year.' The EU MDR does not have these explicit quantity limitations.

The IMDRF definitions provide criteria for harmonization, but there are differences in detailed application (especially exclusion criteria) when adopted by the EU and the Australian TGA, etc.

Regarding the scope and conditions of exemptions for custom-made devices (CMDs), both the FDA and the EU MDR exempt CMDs from their respective premarket authorization or approval procedures—namely, the 510(k) or PMA in the United States and CE marking in the European Union. In Korea, the MFDS exempts CMDs only from ‘change’ authorization or notification requirements, rather than from initial market authorization.

With respect to quality management system (QMS) or good manufacturing practice (GMP) requirements, the FDA applies its Quality System Regulation (QSR) to CMDs but exempts them from design control requirements under §820.30. The EU MDR mandates that manufacturers maintain a QMS proportionate to the risk class of the device, as stipulated in Article 10(9), and does not provide specific exemptions for CMDs. The MFDS requires adherence to quality control procedures but does not explicitly exempt CMDs from GMP requirements.

For unique device identification (UDI) labeling and registration obligations, the EU MDR explicitly exempts CMDs from UDI and EUDAMED registration, with certain specific exceptions. The FDA exempts CMDs from registration and listing

requirements. In contrast, the MFDS does not have specific exemption provisions related to UDI or device registration for CMDs.

In terms of manufacturer obligations, the EU MDR requires manufacturers to prepare specific statements and documentation in accordance with Annex XIII. The FDA requires manufacturers to maintain supporting data for annual Custom Device Exemption (CDE) reports and QSR records. The MFDS mandates the retention of GMP records for CMDs.

Reporting obligations also differ by jurisdiction. The FDA requires the submission of detailed annual reports for CDEs. Under the EU MDR, manufacturers must include post-market surveillance (PMS) results within the Annex XIII documentation instead of submitting a Periodic Safety Update Report (PSUR), and reporting of serious incidents remains mandatory. The MFDS requires manufacturers to submit usage reports for CMDs, general adverse event reports, and, where applicable, reports for devices subject to tracking management.

Finally, regarding the involvement of notified bodies or review agencies, the EU MDR requires notified body participation in the conformity assessment process only for Class III implantable CMDs. In the United States, CMDs under the FDA's CDE pathway are exempt from premarket authorization, so there is no review agency involvement. In Korea, the MFDS generally requires compliance with standard authorization and review procedures, except for the exemption from 'change' authorization or notification for CMDs.

Table 24. Comparison of CMD Regulations by Country

Item	Korea (MFDS)	U.S.A FDA (CDE)	EU MDR	IMDRF recommendation
	Custom-Made Device	**Custom Device Exemption**	**Custom-Made Device**	**Personalized Medical Devices**
Definition	Subject to exemption from variation authorization under specific conditions (physician request, patient characteristics, absence of alternatives, 3D printing/orthopedic devices/human tissue replacement, etc.)	Physician / dentist prescription, specific patient / physician needs, necessary deviation from performance standards / PMA requirements, general unavailability, rare condition, limited to ≤5 per year	Written prescription from authorized professional, exclusive use for specific patient, specific design characteristics. Excludes mass-produced/adaptable devices	Presentation of classifications (Custom-made, Patient-matched, Adaptable) Level of adoption varies by country
Key Exemptions	**Market authorization** Change of authorization / notification exemption limited to 5times per year **IDE:** Regulation unclear (exempt by exemption from authorization) **GMP:** No exemption Quality control procedure compliance required **UDI/Registration:** No exemption	**Market authorization** 510(k),PMA exemption **IDE:** Exemption (except for safety / effectiveness evaluation for commercial distribution) **QSR:**Design control (820.30) exemption **Registration/Listing:** Exemption	**Market authorization** CE marking exemption **Conformity assessment** Annex XIII procedure applied instead of standard procedure **UDI:** Exemption **EUDAMED registration:** Exemption (required for specific reporting/ Class III implant certificate)	No legal exemption as it is a recommendation. Adoption and scope determined by each country's regulatory authority.
Key Regulatory Requirements	**Prescription requirements** Written request from attending physician required **Documentation:** GMP records,	**Prescription requirements** Physician/dentist prescription mandatory **Documentation:** QSR compliance	**Prescription requirements** Written prescription from authorized professional mandatory **Documentation:** Annex XIII statement	**Prescription requirements** Generally recommended for CMDs **Documentation:** General principles related to QMS

	(if applicable) tracking records	(excluding design control), Annual report preparation	and documentation, QMS documentation	and technical documentation recommended
	Labeling: Compliance with general medical device requirements	**Labeling:** "custom device", including prescribing physician name, patient identification information (if applicable)	**Labeling:** "custom-made device" statement mandatory	**Labeling:** Clear identification and usage information recommended
	PMS: Adverse event reporting obligation	**PMS:** QSR compliance, MDR / corrections and removals reporting obligation	**PMS:** Post-market experience review / documentation / corrective action according to Annex XIII, serious incident reporting (Art 87), trend reporting (Art 88), PSUR is part of Annex XIII documentation	**PMS:** Risk-based PMS activities recommended
	Reporting obligations: CMD usage report Adverse event report (if applicable) tracking report	**Reporting obligations:** Annual Report submission mandatory MDR reporting, corrections/removals reporting	**Reporting obligations:** Serious incident / FSCA reporting, trend reporting, potential submission of device list to competent authority upon request	**Reporting obligations:** Serious incident reporting recommended

Table 25. Advantages and Disadvantages of CMD Regulations by Country

Framework	Advantages	Disadvantages
MFDS (CMD)	'CMD' definition and conditions for change exemption are relatively clear (5 times per year)	Lack of clear distinction between CMD and PMMD results in unclear regulatory pathways Limited patient access due to exemption regulations focused on change authorization and certification Limited applicability due to the annual limit of 5 times Regulatory compliance obligations exist due to the application of the same regulations as general medical devices, including UDI labeling and GMP compliance obligations (lack of clear regulations on exemptions)
FDA (CDE)	Clear exemption criteria presented (5 units, rare condition, etc.) Reduced burden due to QSR design control exemption Systematic post-market management through annual reports Rapid patient access possible due to 510(k)/PMA/IDE exemptions	Clear exemption criteria presented (5 units, rare condition, etc.) Burden of proving 'rare condition' and 'absence of alternative devices' Overall QSR compliance obligations still exist
EU MDR (CMD)	Clear distinction between 'CMD' and PMMD according to explicit guidelines Reduced administrative burden due to CE marking, UDI, and EUDAMED registration exemptions Clear procedure presented in AnnexXIII Risk-based approach (NB involvement only for Class III implantable)	Potential burden due to full application of QMS (Art 10(9)) requirements (especially for small manufacturers) AnnexXIII documentation requirements may be comprehensive Ambiguity in the applicability and method of PSUR application
IMDRF (CMD)	Efforts to provide international harmonization and standardized terminology Role as a reference for regulatory development	Lack of legal binding force Limitations in practical harmonization due to different adoption and application by countries

While each regulatory system shares the common goal of alleviating the regulatory burden by considering the characteristics of CMDs, there are distinct differences in the scope of definitions, exemption conditions, and post-market management methods. The FDA's CDE enhances management through clear criteria and annual reporting, but its scope may be limited. The EU MDR reduces administrative burden through CE marking and UDI exemptions but requires full QMS application and compliance with Annex XIII procedures, and mandates Notified Body involvement for Class III implantables. The MFDS supports rapid changes by providing exceptions for a specific category called 'CMD,' but the absence of regulatory definitions for CMDs and PMMDs results in a situation where CMD regulations are relatively unclear.

