PRZEGLĄD PRAWA MEDYCZNEGO

Legal and regulatory requirements related to medical devices intended for persons with disabilities

Reference version

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Summary

The following article is in the form of an analysis, in which the author presents the industry's reaction and an analysis of the current state of the law and the industry's reaction after the 2021 legal changes that came into effect for the medical devices sector. Until 2021, three medical directives were in force: Directive 98/79/EC, Council Directive 93/42/EEC, and Council Directive 90/385/EEC, which were replaced by two regulations: Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. In the following article, the author will outline the reasons for the changes, what responsibilities these changes have brought to medical device producers, particularly of devices for people with disabilities, and what benefits have flowed to the industry and end users of medical devices after these regulations came into effect.

Key words

MDR regulation, changes to the medical directive, Regulation 2017/746

Introduction

The topic of legal aspects related to medical devices has become very relevant following the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (MDR – Medical Device Regulation), which came into force on May 26, 2021. The postponement of this date was intended to enable Member States and healthcare institutions to focus their efforts on combating the virus. In Poland, on May 26, 2022, a new Medical Devices Act came into force, intending to implement the guidelines contained in the regulation into the national law on medical devices of 2010, thereby creating a new law on medical devices of April 7, 2022.

Medical devices, in particular those used to provide people with disabilities with products that help them function in everyday life after diagnosis and treatment of bodily dysfunctions, are a sector undergoing dynamic and rapid technological progress. Thanks to technological progress and new technical/design solutions, persons with physical disabilities are increasingly able to perform everyday tasks (mostly in the area of mobility) similarly to people without disabilities. Although the use of these innovative solutions can greatly reduce their discomfort in everyday life, it can also expose them to risks associated with the use of devices that have not been fully tested or whose safety has not yet been proven. Rapid technological progress poses major challenges for legal institutions, which are responsible for ensuring citizens' safety and interests. This has prompted the European Union's legal authorities to review the regulations on medical devices and in vitro diagnostics, adapting them to changes in the medical device sector by introducing a new regulation that came into force on May 26, 2021. This paper attempts to systematize the changes that have occurred since the regulation entered into force, in particular regarding products manufactured individually for persons with disabilities. It outlines the obligations of orthopaedic supply providers and shows how medical device users will benefit.

Analysis of the causes and necessity of introducing changes

The main determinant of regulatory changes in the area of medical devices was a series of medical incidents threatening the lives of device users. One of the most high-profile medical incidents involved 500,000 breast implants. The incident concerned the use of technical silicone in the implants' construction, which negatively impacted the human body in the event of

implant rupture and leakage. An incident was also reported involving the improper design of the ASR hip replacement system, resulting in loosening during use and misalignment of the endoprosthesis components, leading to infections, bone fractures, dislocations, metal sensitivity, and pain. This incident affected approximately 54,000 patients. Another important factor driving regulatory changes is the emergence of new technologies in the medical device sector, such as standalone software, smart prostheses/implants, rehabilitation support equipment, devices that deliver chemical substances/mixtures into the body, and devices based on nanomaterials.

It was not just the technical conditions that influenced the need to introduce changes, but also the fact that European directives are implemented by each member state, leading to differing interpretations of the provisions and varying levels of patient and public health protection across the European Union. This legal situation disrupted the creation of a single EU market, which is the basis of the European Union's founding principles.

The rules on medical devices in force until May 26, 2021 were created in the early 1990s and were not updated throughout the early 21st century, despite the rapid technical and scientific progress happening during that time. It was difficult to classify new medical devices entering the market, such as exoskeletons, active upper- and lower-limb prostheses, and dynamic orthoses.

Other shortcomings resulting from the applicable legal regulations included the inability of interested parties (patients, product users, healthcare professionals) to obtain documents and reliable information confirming that the product they were using had undergone appropriate testing, its conformity assessment with applicable regulations, whether it was safe, and whether its therapeutic efficacy had been proven and confirmed by appropriate clinical evaluation. Problems with accurate assessment of the device were exacerbated by the lack of precise definitions in the provisions related to the classification of products at the borderline between medical devices, medicinal products, cosmetics, and food. The lack of defined guidelines for notified bodies without external control over the quality and effectiveness of their activities only exacerbated this problem.

