PRZEGLĄD PRAWA MEDYCZNEGO

# Medical software as a medical device. Selected legal and regulatory issues against the background of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

**Reference version**

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| Original title | Oprogramowanie medyczne jako wyrób medyczny. Wybrane zagadnienia prawno-regulacyjne na tle rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/745 z 5 kwietnia 2017 roku |
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| Publication date | September 23, 2023 |
| Translation published on | November 26th, 2026 |
| Original URL | https://doi.org/10.70537/xaap5z84 |
| Original language | Polish |

**Editorial statement**

This article is a full translation of a paper originally published in the Medical Law Quarterly and is published here as a secondary publication (translation). Only the original version underwent double-blind peer review; this translated version has been prepared by a third party and has undergone editorial review for accuracy and clarity only.

**The paper should be referenced as:**

Kałczyński, P. (2023). Medical software as a medical device. Selected legal and regulatory issues against the background of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. Przegląd Prawa Medycznego, 5(1-2), 98–132. https://doi.org/10.70537/xaap5z84

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**Summary**

The aim of this paper is to analyze the changes introduced by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices regarding the qualification and classification of software as a medical device. The results of this analysis allow an attempt to answer the question of how far the new regulations ensure a balance between protecting the patient and user and ensuring the availability of innovative medical technologies. The assessment of the new regulations in the EU was made against the background of the regulations adopted for the approval of software as a medical device in the United States. Conclusions arising from the above assessment also include the author's proposal to amend the new regulations as a de lege ferenda postulate.

## Background

The processes currently taking place within healthcare systems lend fundamental importance to the regulatory requirements governing medical software and warrant their in-depth analysis. The most significant of these processes include: the ongoing digitalisation of healthcare systems (in Poland, prominent examples of this process are electronic referrals and electronic prescriptions under the P1 Platform)[1]; the growing importance of modern technologies in the diagnosis and treatment of diseases, with particular emphasis on the use of artificial intelligence in this field[2]; and the development of telemedicine in connection with the SARS-CoV-2 pandemic, particularly in the form of teleconsultations[3].

The concept of a medical device is of particular relevance to medical software, as it provides a basis for product categorisation. This is especially important because medical devices are subject to a separate legal framework, which governs, inter alia, the conditions for placing medical devices on the market, making them available on the market and putting them into service within the European Union (hereinafter: the EU), where they are intended for human use. The principal source of the aforementioned regulatory framework is Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 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[4]. On 26 May 2021, the MDR replaced Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, which had been in force for almost 30 years[5].

As a regulation, the new legislation is directly applicable in all EU Member States, thereby contributing to consistency in the interpretation of its provisions[6]. This legislative initiative reflects the EU's efforts to facilitate cooperation between Member States in the field of

[1] Ministerstwo Zdrowia (Ministry of Health, Poland), *Zdrowa przyszłość. Ramy strategiczne rozwoju systemu ochrony zdrowia na lata 2021–2027, z perspektywą do 2030 r.*, załącznik do uchwały nr 196/2021 Rady Ministrów z dnia 27 grudnia 2021 r., pp. 117 et seq., electronic version of the document: https://www.gov.pl/attachment/4a9bd160-e052-4a52-8fd4-b7c546d556f8 (accessed: 22 December 2022).
[2] P. Kaźmierczyk, M. Kupis, M. Maj, *Biała Księga. AI w praktyce klinicznej. Stosowanie sztucznej inteligencji przy udzielaniu świadczeń zdrowotnych*, version 1.0, Warsaw, June 2022, p. 27, electronic version of the document: https://aiwzdrowiu.pl/wp-content/uploads/2022/06/BIA_A-KSIE_GA_AI-W-ZDROWIU_2022.pdf (accessed: 22 December 2022).
[3] *Zdrowie Polaków po pandemii. Co możemy zrobić razem*, Deloitte, Pracodawcy Medycyny Prywatnej, 30 December 2020, p. 39, electronic version of the document: https://medycynaprywatna.pl/wp-content/uploads/2021/01/FINA%C5%81_raport-PMP-2.pdf (accessed: 22 December 2022).
[4] OJ EU L 117, 5.05.2017, pp. 1–175; hereinafter: MDR.
[5] OJ EC L 169, 12.07.1993, p. 1; hereinafter: MDD.
[6] K. Stelmasiak, M. Świerczyński, Z. Więckowski, *Badania kliniczne wyrobów medycznych wykorzystujących inteligentne algorytmy – wstęp do dyskusji*, "Prawo w działaniu" 2022, vol. 50, *Sprawy cywilne*, p. 118.

healthcare[7]. However, the MDR does not provide an exhaustive framework for the placing of medical devices on the market. Certain matters, such as the national register of distributors, the advertising of medical devices and penalties for infringements of the Regulation, have been left to regulation by the Member States. In Poland, these matters are governed by the Medical Devices Act of 7 April 2022[8], which also aligns Polish legislation with the requirements arising from the MDR.