B. (FDA and EU MDR) Patient-Matched Medical Device

1) FDA Patient-Matched Medical Device

The 'Design Envelope' is a crucial concept in regulating PMMDs. While the FDA considers it as a single 'product,' it actually establishes boundaries encompassing an infinite range of variations that differ slightly from patient to patient.

Patient-matched devices, by their very nature, are manufactured to fit each patient precisely, so every device is inevitably slightly different. From the FDA's perspective, it is impossible to review such a large number of individual devices one by one. This is where the concept of the 'Design Envelope' emerges. It's like the manufacturer predefining the 'maximum' and 'minimum' allowable variations when creating PMMDs and obtaining FDA approval for them.

The management of the “Design Envelope” is a fundamental consideration in the regulatory oversight of personalized medical devices (PMMDs), particularly when navigating the FDA’s 510(k) and Premarket Approval (PMA) pathways. The design envelope refers to the defined set of parameters within which a device may

be customized or adjusted, while still conforming to validated manufacturing processes and performance standards. Establishing a clear design envelope is crucial for several reasons.

First, it enables a more efficient FDA review process. When a device is manufactured within a well-defined design envelope, it is presumed to adhere to previously verified manufacturing methods and quality standards. This means that the FDA does not need to review every individual device variation, which would be impractical for highly customized devices. Instead, the agency can focus its review on whether the device remains within the established envelope, thereby streamlining the marketing authorization process and facilitating more efficient regulatory oversight.

Second, a clearly defined design envelope offers significant advantages to manufacturers. It allows them to produce a variety of PMMDs tailored to individual patient needs without the administrative burden of seeking separate change authorizations for each variation. This flexibility not only saves time and costs but also supports innovation and rapid response to patient-specific requirements.

Third, the design envelope plays a vital role in ensuring the safety and effectiveness of PMMDs. Once the manufacturing process and device performance have been validated across the entire envelope, all devices produced within these boundaries can be

assumed to meet a consistent standard of safety and efficacy. This approach reduces the risks associated with uncontrolled customization and provides assurance to both regulators and patients.

In relation to the FDA's 510(k) and PMA review pathways, the design envelope serves as a practical solution to the challenges posed by the variable nature of PMMDs. Traditional review processes are based on fixed device characteristics and performance metrics, making them difficult to apply to devices that are inherently different for each patient. By clearly defining and substantiating the design envelope, manufacturers can provide the FDA with a standardized basis for review. This allows the agency to determine whether new device iterations fall within the pre-approved envelope by referencing predicate devices for 510(k) submissions or by evaluating clinical and performance data that apply to the entire envelope for PMA submissions. In this way, the design envelope bridges the gap between the need for regulatory rigor and the realities of personalized device manufacturing.

In summary, the clear management of the design envelope is essential for achieving regulatory efficiency, supporting manufacturer flexibility, and, most importantly, ensuring patient safety and device effectiveness in the context of FDA review for personalized medical devices.

2) EU MDR Patient-Matched Medical Device

The core concept of European PMMDs is also to manufacture within a specified design envelope, using scaling based on anatomical references or complete anatomical features derived from patient imaging data to match the patient's anatomical structure.

Unlike CMDs, PMMDs must follow the standard MDR regulatory pathway and require CE marking. It is understood that obtaining authorization by defining the design range is similar to the FDA's approach to Patient-Matched Devices.

Because PMMDs follow the general MDR pathway, the technical documentation, according to MDR Annex II (Technical Documentation, Part 1), 1.1(i), must include a description or complete list of the various configurations/variations of the device intended to be placed on the market (documentation of variations, configurations, and design range).

Furthermore, according to MDR Annex II (Technical Documentation, Part 2), Verification and Validation (V&V) data for PMMDs must demonstrate that the entire device included in the Design Envelope conforms to the General Safety and Performance Requirements (GSPR).

In conclusion, for PMMDs, demonstrating V&V across a potentially infinite range of variations within the design range will be a major

challenge. Manufacturers must justify a V&V strategy that provides a high level of confidence in all possible outcomes without testing all products. This will likely rely heavily on design input verification (e.g., ensuring patient data is correctly interpreted), design process verification (e.g., algorithms or methods used for matching/application), manufacturing process verification (ensuring variations can be produced consistently), and representative product or worst-case testing within the design range. Therefore, demonstrating the ability to ensure conformity for all variations is understood to be a critical part of the technical documentation review.

C. Conclusions and Suggestions

A comparative analysis of the regulatory frameworks for CMDs of the Korean MFDS, the US FDA, the European EU MDR, and the IMDRF confirmed that all regulatory systems acknowledge the unique characteristics of CMDs and provide for the relaxation of specific regulatory requirements or offer differentiated pathways. They commonly share the concept that CMDs are manufactured for specific patients based on medical professional prescriptions or requests, and it was observed that they impose basic quality control and post-market surveillance responsibilities on manufacturers.

However, differences exist in the detailed regulatory approaches. These differences include the permissible scope of CMDs (e.g., MFDS and FDA limit CMDs to 5 units per year), the scope of premarket authorization exemptions (e.g., FDA's 510k/PMA exemption vs. EU's CE marking exemption), the application methods of quality system requirements (e.g., FDA's exemption of design controls vs. EU's full QMS application), UDI and registration requirement exemptions, and post-market reporting mechanisms (e.g., FDA's annual reports vs. EU's Annex XIII documentation/incident reporting vs. MFDS's use reporting), etc., where different regulatory strategies are adopted.

These differences can be interpreted as the result of each regulatory authority's efforts to find different equilibrium points among ensuring patient safety, promoting innovation, and alleviating regulatory burden. While the FDA pursues strict management through clear criteria and reporting obligations, the EU attempts to reduce administrative burden through CE marking and UDI exemptions while ensuring safety through QMS and Annex XIII procedures. The MFDS focuses its management primarily on CMDs among PMDs by exempting change authorization/notification only for CMDs under specific conditions, and the absence of clear regulations for managing other PMDs results in a somewhat inadequate management system.

PMDs have significant potential to establish themselves as a core element in realizing patient-centered healthcare. Effective and efficient regulatory frameworks are essential for realizing this potential while ensuring patient safety.

However, the Korean regulatory system still appears to be somewhat inadequate compared to these international trends. Although regulatory easing and rapid use systems have been introduced for some PMDs (CMDs), particularly those using 3D printing technology, the scope of application is limited, and there is still insufficient consideration for PMDs utilizing other advanced technologies such as AI (especially Patient-Matched Medical Devices). Therefore, to rationally improve the domestic PMD regulatory system, it will be necessary to seek regulatory measures suitable for the domestic healthcare environment and technological level by referring to the advantages of the U.S.'s strict exemption conditions and Europe's comprehensive management system. In particular, it is necessary to establish a balanced regulatory system that ensures patient safety while simultaneously enhancing innovative technological development and patient accessibility.

III. FINDINGS and POLICY RECOMMENDATIONS

Currently, the PMDs market is experiencing rapid growth, but the Korean regulatory framework is failing to adequately reflect these changes. Therefore, to promote international regulatory harmonization and the development of domestic industry, this study proposes to establish clear definitions for 'Custom-Made Medical Device, CMD' and 'Patient-Matched Medical Device, PMMD,' and to develop a differentiated marketing authorization management system, etc., that reflects the characteristics of each type.