Changes introduced

The most important changes in the EP regulation on medical devices concern strengthening the regulatory approach by increasing supervision by notified bodies and improving procedures for assessing compliance with essential requirements and procedures related to clinical trials.

The form of market surveillance has also changed, and provisions to improve transparency and traceability for medical devices have been introduced, taking into account international guidelines. Two directives have been replaced by legislation: Directive 90/385/EEC and Directive 93/42/EEC, by a single act, the EU MDR Regulation. The proposed legal act in the form of a regulation is directly implemented in each Member State, providing the same legal and technical conditions for medical devices throughout the EU at the same time. Decisions on whether a given device is subject to the regulation under consideration are made by a selected Member State with the support of the Commission. The regulation specifies the requirements for medical devices containing medicinal products and includes non-medical devices that are implanted or invasive in relation to the body. It clearly describes which devices are excluded from this regulation. All devices containing living biological substances of other origins are excluded from this regulation. It clearly describes the requirements for devices that contain nanomaterials, the status of harmonized standards, and the need to maintain the rules for CE marking of devices. The regulation also clearly confirms the need to apply other directives to medical devices, such as the EMC (Electromagnetic Compatibility) Directive, the Machinery Directive, and rules concerning ionizing radiation emissions. The regulation specifies the obligations of importers and distributors, authorized representatives, and OEM manufacturers, and confirms that EU-associated countries, i.e., Switzerland, Norway, and Turkey, are to apply it. The regulation also focuses on harmonizing the definitions of basic concepts across all regulations, including the classification of products and assessment of conformity with essential requirements.

This regulation introduces the obligation for all medical device manufacturers to have a quality management system in place and to employ a person qualified in the field of manufactured devices, as well as a person to represent them in superior institutions. The regulation generates an obligation to provide patients with implants with full information about the implant and to introduce a system of unique device identification codes, known as UDI (Unique Device Identifier), within the organization. The regulation also increases access to the EUDAMED database. Thanks to the regulation for Class III devices, this database provides public access to key device documents regarding their safety, performance, and clinical evaluation. The

regulation introduced greater supervision of notified bodies and gave notified bodies greater powers to supervise manufacturers. The Regulation has increased the requirements for conducting clinical evaluations (according to the requirements of EN ISO 14155:2011) and strengthens the European clinical trial registration system.

This regulation has changed the rules for reporting medical incidents. The regulation requires that incidents be reported via a central portal for reporting serious incidents. The central portal for reporting serious incidents allows patients and doctors to submit reports and enables the FSCA (Field Safety Corrective Action) to review the reported incidents. The regulation has strengthened the position of national authorities in the field of market surveillance and enabled the establishment of new market surveillance groups/committees.

The Regulation also clearly describes a medical device manufactured to individual order, known as a custom-made device. Such a device means a device manufactured specifically in accordance with a medical order issued by a person authorized under national law based on their professional qualifications, which determines – under the responsibility of that person – specific design characteristics, and is intended for the exclusive use of a specific patient solely for the treatment of his or her medical condition or to meet his or her individual needs. However, mass-produced devices that need to be adapted to meet the specific requirements of a professional user, or devices mass-produced using industrial manufacturing processes in accordance with medical orders from authorized persons, are not considered custom-made devices. In accordance with the regulation, manufacturers of custom-made devices must prepare, update, and store device documentation for at least 10 years, allowing access to the relevant state authorities. The storage period is extended to at least 15 years for implantable devices. In particular, a statement should be maintained that the device is intended for the exclusive use of a specific patient or user, identified by name, initials, or a numerical code. Manufacturers of custom-made devices are also required to supervise the device and monitor complaints and medical incidents reported with the device.