The fundamental objectives of the MDR are set out in Recital 2 of its Preamble: "to ensure the smooth functioning of the internal market as regards medical devices, taking as a basis a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other". The objectives of the MDR, as formulated above, are therefore characterised by their equal standing and universal applicability to all groups within the product category under consideration, including software qualifying as a medical device (Medical Device Software, hereinafter: MDSW). The view that the MDR constitutes an example of contemporary legislation governing new technologies should be endorsed[9]. This categorisation also makes it possible to distinguish MDSW from software which, although used in connection with healthcare, is not classified as a medical device and is therefore not subject to the legal regime applicable to such products. The MDR does, in fact, provide guidance as to which types of software are not to be regarded as medical devices[10]. These primarily include general-purpose software used in healthcare and software intended for lifestyle and well-being applications. Examples of general-purpose software include communication systems used in the provision of telemedicine services and in the performance of remote procedures as part of telesurgery[11]. The same category of software also includes information systems whose sole purpose is to archive, collect and transmit data. Lifestyle-related software, in turn, includes mobile applications designed to monitor sleep, support weight

[7] See K. Kokocińska, *Działania władzy publicznej na rzecz rozwoju innowacyjnych technologii w sektorze ochrony zdrowia (polityka unijna i krajowa)* [in:] *Innowacyjne technologie w ochronie zdrowia. Aspekty prawne*, ed. K. Kokocińska, Warsaw 2020, p. 16.
[8] Journal of Laws of 2022, item 974.
[9] K. Stelmasiak, M. Świerczyński, Z. Więckowski, *Badania kliniczne wyrobów medycznych…*, p. 113.
[10] See Recital 19 of the MDR Preamble.
[11] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, pp. 20 et seq., electronic version of the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).

management and facilitate stress management[12]. However, given the absence of detailed provisions in the MDR enabling a clear distinction to be drawn between MDSW and other types of software, the general categories of software identified above as not constituting medical devices do not, in themselves, facilitate the classification of software as MDSW, as discussed in detail in the subsequent part of this article.

The growing importance of MDSW is not solely attributable to the wide range of medical applications for which this type of software can be used. Examples of MDSW include software designed to measure blood glucose levels, calculate the required insulin dose and control an insulin pump so that it administers the calculated dose (closed-loop insulin delivery system). Other examples include software which, on the basis of transrectal ultrasound (TRUS) findings, age and *in vitro* diagnostic results, calculates a patient's risk of developing prostate cancer, as well as mobile applications designed to send notifications to the user and/or healthcare professionals when an irregular heartbeat is detected, with a view to identifying cardiac arrhythmias[13]. MDSW has also proved more effective than clinicians[14] and currently available solutions[15] in the early detection and diagnosis of certain diseases (e.g. heart disease). Equally significant is the social role played by MDSW, as it contributes to greater user involvement in managing their own health. Finally, the economic dimension also provides grounds for analysing the subject matter of this publication. In 2021, the global market for software as a medical device was valued at USD 1,048 million, and its value is expected to reach USD 10,190 million by 2028 (representing a compound annual growth rate (CAGR) of 38.39%)[16].

[12] W. Hartung, J. Schalago, C. Rossi, R. Pavkov, *Software as a Medical Device Fundamentals*, "Pharmaceutical Engineering" July-August 2021, vol. 41, no. 4, p. 48, electronic version of the document: https://ispe.org/sites/default/files/attachments/public/PE_JulyAug21_CompleteIssue_LR.pdf (accessed: 22 December 2022).

[13] Ibid. p. 7.

[14] Software based on an artificial intelligence system, developed by Google Health and Imperial College London, proved more effective than a radiologist in identifying breast cancer in mammography results, F. Walsh, *AI 'outperforms' doctors diagnosing breast cancer*, https://www.bbc.com/news/health-50857759 (accessed: 22 December 2022).