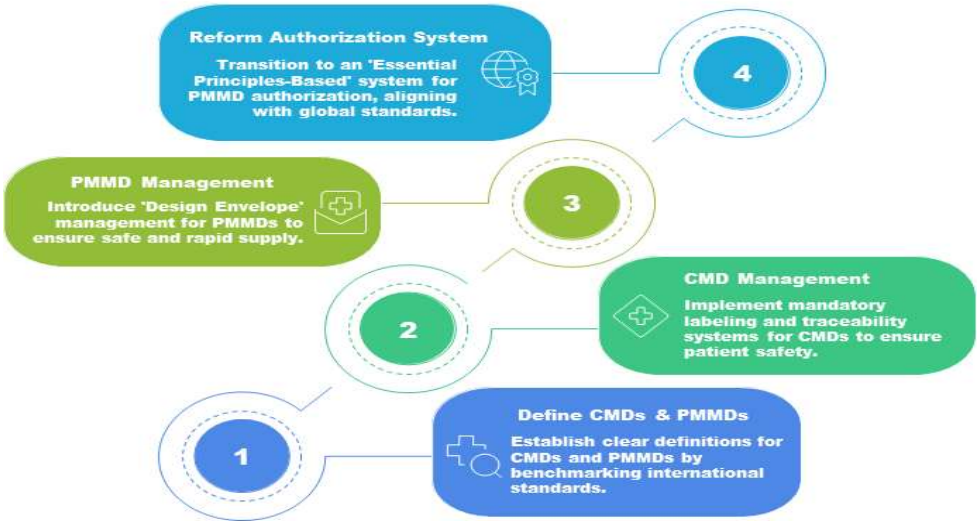


Figure 12. Enhancing PMDs Regulation

The main proposals are as follows:

First, to establish definition regulations for CMDs and PMMDs that are appropriate for the domestic situation, by benchmarking international definitions from organizations such as the International Medical Device Regulators Forum (IMDRF), the European Union (EU), and the United States (FDA).

Second, for CMDs, to propose measures such as mandating the labeling of 'This product is a Custom Made Device' through revisions of current management regulations, introducing a patient safety management system through traceability along with exemption from the obligation to affix a Unique Device Identification (UDI), and further, implementing a system (e.g., utilizing re-evaluation or product renewal systems) to manage repeatedly reported CMD products as newly authorized PMMDs or to amend existing marketing authorizations.

Third, for PMMDs, to propose establishing a regulatory environment that ensures safety while enabling rapid supply according to patient conditions, by introducing the concept of 'Design Envelope' management, similar to the United States and Europe.

Lastly, to propose managing the current Korean medical device product marketing authorization certificate management system by transitioning it from a detailed specification listing method to a 'Essential Principles-Based Marketing Authorization Management' system focused on essential content such as the mechanism of action and intended use, for rational marketing authorization

management of PMMDs. It is also necessary to internationally harmonize the marketing authorization certificate management system by comparing Korean marketing authorization certificate management regulations with those of other countries such as Europe and the United States.

It is expected that these proposed regulatory improvement measures will greatly contribute to enhancing patient safety, promoting innovation in the medical device industry, and advancing Korean PMDs-related regulations through harmonization with international regulations.

Table 26. Enhancing PMD Regulation: Proposals for Clarity, Tailored Management, and Harmonization

Proposal	Details	Goal
Define CMDs and PMMDs (International Benchmarking)	Adopt definitions from IMDRF, EU, and FDA to suit the Korean context.	Clear categorization of CMDs and PMMDs.
CMD Management	- Mandatory labeling: "This product is a Custom Made Device". - Patient safety via traceability (UDI exemption). - System to manage repeated CMDs as new PMMDs/amend authorizations.	Enhanced patient safety, clear identification, and management of frequently produced CMDs.
PMMD Management	Introduce 'Design Envelope' management (like the US and EU) for faster supply while ensuring safety.	Safe and rapid supply of PMMDs based on patient needs.
Marketing Authorization System Reform	Shift from detailed specification listing to 'Essential Principles-Based Marketing Authorization Management' (focus on mechanism and intended use). International harmonization.	Rational authorization for PMMDs and alignment with global standards.

1. Clarification of CMD and PMMD Definition Regulations

While the current Korean Medical Device Act and related regulations provide a robust foundation for ensuring the safety and effectiveness of medical devices, they reveal limitations when confronted with the new paradigm of personalized medical devices. In particular, concepts that are internationally distinguished and managed, such as 'Custom-Made Medical Device (CMD)' and 'Patient-Matched Medical Device (PMMD),' are not clearly defined or are used interchangeably in Korea, causing ambiguity in regulatory application.

※ For example, stent products from Korean company X, despite having differences only in diameter and length, are managed as CMDs on a patient-by-patient basis due to the absence of clear definitions distinguishing CMDs and PMMDs in Korean regulations.

Currently, the MFDS (Ministry of Food and Drug Safety)'s 'Regulations on the Marketing Authorization, Notification, and Review of Medical Devices' Article 19, Paragraph 9, provides exceptional supply procedures for 'patient-tailored medical devices.(CMDs)' However, these regulations only permit the supply of orthopedic devices or human tissue/function replacement products, manufactured or imported using previously authorized 3D printers, etc., according

to the patient's physiological and pathological characteristics, upon a physician's request and with patient consent, limited to 5 times per year without variation marketing authorization (certification). While this can be evaluated as a positive attempt to address the urgent needs of specific patients, it differs somewhat from the internationally accepted definitions and management methods of CMDs and PMMDs.

Internationally, CMDs refer to small-volume production devices uniquely designed for specific patients under the responsibility of a medical professional, while PMMDs refer to a group of devices produced under the manufacturer's responsibility within a pre-verified 'Design Envelope' to match the patient's anatomical structure. However, current Korean regulations only have regulations for 'CMDs.' The terminology in Korean regulations uses 'PMMD,' which can cause confusion. A larger problem is that these unified exemption regulations make it difficult to adequately manage PMDs (CMDs or PMMDs) with various forms and risk levels. For example, if there are products clearly classified as PMMDs, the establishment and verification of the design envelope, and consistent management of the manufacturing process within that range, are very important. Nevertheless, the absence of regulations that clearly stipulate this raises concerns about management gaps under the current management system.

Furthermore, the Korean medical device product marketing authorization certificate management system tends to focus on formal management that lists very detailed information such as shape, structure, and raw materials. This can create difficulties in the rapid authorization and change management of PMMDs, which allow for various modifications. This hinders the rapid market entry of innovative personalized medical devices and can ultimately negatively impact the expansion of patient treatment opportunities.

These problems can hinder the growth of the domestic personalized medical device market and the securing of international competitiveness, suggesting the need for a more sophisticated and rational regulatory system to ensure patient safety and product effectiveness.

Considering international regulatory trends and the Korean medical device regulatory environment comprehensively, this study proposes revisions (draft) to the current Medical Device Act and 「Regulations on the Marketing Authorization, Notification, and Review of Medical Devices」 to clearly distinguish between 'CMD and PMMD.'

Table 27. Proposed Amendments to the Medical Device Act Regarding Exemptions for Marketing Authorization, Certification, and Notification of Custom-Made Devices

Existing Text	Proposed Revision
<New Article>	Article 15-3 (Manufacture, etc., of Custom-Made Devices) ① Notwithstanding Articles 6(2), 15(2), or 15(6), a person intending to manufacture or import a medical device that meets all of the following requirements (hereinafter referred to as a "Custom-Made Device") for the purpose of expanding patient treatment opportunities and facilitating effective disease management, may not be required to obtain authorization or certification, or submit a notification for the respective medical device: 1. A medical device manufactured solely for the use of a specific individual (patient or medical professional), according to a written request (including electronic documents) from a legally qualified healthcare professional as defined by the Medical Service Act or other relevant laws (hereinafter referred to as a "healthcare professional"); 2. A medical device manufactured under the responsibility of the relevant healthcare professional, who assigns specific design characteristics that reflect the unique anatomical, physiological, or pathological condition of the specific patient. However, this shall not include design characteristics that the manufacturer can propose without the involvement of the healthcare professional;

Existing Text	Proposed Revision
	3. A medical device used only in cases where commercially available general medical devices or Patient-Matched Medical Devices cannot meet the individual patient's specific needs or achieve an appropriate level of performance. ② The detailed criteria and procedures necessary for the manufacture, import, supply, and post-market management of medical devices under paragraph (1) shall be prescribed by the Prime Minister's Decree.