The size of the EU market for medical devices is based on approximately 500,000 different types of medical devices and in vitro diagnostic medical devices. These products include medical equipment (X-ray machines, CT scanners), breast and large joint implants (endoprostheses), lower and upper limb prostheses, orthoses, walking aids, and applications that support software for electronic systems that assist, monitor, or diagnose the body.

The medical device market in Poland is supervised by the Market Surveillance Department operating within the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. One of the tasks of this Department is to verify entities operating on the Polish market in terms of their compliance with applicable legal regulations and the compliance of the products they manufacture or distribute. In particular, it verifies whether these products meet the requirements of the Medical Devices Act and related regulations of the Minister of Health. Therefore, as a manufacturer of medical devices, it is worth making every effort to ensure that the company's activities, and the product itself, fully comply with the requirements of these legal acts.

Market analysis following the implementation of the regulation

Multiple changes followed the introduction of the regulation, mainly in the assessment of the conformity of medical devices, the control of medical devices placed on the market, and their availability on the market.

This approach made it possible to clearly define what constitutes a medical device and what does not. The division into product families, product types, and product versions was clearly defined. All these changes were dictated by the market orientation, so that all manufacturers/distributors would operate in a consistent manner, and that the nomenclature they used for a given device was unambiguous and identical, so that all manufacturers/distributors would use the same name for a device with a selected functionality that satisfied a selected need, e.g., prosthetic foot. As part of the standardization of medical device nomenclature, it has become recommended to use nomenclature for a product in accordance with the accepted nomenclature in:

- GMDN – Global Medical Device Nomenclature, GMDN Agency, www.gmdnagency.org;
- UMDNS – Universal Medical Device Nomenclature System, ECRI Institute, www.ecri.org;
- GIVD – Global InVitro Diagnostic Classification (code system used exclusively for in vitro diagnostic medical devices);
- MedTech Europe, www.medtecheurope.org.

With the implementation of the regulation, the Eudamed database was made available. There are 667 entities registered in the Polish database, of which 426 are manufacturers, 207 are importers, and 22 are authorized representatives. Among these entities, we also find 12 manufacturers of treatment sets (as of June 20, 2024).

Significant changes have taken place in the case of notified and certifying bodies for both medical devices and the management system itself in entities conducting business activities related to medical devices (manufacturers of serial medical devices, distributors, importers, and entities operating as healthcare services). The criteria set out in the regulation were met by 39 entities across the European Union, two of which are from Poland. Among the notified bodies registered in Poland and operating on the Polish market are TUV Nord Polska Sp. z o.o. with identification number 2274 and Polish Centre for Testing and Certification with identification number 1434. (as of 20 January 2024).

EU regulations have imposed a number of obligations on entities operating in the medical device market related to the identification of medical devices using a UDI code. A unique device identifier (UDI) is a numeric or alphanumeric code associated with a specific medical device. This code enables the unambiguous identification of a specific medical device on the market and facilitates its traceability at every stage of its life cycle (from manufacture, through use, to recycling). The UDI should consist of the following components:

- device identifier (UDI-DI code);

- production identifier (UDI-PI code).

The UDI code procedure complements the long-standing guidelines for the labeling of mass-produced medical devices.

Under the new rules, each manufacturer must assign a UDI code to their device and to all higher levels of packaging before placing the device on the market. The UDI code carrier shall be placed on the device label and on all higher levels of packaging.

Before placing a device on the market, the manufacturer shall ensure that the information relating to the device referred to in Annex VI, Part B of Regulation 2017/745 on medical devices is correctly submitted and transmitted to the UDI database.

Within the EU, the manufacturer is required to assign a Basic UDI-DI code to its device in addition to the UDI code.

The Basic UDI-DI code is an important tool for entering information into the central database and is indicated in relevant documents (e.g., certificates, declarations of conformity, technical documentation, reports describing the safety and clinical effectiveness of the device). The Basic code enables access to information related to a selected medical device entered into the European database of medical devices. Using the Basic code, it will be possible to search for all information contained in the database.