[15] An example can be the algorithms used in Pocket ECG diagnostic technology, which is designed to detect cardiac arrhythmias and enables remote monitoring. This solution proved to be 6 times more accurate than 24-hour ECG recording using a Holter monitor. E. Rutkowski, *Medical Devices and Equipment in Poland. Report 2021*, Polska Agencja Rozwoju Przedsiębiorczości 2021, p. 16, electronic version of the document: https://medical.trade.gov.pl/pl/f/v/610672/PPE_PL_Medical-Devices-and-Equipment-Poland-Report2021.pdf (accessed: 22 December 2022).

[16] Electronic version of the document: *The Software as a Medical Device Report 2022-2028*, https://www.globenewswire.com/en/news-release/2022/06/24/2468710/0/en/Global-Software-as-a-Medical-Device-Market-is-Booming-At-a-CAGR-of-38-39-with-New-Technology-Trending-Applications-Revenue-Growth-by-Top-Leading-Players-and-Future-Demands-and-Fore.html (accessed: 22 December 2022).

There is no doubt that the socio-economic significance of MDSW is considerable and will continue to grow. Accordingly, achieving a balance between the objectives of the MDR, namely establishing regulatory requirements aimed at ensuring a high level of protection of the life and health of patients and users, and creating conditions conducive to the use and development of modern technological solutions within healthcare systems, is particularly important in the context of MDSW. Access to such solutions contributes to improving the level of protection of life and health. However, a necessary condition for the implementation of innovative solutions is their commercialisation and the associated placing on the market[17]. Without commercialisation, the results of research and development activities remain merely research outputs which, as such, are not available to patients and cannot be effectively used to achieve the social and economic objectives of the technology concerned. These circumstances make the proper placing of MDSW on the market a matter of particular significance.

The aim of this article is to provide an overview of the issues surrounding the qualification and classification of software as a medical device in the light of the changes introduced by the MDR. Furthermore, it seeks to answer the question of the extent to which the new regulatory framework ensures a balance between the aforementioned objectives of the MDR in the case of software as a medical device.

The article is divided into three parts. The first examines the development of EU regulations concerning medical software. Since a comprehensive assessment of the new regulations governing MDSW requires them to be considered against the background of regulations on software as a medical device in force outside the EU, the second part discusses selected competing regulatory frameworks from an international perspective, with particular emphasis on those applicable in the United States. The third and principal part of the article analyses the principles adopted under the MDR for the qualification and classification of MDSW, as well as the impact of changes to MDSW following its placing on the market. This part of the article also puts forward a proposal for amending the applicable provisions by way of a *de lege ferenda* recommendation.

[17] A.H. Jasiński, *Komercjalizacja jako element modelu procesowego innowacji*, pp. 13 et seq., electronic version of the document: https://dspace.uni.lodz.pl/xmlui/bitstream/handle/11089/30127/11-25_Komercjalizacja%20jako%20element.pdf?sequence=1&isAllowed=y (accessed: 22 December 2022).

## 1. Software and medical devices under the MDD

Originally, the MDD did not allow software to be recognised as a standalone medical device. Under Article 1(2)(a) of the MDD, only an instrument, apparatus, appliance, material or other article incorporating software could be classified as a medical device[18]. Given this 'lack of independent status' of software under the legal framework then in force, it was automatically classified, pursuant to implementing rule 2.3 of Annex IX to the MDD, in the same risk class as the device which it controlled or the use of which it influenced.

A significant turning point in the perception of software as a medical device occurred in 2007, following an analysis conducted by the Swedish supervisory authority, Läkemedelsverket, concerning the top ten incidents in the healthcare sector[19]. The findings of the analysis indicated that incidents were frequently caused by software malfunctions, resulting, for example, in the loss of database records, the prescription of medication to the wrong patient, incorrect calculation of a medicinal product's dosage, or failure to issue an alert concerning a patient's allergy to a particular active substance. Some of these incidents resulted in patient deaths. Moreover, inspections carried out by Läkemedelsverket revealed that software used in the healthcare sector which should have been classified as a medical device had not undergone a conformity assessment procedure and had not been affixed with the CE marking[20].