Table 28. Proposed Revision of Article 2 (Definitions) of the 「Regulations on the Marketing Authorization, Notification, and Review of Medical Devices」 for Establishing PMMD Definition Regulations

Existing Text	Proposed Revision
Article 2 (Definitions) The terms used in these regulations are defined as follows: 1. ~ 26. (Omitted) <New Article>	Article 2 (Definitions) The terms used in these regulations are defined as follows: 1. ~ 26. (Same as current) 27. 'Patient-Matched Medical Device, PMMD' refers to a medical device that meets all of the following requirements: (a) A medical device manufactured within a design and manufacturing range (hereinafter referred to as 'design range') that the manufacturer has pre-established and verified for safety, performance, and quality, and in which features such as shape, structure, and dimensions are adjusted to match the individual patient's anatomical, physiological, or pathological condition.

Existing Text	Proposed Revision
	(b) A medical device designed and manufactured under the manufacturer's responsibility and that can generally be produced in batches or continuously through verified and reproducible manufacturing processes. However, consultation with medical professionals or the use of patient data (e.g., medical imaging information) may be involved in the design process.

‘CMD’ definition reflects the core elements of IMDRF N49 and EU MDR Article 2(3), aiming to clarify the essential characteristics of CMDs, namely the leading role and responsibility of medical professionals in design, exclusivity for specific patients, and use limited to cases where alternatives are not available. Through this definition, 'PMMD' was explicitly excluded to prevent conceptual confusion.

‘PMMD’ definition fundamentally reflects the PMMD concept of IMDRF N49 and MDCG 2021-3. The most important characteristics are that personalization is performed within the 'design range' established and verified by the manufacturer, and that the manufacturer has full responsibility for the design and quality of the final product. This is a fundamental difference from CMDs, which are uniquely designed according to a specific prescription from a medical professional.

2. Proposed CMD Regulatory Framework

Instead of the current management method in Korean regulations that only exempts variation marketing authorization (including certification), we propose adopting an approach similar to the EU MDR's Annex XIII or the FDA's CDE system, covering both new and variation marketing authorization (including certification), considering the characteristics of CMDs.

1) Requirements for Marketing Authorization Exemption, etc.

To align with the unique characteristics of custom-made devices (CMDs) and to incorporate global best practices - such as those established under the EU MDR Annex XIII and the US FDA’s Custom Device Exemption (CDE) framework - it is proposed that Korea’s regulatory system for CMDs be revised to exempt both new and modified CMDs from standard pre-market marketing authorization, product certification, or notification requirements. However, this exemption would be contingent upon strict conditions that ensure patient safety, device effectiveness, and robust post-market oversight.

Under this proposed pathway, CMDs would be permitted for supply only when all of the following conditions are met :

- **Written Request and Design Responsibility of the Medical Professional :** A qualified medical professional, as defined under the Medical Service Act, must issue a written request (which may be in electronic form)

specifying the unique anatomical, physiological, or pathological condition of a specific patient and detailing the necessary design characteristics to address that condition. The medical professional would bear the final responsibility for these design characteristics.

- **Demonstration of Exclusivity for a Specific Patient :** The CMD must be manufactured exclusively for the individual patient identified in the written request.
- **Demonstration of Irreplaceability and Necessity :** The medical professional must provide a written justification confirming that neither commercially available general medical devices nor patient-matched medical devices (PMMDs) can adequately meet the specific needs of the patient or achieve the required level of clinical performance.
- **Manufacturer's Declaration of Conformity :** The manufacturer must independently verify and maintain documentation demonstrating that the device complies with the general safety and performance requirements (GSPRs) applicable to medical devices—such as raw material safety, biological safety, and other relevant criteria—with the exception of the design characteristics specified by the medical professional. This approach is analogous to the FDA's CDE requirements.
- **Limited Production Volume :** In line with current domestic regulations and the FDA's CDE system, the annual production (or supply) volume for a specific "device type" would be limited (e.g., up to 5 units per year), with the possibility of increasing this limit if justified. For newly

authorized products, additional measures would be considered to confirm that the manufacturer has prior experience or a track record in producing devices of the same “device type,” thereby ensuring at least a minimal level of safety and effectiveness. The definition of “device type” would be specified as a group of devices with substantially similar intended uses, designs, materials, and functions, in accordance with FDA CDE guidance.

- **Pre- and Post-Market Reporting :** The manufacturer must notify the Ministry of Food and Drug Safety (MFDS) prior to the manufacture or import of a CMD, and must report usage details within 15 days after the device is used, as stipulated under current regulations. This reporting mechanism is designed to enhance regulatory oversight and ensure timely management of CMDs in the market.

By adopting this approach, Korea would establish a regulatory framework that balances the need for flexibility and innovation in personalized medicine with robust safeguards to protect patient safety and public health. This proposal reflects the integration of international best practices while addressing the unique requirements of the Korean regulatory environment.

2) Labeling requirements

This is consistent with the labeling requirements of the FDA CDE guidance, and we propose a plan to revise the current Korean regulations on the labeling of medical devices to reflect the specificity of CMDs.

This is to ensure that users (patients and medical professionals) clearly recognize that the medical device is a CMD specifically manufactured for a particular patient, and not a product that has undergone the general marketing authorization process. Accordingly, we propose establishing a new regulation to mandate the display of the statement 'This product is a Custom Made Device' on the container, packaging, or accompanying documents of the CMD (Revision of the Regulations on the Labeling of Medical Devices).

In addition to this, CMD labeling must include the following information:

- Patient identification information (e.g., patient initials, unique number, etc., considering personal information protection)
- Name and affiliated institution of the prescribing medical professional
- Trade name and address of the manufacturer
- Manufacturing date or expiration date (if applicable)
- Sterilization status (if applicable)
- Precautions for storage or handling
- Other information necessary for the safe and effective use of the CMD

With respect to items 1) and 2), it is proposed that the Enforcement Regulations of the Medical Device Act be amended in accordance with the provisions presented in Table 29.

Table 29. Proposed Amendments to the Medical Device Act and its Enforcement Rules Regarding Compliance Requirements, etc., for Custom Made Devices

Proposed Amendment to the Medical Device Act	Proposed Amendment to the Enforcement Rules of the Medical Device Act
Article 15-3 (Manufacture, etc., of Custom-Made Devices) ① Notwithstanding Articles 6(2), 15(2), or 15(6), a person intending to manufacture or import a medical device that meets all of the following requirements (hereinafter referred to as a "Custom-Made Device") for the purpose of expanding patient treatment opportunities and facilitating effective disease management, may not be required to obtain authorization or certification, or submit a notification for the respective medical device: 1. A medical device manufactured solely for the use of a specific individual (patient or medical professional), according to a written request (including electronic documents) from a legally qualified healthcare professional as defined by the Medical Service Act or other relevant laws (hereinafter referred to as a "healthcare professional"); 2. A medical device manufactured under the responsibility of the relevant healthcare professional, who assigns specific design characteristics that reflect the unique anatomical, physiological, or pathological condition of the specific patient. However, this shall not include design characteristics that the manufacturer can propose without the involvement of the healthcare professional;	Article 34-4 (Compliance Requirements, etc., for Custom-Made Device Manufacturers) ① A person intending to manufacture or import a Custom-Made Device pursuant to Article 15-3(2) of the Act shall comply with the following: 1. Prior to manufacturing or importing a Custom-Made Device, prepare and maintain the following materials and report them to the Minister of Food and Drug Safety: a. A written request from a healthcare professional, including the following: 1) Information on the specific patient 2) Specific design specifications of the device 3) Reasons why commercially available general medical devices or Patient-Matched Medical Devices cannot meet the individual patient's specific needs or achieve an appropriate level of performance b. Materials demonstrating that the medical device is manufactured in accordance with the design specifications c. Materials demonstrating that the medical device meets the applicable general safety and performance requirements 2. Indicate the statement "This product is a Custom-Made Device" on the device container or packaging, and, notwithstanding