Along with the Commission Implementing Decision (EU of June 6, 2019), four entities were designated to provide manufacturers with lists of UDI codes to enable manufacturers to generate codes for their medical devices according to the adopted format. The UDI HRI and AIDC formats and the basic UDI-DI formats can be and are approved by the EU for use by each issuing entity. These standards are also recommended by the US Food and Drug Administration (FDA), the European Commission, and other regulatory bodies around the world. The main objective of this unique medical device identification (UDI) is to improve patient safety and streamline business processes in the healthcare sector. The solutions proposed and implemented through unique device identification (UDI) provide unambiguous marking and identification of medical devices throughout their entire life cycle – from production through supply chains to use in healthcare at both the local and global levels.

In Poland, there is currently one entity that is accredited to use and create UDI standards as the basis for the national UDI. This company received accreditation from the European Commission on June 10, 2019.

Due to the current legal situation, we are in a transition period. This is due to the fact that not all manufacturers are prepared to meet the stringent requirements of the regulation before the end of the current transition period. Failure to meet this requirement would force manufacturers to stop supplying their products. In order to eliminate concerns about the lack of availability of certain medical devices on the EU market, the implementation period for these directives has been extended. The transition period expires on December 31, 2027, or December 31, 2028, depending on the risk class of the device. The first date applies to Class IIB and Class III devices, and the second to Class IIA and Class I devices.

In individual areas of the EU, it has been determined that: “the overall capacity of conformity assessment bodies (‘notified’) is insufficient to perform the tasks required of them.” This poses

a market challenge for supply and demand, as once certificates issued under the directives expire and without a valid MDR certificate, manufacturers can no longer place these medical devices on the EU market. This situation could lead to limited availability or even a shortage of medical devices. The end result of this situation would be reduced patient safety, generating additional risks.

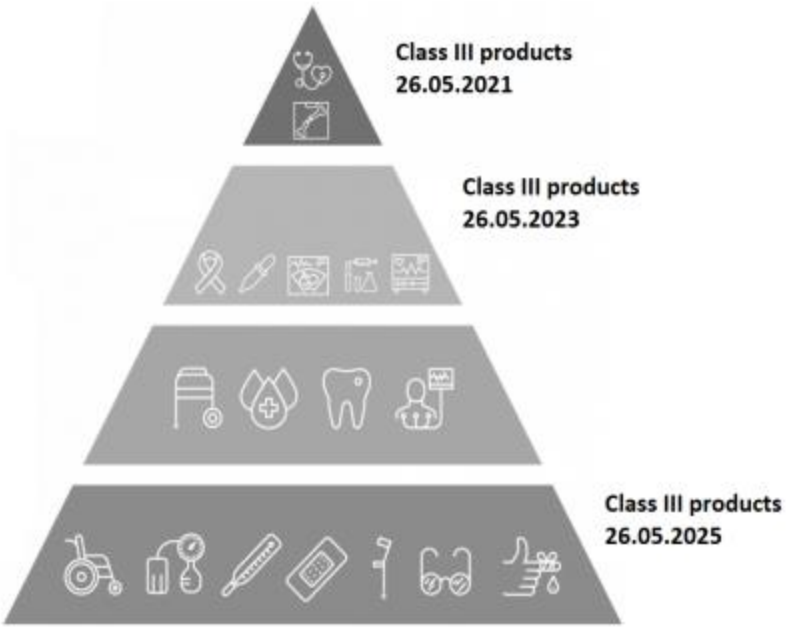

Fig. 1 Pyramid of UDI standard implementation in the EU [based on EUDAMED]

UDI System standards are essential for enabling the effective and efficient use of developed normative quality standards for medical devices by all stakeholders worldwide. The UDI System of standards aims to support all interested parties in efficient and effective procedures to enable operational compliance within organizations, between organizations, and across borders. A single standard will ultimately contribute to accelerating the implementation processes for new devices and increase compliance (in terms of quality, production, and documentation) for existing products on the market.

The EU Regulations introduced the Basic UDI-DI device identifier. Basic UDI-DI (BUDI-DI) is a key element enabling the connection of various modules of the European Database on Medical Devices (EUDAMED). According to EU regulations, BUDI-DI is the "Primary device model identifier." BUDI-DI (GMN) is used to register medical devices and is assigned

independently of packaging/labeling, and also differs from the identifier of commercial units in the supply chain (UDI-DI/GTIN).

For this purpose, it was necessary to develop a device identifier, i.e., GMN (Global Model Number) (Fig. 2). The Global Model Number allows users to uniquely identify a device model throughout its entire life cycle: design – production – procurement – use – maintenance – disposal.

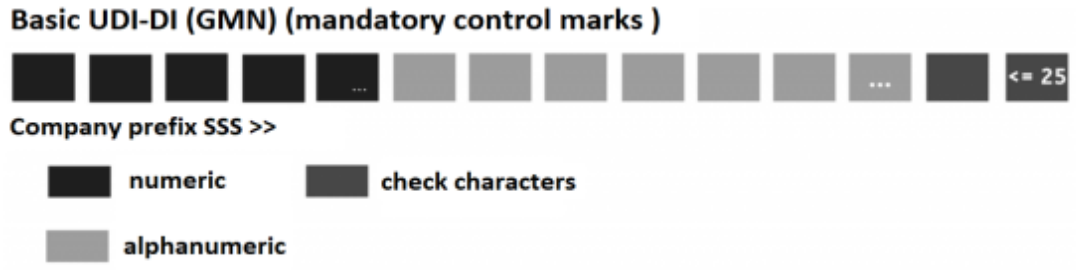

Fig. 2 Structure of the BASIC UDI-DM (GMN) code [based on EUDAMED]

The new identifier will primarily serve regulators and will not physically appear on the product packaging (it will not be represented in any data carrier, e.g., a barcode) (Fig. 3).

Fig. 3 Example of an individual medical device identifier [based on existing systems]

Different devices may be placed on the market based on the same technical specifications. GMN will be used to group these devices within a single model. BASIC UDI-DI will be the main access key to the database and for entering information about specific medical devices in

the EUDAMED database (Fig. 4). It should be noted that Basic UDI-DI (GMN) has a maximum length of 25 characters, including two mandatory check characters.

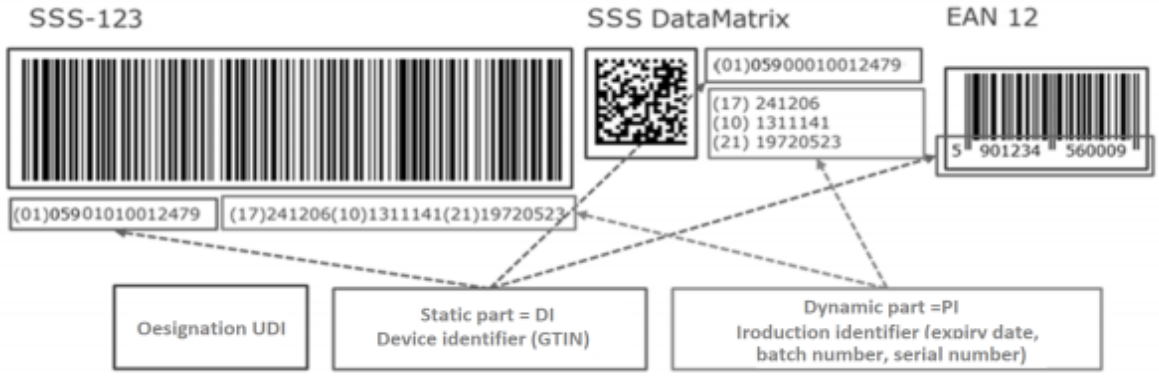

Fig. 4. Example structure of BASIC UDI-DI [based on current product labeling systems]

The implementation of UDI will lead to increased patient safety and improved efficiency in the healthcare supply chain. The UDI system will enable the unambiguous identification of medical devices. The data obtained through the implementation of the UDI system will reduce certain medical errors, enable more effective monitoring of adverse events, and allow for more efficient recall of defective medical devices from the supply chain. (Table 1).