Proposed Amendment to the Medical Device Act	Proposed Amendment to the Enforcement Rules of the Medical Device Act
3. A medical device used only in cases where commercially available general medical devices or Patient-Matched Medical Devices cannot meet the individual patient's specific needs or achieve an appropriate level of performance. ② The detailed criteria and procedures necessary for the manufacture, import, supply, and post-market management of medical devices under paragraph (1) shall be prescribed by the Prime Minister's Decree.	Article 43(1), include the following information in the accompanying documents: a. Patient identification information (e.g., patient initials, unique number, etc., considering personal information protection); b. Name and affiliated institution of the prescribing healthcare professional; c. Trade name and address of the manufacturer; d. Manufacturing date or expiration date (if applicable); e. Sterilization status (if applicable); f. Precautions for storage or handling; g. Other information necessary for the safe and effective use of the medical device; 3. The quantity of medical devices that can be manufactured or imported and supplied pursuant to Article 15-3 of the Act shall not exceed 5 units per year for each device type for manufacturers with experience in manufacturing products of the same 'device type,' and if it is necessary to modify an authorized, certified, or notified product, do not manufacture or import more than 5 units per year per authorized, certified, or notified product 4. Manufacture and import and supply medical devices according to Annex 2(2) or Annex 4(3) 5. The manufacturer or importer of the medical device shall report the following information to the Minister of Food and Drug Safety within 15 days from the date the medical device is used

Proposed Amendment to the Medical Device Act	Proposed Amendment to the Enforcement Rules of the Medical Device Act
	a. Information on the patient who used the medical device (including the supply date and the usage date, if verifiable) b. Information on the healthcare professional who requested the medical device c. Detailed information on any adverse events resulting from the use of the medical device 6. Retain the records from subparagraphs 1 to 5 for 5 years from the date of manufacture (or for a period corresponding to the product's lifespan if the product's lifespan exceeds 5 years) 7. Upon request from the patient or the prescribing healthcare professional, or the Minister of Food and Drug Safety, or in the event of a safety-related issue, promptly provide relevant information to the patient or the prescribing healthcare professional, or the Minister of Food and Drug Safety 8. Upon recognition of a safety issue related to the medical device, including adverse event reporting management, promptly identify the patient and the prescribing healthcare professional who used the device and take necessary safety measures (e.g., recommendation for discontinuation of use, recall, etc.) ② The Minister of Food and Drug Safety may review whether medical devices repeatedly reported as Custom-Made Devices require a transition to management as Patient-Matched Medical Devices, and if such action is deemed necessary, may order variation authorization or other appropriate measures.

3) Unique Device Identification (UDI) and Securing Patient Traceability

Due to their uniqueness and extremely small production volume characteristics, CMDs are excluded from the mandatory application of the standardized UDI system (affixing to containers/packaging and information registration) that applies to general medical devices. This is a similar approach to the EU MDR.

Table 30. Proposed Amendment to the Regulations on the Indication and Management of Medical Device Standard Codes

Existing Text	Proposed Revision
Article 3 (Scope of Application) This Notice applies to medical devices distributed or sold domestically and does not apply to medical devices intended **for export.**	Article 3 (Scope of Application) This Notice applies to medical devices distributed or sold domestically and does not apply to medical devices intended **for export or Custom-Made Devices..**

However, to address the potential traceability gap resulting from the UDI exemption, the following obligations for establishing and operating a robust patient tracking management system are imposed on manufacturers. (Refer to the proposed amendment of the Enforcement Rules of the Medical Device Act in Table 29 above)

Manufacturers of custom-made devices (CMDs) are subject to comprehensive record-keeping obligations to ensure traceability, accountability, and patient safety. For each CMD, manufacturers must create and retain detailed records for a specified period—typically at least five years or for the duration of the

product lifecycle. These records must include patient identification information, with appropriate safeguards to protect personal data; the name, affiliated institution, and contact details of the prescribing medical professional; the specific design specifications of the CMD, including the medical professional's prescription or request; information on the primary raw materials and components used, including relevant manufacturing or lot numbers; the date of manufacture and, if applicable, sterilization details; the date of supply and the identity of the medical institution receiving the device; and, where verifiable, the actual date of use or implantation.

In addition to record keeping, manufacturers are required to provide relevant information promptly upon request from the patient or the prescribing medical professional, or in the event of a safety-related concern. This ensures transparency and facilitates effective communication with stakeholders in the event of device-related issues.

Furthermore, manufacturers must establish robust procedures to enable the rapid identification of patients who have received a CMD in the event of adverse events or the identification of safety issues. These procedures must support the timely implementation of necessary safety measures, such as recommendations for discontinuation of use or the initiation of a recall, thereby upholding the highest standards of post-market surveillance and patient protection.

4) Management of CMD Transition to PMMD (using Variation Authorization, Re-evaluation, or Product Renewal System)

(Refer to the proposed amendment of Article 34-4, Paragraph 2 of the Enforcement Rules of the Medical Device Act in Table 29 above)

If possible, we propose to review whether a transition to PMMD management is necessary for products with repeated CMD reporting. If such products exist, we propose to operate the marketing authorization management system in a way that resolves potential risks that may arise from past regulatory ambiguities by requiring manufacturers to obtain variation authorization (or authorization update using re-evaluation or product renewal systems) based on Real-World Data or Real-World Evidence and mandatory CMD records (see 1) to 3) above).

3. Proposed PMMD Regulatory Framework

PMMDs refer to a group of products manufactured under the manufacturer's responsibility within a pre-verified 'design envelope' to match the anatomical structure of individual patients. This is fundamentally different from custom-made medical devices (CMDs), which are manufactured on a one-off basis according to the specific instructions of a medical professional, and therefore requires a separate regulatory approach. It is necessary to establish rational marketing authorization and management systems (draft) that consider the characteristics of PMMDs, and in particular, management of the 'design envelope' is crucial.

Accordingly, if the definition regulations for PMMDs are clearly reflected in the Regulations on the Marketing Authorization, Notification, and Review of Medical Devices, it will also be necessary to change the technical documentation review requirements for marketing authorization review to consider the 'design envelope' (including clarifying the scope of data submission for verifying the validity of the design envelope).

The concept of a “Design Envelope” is fundamental in the regulation of patient-matched medical devices (PMMDs) in both the United States and Europe. The design envelope refers to the predefined and verified design space established by the manufacturer, encompassing the minimum and maximum allowable limits and all possible combinations of key design variables such as dimensions, shape, material properties, and performance characteristics. This approach allows manufacturers to accommodate the inherent variability required for patient-specific customization while maintaining regulatory oversight and assurance of safety and effectiveness.

To comply with regulatory expectations, manufacturers must clearly define and substantiate the design envelope through comprehensive technical documentation. First, the manufacturer is required to provide a precise definition of all relevant design variables for the PMMD and specify the allowable range for each variable, including minimum and maximum values and applicable tolerances. This detailed definition ensures that all potential device iterations are captured within the scope of regulatory review.

Second, the manufacturer must present a robust scientific rationale for the establishment of the design envelope. This rationale should address how the defined design space is sufficient to accommodate the anatomical diversity of the intended patient population, meet clinical requirements, and achieve the intended performance of the device. The rationale should be grounded in scientific evidence and clinical considerations.