Table 1. Summary of benefits following implementation of the guidelines from the regulation for various stakeholders

MANUFACTURERS	INSTITUTIONS USING THE PRODUCT (hospitals, clinics)	SUPERVISORY/REGULATORY BODIES
Patient safety	Patient safety	Patient safety
Traceability	Traceability	More effective market monitoring
Cost optimisation	Properly identified medical devices	Increased efficiency of adverse event reporting
Data quality	One identified management system	Faster product recall (including from international markets)
Manufacturing process efficiency	-	-
Manufacturing process accuracy	-	-

Discussion

New regulations, EU Regulation (EU) 2017/745 of April 5, 2017 (Medical Device Regulation – MDR), introduced regulatory changes to the EU market for medical devices. The authors of the regulation assume that all regulations will be implemented by manufacturers and distributors by 2025. The shortcomings observed in the existing regulations concerned the difficulty in clearly identifying medical devices available on the market. In particular, there were difficulties in how to perceive a product whose own name or trade name, model name, type, or model often suggested that it was a medical device when, in fact, it was not. The new regulation eliminates this problem by introducing clear definitions of product names, trade names, product type, and product model, as well as the mandatory implementation of the UDI (Unique Device Identifier) system. UDI codes can be in the form of a string of numbers or numbers and letters that can be easily converted into barcodes or QR codes using automatic reading technologies, e.g., 2dMatrix technology. The authors of the regulation intend for the obligation to create codes to apply to all members of the product manufacturing and distribution chain, to enable quick and easy identification of the source of technical/legal non-compliance arising in relation to the product. This will allow rapid implementation of corrective/remedial measures concerning the broadly understood safety of medical devices. The author intends that this will allow for the rapid identification of the entity manufacturing the device and the source of the causes generating hazards associated with the medical device. The implementation of UDI codes is also intended to make it easier for supervisory authorities and users of medical devices to obtain reliable information about a medical device. Has the device been registered as a medical device and is it listed in the Eudamed database? The main purpose of creating a medical device database is to make it possible to obtain all necessary data and information about them from a single place. The authors intended the database to be easily accessible to the general public and healthcare professionals. Centralization of information storage in a systematic form according to selected criteria (in the regulation, this takes the form of six modules) will, in the author's opinion, make it easier for those seeking information about a medical device to obtain reliable and verified information about the device. The product documentation contained in the database will be identical, which will make it easier for healthcare professionals and potential future users to evaluate and verify medical devices according to selected criteria (e.g., therapeutic effectiveness). Thanks to this database, end users of medical devices and healthcare professionals will be able to obtain descriptions of the results of clinical trials and performance studies of medical devices, as well as access to information collected from market surveillance

and monitoring for a selected device, and reported medical incidents related to a selected device. Those interested in a selected medical device in this database will also find standard information about the device, including the manufacturer, the unique device identifier (UDI), and the notified and certifying body that certified the device and supervises the manufacturer and the device. The proposed database will also record all types of medical incidents, which can be reported through this database by both healthcare professionals and users of medical devices.

Proper labeling of medical devices plays a key role in patient safety. It also impacts the functioning of medical facilities where the selected medical device is used (hospitals, clinics), regulatory institutions (authorities, regulators), and the manufacturers themselves.

In summary, the analysis concluded that the introduction of these legal regulations meant that the MDR imposed several new obligations on manufacturers, distributors, and sales representatives of medical devices, the purpose of which is not clearly defined. The analysis of the regulation showed that these new obligations on manufacturers will translate into transparency of public information about medical devices, their therapeutic effectiveness, transparency of public information with information about competing products and substitutes, and monitoring of medical incidents related to the device. This approach seems appropriate to standardize information for professionals—healthcare workers—as it forms the basis for decisions related to treatment or therapy, thereby affecting patient health. In the interest of the end user of a medical device (who has average technical and medical knowledge), this information should be reliable and easy to understand.

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