Third, and most critically, the manufacturer must submit verification and validation (V&V) data demonstrating that all PMMDs produced within the defined design envelope are consistently safe and effective. This typically involves several key methodologies:

- **Worst-case scenario testing:** The manufacturer should identify and produce representative samples that reflect the most extreme or least favorable combinations of design variables within the envelope. These samples must undergo rigorous performance and safety testing - such as assessments of mechanical strength, durability, and biocompatibility - to confirm that even the most challenging configurations meet all applicable acceptance criteria. The importance of considering worst-case designs is also emphasized in the IMDRF N74 guidance.

- **Representative sampling testing:** A statistically significant number of samples, representing various combinations within the design envelope, should be tested to provide evidence of consistent device quality and performance across the full spectrum of permitted variations.
- **Computer modeling and simulation:** Advanced simulation techniques, such as finite element analysis (FEA), should be employed to predict critical parameters like stress distribution, deformation, and fatigue life for different design variations within the envelope. These computational predictions must be cross-validated against physical test results to ensure their reliability.
- **Manufacturing process validation:** The manufacturer must demonstrate, through process validation activities, that all product variations within the design envelope can be manufactured to a consistent quality standard, regardless of the specific combination of design variables.

By rigorously defining, justifying, and validating the design envelope, manufacturers can ensure regulatory compliance, facilitate efficient review under frameworks such as the FDA's 510(k) and PMA or the EU MDR, and, most importantly, uphold the safety and effectiveness of patient-matched devices in clinical practice.

Table 31. Proposed Revision of the 「Regulations on the Marketing Authorization, Notification, and Review of Medical Devices」 for PMMD Marketing Authorization, etc., Review

Existing Text	Proposed Revision
Article 9 (Shape and Structure) Shape and structure shall be described in accordance with the following subparagraphs. 1. ~ 4. (Omitted) <New Article>	Article 9 (Shape and Structure) Shape and structure shall be described in accordance with the following subparagraphs. 1. ~ 4. (Omitted) 5. In the case of PMMDs, the shape, structure, weight, and dimensions, etc., may be described based on the pre-defined design envelope, including all design variables (dimensions, shape, material properties, etc.) that can be varied to match individual patients and their allowable ranges (minimum and maximum values, tolerances, etc.).
Article 12-2 (Performance ① ~ ② (Omitted) <New Article>	Article 12-2 (Performance ① ~ ② (Omitted) ③ For PMMDs, the physical, chemical, electrical, and mechanical characteristics, and the characteristics of the medical device software claimed by the product shall be described, considering the design envelope, including design variables and their allowable ranges.
Article 26 (Types and Scope of Review Data, etc.) ① The types of data to be submitted for the review of technical documentation, etc., are as follows. 1. ~ 7. (Omitted) <New Article>	Article 26 (Types and Scope of Review Data, etc.) ① The types of data to be submitted for the review of technical documentation, etc., are as follows. 1. ~ 7. (Omitted) 8. For PMMDs, documentation of the design envelope (allowable ranges and combinations of each design variable, including dimensions, shape, and material properties) and its establishment rationale

Existing Text	Proposed Revision
Article 29 (Requirements for Submitted Materials) ① The requirements for the submitted materials for the review of technical documentation, etc., are as follows. However, in the case of test data under subparagraph 4 of paragraph 1 of Article 26, if the test data is older than 3 years from the date of issuance based on the submission date, data confirming that there have been no changes to the product after the test must be additionally submitted. 1. ~ 13. (Omitted) <New Article>	Article 29 (Requirements for Submitted Materials) ① The requirements for the submitted materials for the review of technical documentation, etc., are as follows. However, in the case of test data under subparagraph 4 of paragraph 1 of Article 26, if the test data is older than 3 years from the date of issuance based on the submission date, data confirming that there have been no changes to the product after the test must be additionally submitted. 1. ~ 13. (Omitted) 14. For PMMDs, the following materials must be additionally submitted: a. Materials regarding the design envelope (allowable ranges and combinations of each design variable) and the rationale for its establishment. b. Verification and Validation (V&V) data demonstrating the safety and performance of all variations within the design envelope (including worst-case testing, representative sampling testing, computer modeling and simulation, manufacturing process validation, etc.).

4. Proposed Reorganization of the Medical Device Product License Management System (in Korea)

For the rational and efficient marketing authorization management of medical devices with various potential modifications depending on the patient's condition, such as PMMDs among PMDs, a fundamental review and reorganization of the current Korean medical device product marketing authorization certificate management system is necessary.

The current Korean medical device product marketing authorization certificate management method focuses on formal management that lists very detailed information such as shape and structure, and raw materials. This makes it difficult to reflect the characteristics of products like PMMDs, where various modifications within a design range are inherent.

According to the current 「Regulations on the Marketing Authorization, Notification, and Review of Medical Devices」, etc., medical device marketing authorization certificates are required to include very detailed information such as the product name, shape and structure, raw materials, performance, intended use, directions for use, and test specifications. This method may be suitable for standardized mass-produced medical devices, but it causes various problems for PMMDs.

※ In 2025, the MFDS is conducting research to prepare regulatory improvement measures for change authorization management (planning to transition from the current Positive system to a Negative system). However, it is believed that if the fundamental method of managing medical device product marketing authorization certificates is not changed, problems will still arise in the rational authorization management of a large number of PMMD products in the future.

PMMDs, by their nature, can be modified in various shapes, dimensions, and sometimes even detailed structures within a single 'design envelope' to match individual patients' anatomical structures or specific conditions. If marketing authorization certificates were required to specify all these

possible variations in advance, it would be practically impossible or create an enormous administrative burden. For example, a patient-specific bone fixation plate with a specific range of lengths, diameters, and angles could have hundreds or thousands of possible variation combinations. Each time these variations occur, even if it is a minor adjustment within the pre-verified design envelope, current regulations require going through marketing authorization change procedures (minor or major change). This hinders the rapid supply of PMMDs to patients and imposes excessive regulatory costs on manufacturers, which can discourage innovation.

To overcome these limitations, we propose transitioning the medical device marketing authorization certificate management system away from the existing focus on listing detailed physical specifications to a system that manages based on essential elements such as the device's core mechanism of action, intended use, and the essential safety and performance requirements to be achieved (e.g., the US FDA's General Safety and Performance Requirements, GSPRs).

For example, under this approach, the following key information should be primarily included in the marketing authorization certificate of a PMMD:

- **Product name and item name, class**
- **Mechanism of action and intended use:** Clearly describe how the PMMD works, for what purpose (diagnosis, treatment, mitigation, management, or prevention of which disease), and for which patient group it is intended.

- **Main performance and safety criteria:** Describe the key performance criteria (e.g., mechanical strength range, biocompatibility criteria, etc.) and safety requirements that the PMMD must meet, from a GSPR perspective.
- **Summary or reference of the approved Design Envelope:** In the case of PMMDs, summarize and include the key variables and their ranges of the 'Design Envelope' verified through the marketing authorization review, or specify a reference to the approved document describing the detailed design envelope. This allows manufacturers to produce and supply various patient-specific variations within the authorized design envelope without separate additional change authorization.

Instead of listing specific shapes, structures, dimensions, detailed raw material lists, etc., on the marketing authorization certificate, they are recorded in detail in the Technical Documentation and Design History File (DHF) managed under the manufacturer's Quality Management System (QMS), and the MFDS can manage this by verifying them through GMP audits or, if necessary, reviewing the manufacturer's technical documentation.

Of course, this system transition presupposes the manufacturer's strong QMS operational capabilities and the MFDS's enhanced capacity for effective post-market management and GMP audits. Manufacturers must establish and implement thorough internal

verification and validation procedures to ensure consistent safety and performance of all variations within the design envelope, and the MFDS must be able to strictly verify this through regular GMP audits, etc.

This study only proposed the necessity and direction of changes to the marketing authorization certificate management system. It is deemed necessary to conduct further research to prepare more rational measures for improving the marketing authorization certificate management system in the future, considering its linkage with post-market management and harmonization with international marketing authorization certificate management systems.

■ Enforcement Rules of the Medical Device Act[Attached Form No. 4] <Revised 2024. 3. 8>

No.

Medical Device Manufacturing (Import) Marketing Authorization Certificate

(Establishment Marketing Authorization Number:)

Classification	[ ] Manufacturing / [ ] Import	[ ] Product / [ ] Product Group	
Name (Product Name, Generic Name, Model Name)		Classification Number (Risk Class)	
Shape and Structure			
Raw Materials			
Manufacturing Method			
Performance			
Intended Use			
Directions for Use			
Precautions for Use			
Packaging Unit			
Storage Conditions and Expiration Date			
Test Specifications			
Manufacturer (Importer) Information			
Authorization Conditions			
Effective Period			
Location			
Remarks			

This authorization is granted as specified above in accordance with Articles 6 and 15 of the Medical Device Act and Articles 5(2) and 34 of the Enforcement Rules of the same Act.

Year . Month . Day

Minister of Food and Drug Safety Seal

Figure 13. The Current Korea Medical Device Manufacturing (Import) Marketing Authorization Certificate

■ Enforcement Rules of the Medical Device Act[Attached Form No. 4] <Revised 202X. X. X>

No.

Medical Device Manufacturing (Import) Marketing Authorization Certificate

(Establishment Marketing Authorization Number:)

Classification	[ ] Manufacturing / [ ] Import	[ ] Product / [ ] Product Group	
Name (Product Name, Generic Name, Model Name)		Classification Number (Risk Class)	
Intended Use			
Mechanism of Action			
Key Performance			
Safety Requirements			
Design Envelope			
Directions for Use			
Precautions for Use			
Packaging Unit			
Storage Conditions and Expiration Date			
Test Specifications			
Manufacturer (Importer) Information			
Authorization Conditions			
Effective Period			
Location			
Remarks			

This authorization is granted as specified above in accordance with Articles 6 and 15 of the Medical Device Act and Articles 5(2) and 34 of the Enforcement Rules of the same Act.

Year . Month . Day

Minister of Food and Drug Safety Seal

Figure 14. Proposed Amendments to the Medical Device Manufacturing (Import) Marketing Authorization Certificate

IV. DISCUSSION

The regulatory framework proposals presented in this study are considerations from the perspective of benchmarking regulatory content that is deemed rational by comparing Korean regulations with those of the United States and Europe. It does not propose a separation of items that should be reflected and items that cannot be reflected by analyzing the differences in regulatory environments across countries. For example, regarding the improvement of the CMD regulatory framework, strengthening the role of medical professionals, as in the United States or Europe, would be desirable in terms of ensuring patient safety, but it would also impose additional responsibility and burden on medical professionals, which would require social discussion to support it. As such, further research is deemed necessary to develop more precise PMDs regulatory measures that consider the Korean regulatory environment in the future, and it is expected that only through this process can truly Korean-style PMDs regulations be established.

Similarly, the improvement of the medical device product marketing authorization certificate management system is also the same. This study did not examine the marketing authorization

certificate management systems of each country in detail. However, it is believed that there will clearly be differences in the marketing authorization management methods for PMDs depending on how the marketing authorization certificate management systems of each country are operated. While establishing an advanced country-style medical device product marketing authorization certificate management system is clearly a necessary regulatory improvement task for the future medical device management system, it is necessary to thoroughly review whether this change will increase the burden on medical device manufacturers and importers, and if so, how industry support should be provided to change the regulatory framework. In particular, considering the characteristics of the medical device industry, which has many small and micro-sized companies, policy considerations such as technical support and provision of training programs should also be taken into account to ensure that they do not experience difficulties due to changes in the regulatory environment.

V. CONCLUSION

This study aimed to analyze the current Korean management system for PMDs (CMDs, PMMDs) and to propose rational regulatory measures for PMDs by comparing and analyzing regulatory cases in major overseas countries.

The research results revealed that the Korean regulatory system for PMDs had many shortcomings compared to international management standards, such as operating a system centered on some Custom Made Devices, including 3D printing technology. It was confirmed that current Korean regulations are inadequate to manage the numerous PMDs products that will emerge with the use of advanced technologies.

In contrast, the management regulations for PMDs in the United States and Europe were found to operate more clearly than in Korea. While ensuring patient safety through clear responsibility and strict management conditions, they were operating a rational management system that could supply the most suitable PMDs to patients more promptly through flexible system operation, such as the design envelope management system.

Efforts should be made to equip Korean PMDs regulations with a regulatory framework similar to that of the United States or Europe. To this end, as proposed in this study, clear regulatory definitions for PMDs should be established, and clear regulatory frameworks should be created according to each definition. It is necessary to improve the current CMD-related

regulations in Korea, benchmarking the management standards of the United States or Europe, and to establish regulations for PMMDs, for which there are no clear regulations compared to other countries, in a direction that is harmonized with international management standards. Of course, it is necessary not to simply benchmark, but to further refine PMDs regulatory improvement measures in consideration of the Korean regulatory environment in the future, and additional research for this purpose is deemed necessary. It is expected that only after going through this process can truly Korean-style PMDs regulations be established.

In addition to this, changes in the current medical device product marketing authorization certificate management system are necessary to establish the most rational regulatory management measures for PMMDs, which allow for various modifications. The current marketing authorization certificate management system, which is focused on detailed specifications, cannot adequately accommodate the demands of the personalized medical device era. There must be a transition to a marketing authorization certificate management system that manages only essential management items such as the mechanism of action and intended use. To achieve this, it is also necessary to study the medical device product marketing authorization certificate management systems of advanced countries. It is believed that only when these marketing authorization certificate system changes are accompanied can a rational safety management system that considers the characteristics of innovative medical devices such as PMMDs be completed.

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ABSTRACT IN KOREAN

개인 맞춤형 의료기기에 대한 합리적 규제체계 구축: 개인 맞춤형 의료기기에 대한 글로벌 모범사례 통합

인공지능(AI) 및 3D 프린팅 등 첨단 기술의 발전은 의료기술 분야에 혁신적인 변화를 가져오고 있으며, 이는 환자에 대한 보다 정밀한 진단과 함께 개별 환자의 해부·생리적, 병리적 특성을 고려한 개인 맞춤형 의료기기(Personalized Medical Devices, PMDs)의 개발 및 정밀 치료를 가능하게 하고 있습니다. 특히 3D 프린팅 기술 등 의료기기 제조 기술의 급속한 발전은 PMDs를 환자에게 보다 신속하게 제조하여 공급할 수 있는 환경을 조성하였습니다.

그러나, 현재 한국의 허가 관리체계는 PMDs의 특성(환자 상태를 반영하여 제조 및 공급하는 제품)을 충분히 고려하지 못하고 있습니다. 이는 제조 및 공급 전에 미리 형상, 구조, 치수 등을 세밀하게 정하여 허가를 받도록 운영되는 방식이기 때문에 PMDs를 안전하고 유효하며 효율적으로 관리하는 데 한계가 있는 것입니다. 비록 국내에 대체 치료법이 없는 특정 환자를

위한 '주문 제작형 의료기기(Custom Made Device, CMD)' 관리 제도가 존재하지만, 그 적용이 매우 제한적입니다. 더욱이 한국 규정상 '특정 환자용 의료기기(Patient-Matched Medical Devices, PMMD)'와 같은 다양한 PMDs에 대한 명확한 정의가 부재한 실정입니다. 이러한 정의의 부재는 다양한 PMDs에 대한 허가 관리체계가 명확하게 구축되지 못하는 결과를 초래하며, PMMD로 분류되어야 할 제품들이 CMD로 관리되어 규제 경로를 모호하게 만들고 있습니다.

본 연구는 한국 식품의약품안전처(MFDS)의 PMDs 관리 규제 내용을 분석하고, 나아가 미국(FDA), 유럽(EU MDR), 그리고 국제 의료기기 규제당국자 포럼(IMDRF)의 PMDs(CMD 및 PMMD) 관련 규제를 비교 분석하여, 한국 PMDs에 대한 합리적인 규제 개선 방안 마련을 위한 시사점을 도출하고자 하였습니다.

연구 결과, PMDs 시장이 빠르게 성장하고 있음에도 불구하고, 현재 한국의 규제 프레임워크는 이러한 변화를 적절히 반영하지 못하고 있었습니다. 이에 본 연구는 국제 규제 조화를 촉진하고 국내 산업 발전을 도모하기 위해 '주문 제작형 의료기기(CMD)'와 '특정 환자용 의료기기(PMMD)'에 대한 명확한 정의를 확립하고, 각 유형의 특성을 반영한 차등화 된 허가 관리 시스템을 개발할 것을 제안합니다.

1. CMD 및 PMMD 정의 규정 명확화

IMDRF, EU, FDA 등 국제 정의를 벤치마킹하여 국내 상황에 적합한 CMD 및 PMMD의 명확한 정의를 확립할 것을 제안합니다. 이는 현재 CMD와 PMMD가 명확하게 구분되어 있지 않아 규제 적용의 모호성을 야기하는 문제가 있기 때문입니다. 제안된 CMD 정의는 설계에 있어 의료 전문가의 주도적인 역할과 책임, 특정 환자 전용 사용, 그리고 대체 수단이 없는 경우에만 사용

한다는 핵심 특성을 반영하며, 개념 혼란 방지를 위해 PMMD를 명시적으로 배제합니다. PMMD 정의는 제조업체가 사전 설정하고 검증한 '설계 범위(Design Envelope)' 내에서 개인 맞춤화가 이루어지며, 제조업체가 설계 및 최종 제품 품질에 대한 전적인 책임을 진다는 IMDRF(International Medical Device Regulators Forum) 및 MDCG(Medical Device Coordination Group)의 지침과 권고사항을 반영합니다. 이러한 명확한 구분을 위한 정의 개념 도입은 개인 맞춤형 의료기기의 효과적인 관리를 위한 필수 조건입니다.

2. CMD 규제 프레임워크 제안

현재 변경 허가(인증)만 면제하는 관리 방식에서 벗어나, EU MDR의 Annex XIII 또는 FDA의 CDE 시스템과 유사하게 신규 및 변경 CMD 모두에 대해 표준적인 시판 전 허가, 제품 인증 또는 신고 의무를 면제하는 접근 방식을 제안합니다. 이러한 면제는 환자 안전, 기기 유효성, 그리고 시판 후 안전 관리를 보장하는 엄격한 조건 하에서 이루어져야 합니다. 이 조건에는 자격 있는 의료 전문가의 서면 요청 및 설계 책임, 특정 환자 전용 사용 입증, 대체 불가능성 및 필요성 입증, 그리고 제조업체의 일반 안전 및 성능 요구사항(General Safety and Performance Requirements, GSPR) 준수 선언이 포함됩니다.

또한, 사용자(환자 및 의료 전문가)가 해당 의료기기가 일반적인 허가 절차를 거치지 않은 특정 환자용 CMD임을 명확히 인식하도록 '이 제품은 주문 제작형 의료기기입니다(This product is a Custom Made Device)'라는 문구를 용기, 포장 또는 첨부 문서에 의무적으로 표시하도록 의료기기 표시 규정을 개정할 것을 제안합니다. 이 외에도 환자 식별 정보, 처방

의료 전문가 정보, 제조업체 정보, 제조/유효 기간, 멸균 여부, 보관 주의 사항 등 안전하고 효과적인 사용에 필요한 정보가 포함되어야 합니다.

CMD는 고유성과 극소량 생산 특성을 고려하여 일반 의료기기에 적용되는 표준화된 UDI 시스템(용기/포장 부착 및 정보 등록) 의무 적용에서 제외하되, UDI 면제로 인한 추적성 공백을 해소하기 위해 제조업체에 강력한 환자 추적 관리 시스템 구축 및 운영 의무를 부과할 것을 제안합니다. 여기에는 환자 식별 정보, 처방자, 설계 사양, 원재료 및 부품 정보, 제조/공급/사용 일자 등을 포함한 상세 기록 유지 및 안전 문제 발생 시 신속한 정보 제공 의무 등이 포함됩니다.

아울러, 반복적으로 CMD로 보고되는 제품에 대해 PMMD 관리로의 전환 필요성을 검토하는 시스템을 제안합니다. 이러한 제품이 있을 경우, 제조업체가 실제 데이터/증거 및 의무적인 CMD 기록을 기반으로 허가 또는 변경 허가(또는 재평가/품목 갱신 시스템을 활용한 허가 업데이트 등의 방식 고려)를 받도록 허가 관리 시스템을 운영해야 할 것입니다.

3. PMMD 규제 프레임워크 제안

PMMD는 제조업체의 책임 하에 사전 검증된 '설계 범위(Design Envelope)' 내에서 환자의 해부학적 구조에 맞춰 제조되는 제품군을 의미하며, 이는 의료 전문가의 특정 지시에 따라 일회성으로 제조되는 CMD와는 근본적으로 다릅니다. 따라서, PMMD의 특성을 고려한 합리적인 허가 및 관리 시스템을 구축해야 하며, 특히 '설계 범위' 관리가 핵심적입니다.

제조업체는 PMMD의 모든 관련 설계 변수와 허용 범위를 명확히 정의하고, 이에 대한 과학적 근거를 제시해야 합니다. 또한, 정의된 설계 범위 내에서

생산되는 모든 PMMD가 일관되게 안전하고 효과적임을 입증하는 검증 및 유효성 확인(Validation and Verification, V&V) 데이터를 제출해야 합니다. 이는 최악의 시나리오 테스트, 대표 샘플링 테스트, 컴퓨터 모델링 및 시뮬레이션, 제조 공정 유효성 확인 등을 포함합니다.

4. 의료기기 품목허가증 관리 체계 개선 제안(한국)

PMMD와 같이 환자 조건에 따라 다양한 변경 가능성이 있는 의료기기의 합리적이고 효율적인 허가 관리를 위해, 현재 한국 의료기기 품목허가증 관리체계를 근본적으로 검토하고 개선해야 합니다. 현재 품목허가증에 형상 및 구조, 원재료 등 세부 정보를 나열하는 형식적 관리 방식에서 벗어나, 기기의 핵심 작용 메커니즘, 사용 목적, 그리고 필수 안전 및 성능 요구사항(예: FDA의 GSPR)과 같은 반드시 관리를 해야 할 필요가 있는 핵심적인 내용을 중심으로 관리하는 시스템으로 전환할 것을 제안합니다. 이러한 변화는 제조업체가 허가된 설계범위 내에서 다양한 환자 맞춤형 변형 제품을 별도의 추가 변경 허가 없이 생산하고 공급할 수 있도록 하여, 신속한 시장 진입을 촉진하고 행정 부담을 줄여 줄 것으로 생각됩니다.

이러한 규제 개선 방안들은 환자 안전 향상, 의료기기 산업 혁신 촉진, 그리고 국제 규제와의 조화를 통한 한국의 개인맞춤형 의료기기(PMDs) 규제 발전에도 크게 기여할 수 있을 것으로 판단됩니다.

핵심어 : 개인맞춤형 의료기기(personalized medical devices), 주문 제작형 의료기기(custom made device), 특정 환자용 의료기기(patient - matched medical device), 환자 적용형 의료기기(adaptable medical device);