These findings provided the impetus for amending the definition of a medical device under Directive 2007/47/EC[21], which amended the MDD. Under the revised definition, software could be recognised as a separate medical device, provided that it met the other criteria laid down in the definition of a medical device[22]. Recital 6 of the Directive amending the MDD

[18] The full definition of a medical device in the MDD, prior to its amendment, as set out in the cited provision, read as follows: 'medical device' means any instrument, apparatus, appliance, material or other article, used alone or in combination, including the software necessary for its proper functioning as intended by the manufacturer, to be used for human beings for the purpose of: 1) diagnosis, prevention, monitoring, treatment or alleviation of disease; 2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; 3) investigation, replacement or modification of the anatomy or of a physiological process; 4) control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

[19] L. Philipson, *Information Systems and Medical Devices. A classification and borderline issue*, Medical Products Agency Sweden 2008.

[20] Ibid.

[21] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ EU L 247/21, 21.09.2007, p. 21).

[22] The full amended definition of a medical device: 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

expressly dispelled any doubts in this regard, stating that: "software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device". At the same time, it was emphasised that the intended purpose of the software, and consequently whether it could be recognised as a medical device, was determined by the manufacturer. The MDD was also amended to introduce an obligation to validate software in accordance with the state of the art, taking into account the principles governing its development life cycle, risk management, validation and verification. This obligation, arising from the new Section 12.1a of Annex I to the MDD, applied both to software constituting a standalone device and to devices incorporating software. Finally, as part of the amendments to the MDD, the classification rules set out in Section 1.4 of Annex IX to the MDD were supplemented by providing that standalone software was to be regarded as an active medical device.

Without anticipating the further discussion of the qualification and classification of software as a medical device under the MDR, it should be emphasised at this point that it would be incorrect to attribute a revolutionary character to the MDR on the grounds that it introduced the possibility of recognising standalone software as a medical device[23]. Such a possibility had already existed since the amendment of the MDD by Directive 2007/47/EC. Rather, the significance of the changes introduced by the MDR lies in the new criteria for the qualification and classification of software and their implications for the medical device industry, as discussed in the subsequent part of this article.

## 2. Software as a medical device from an international perspective

Regulatory frameworks governing software as a medical device are by no means unique on a global scale. A significant number of countries have introduced such regulations, although they differ in scope and level of detail.

The EU Member States and Australia have adopted the most comprehensive regulatory frameworks. The scope of the relevant regulations in China, India, Japan and the countries of South America may be described as intermediate. By contrast, the scope of regulations

1) diagnosis, prevention, monitoring, treatment or alleviation of disease; 2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; 3) investigation, replacement or modification of the anatomy or of a physiological process; 4) control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

[23] Cf. M. Kupis, *Stosowanie przepisów Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/745 do sztucznej inteligencji*, "Przegląd Prawa Medycznego" 2022, no. 1, p. 96.

governing software as a medical device in Russia, Canada and the United States is more limited than in the aforementioned countries[24]. As regards the remaining countries, either no data are available or they have not adopted regulations governing software as a medical device. It is worth noting that these differences also extend to terminology. Outside the scope of application of the MDR, software as a medical device is referred to as SaMD[25]. Taking this terminological distinction into account, it is worth examining in greater detail the concept of SaMD, the scope of its regulation and the procedures for placing it on the market, in comparison with the MDR.

### 2.1. The concept and scope of SaMD

In analysing the concept of SaMD, particular attention should be paid to the guidance developed by the International Medical Device Regulators Forum hereinafter: IMDRF)[26]. Established in October 2011, the IMDRF comprises representatives from Australia, Brazil, Canada, China, the EU, Japan, the Russian Federation and the United States. The World Health Organization (WHO) and the Asia-Pacific Economic Cooperation (APEC) are official observers of the IMDRF. The objective of the IMDRF is to establish conditions conducive to achieving convergence in regulatory standards and practices relating to the safety, performance and quality of medical devices[27]. These tasks are pursued, inter alia, through the adoption of "the same technical documents, standards, scientific principles and similar regulatory practices and procedures"[28]. The work carried out within the IMDRF has resulted in guidance addressing various aspects of SaMD operation[29]. According to the definition adopted by the IMDRF, "SaMD is software intended to be used for one or more medical purposes that perform these

[24] K. Cobbaert, G. Bos, *Software as a medical device. Regulatory and Market Access Implication*, 2021, p. 14.
[25] A.S. Grell, *SaMD versus MDSW: what's the difference between Software as a Medical Device and Medical Device SoftWare?*, 1 September 2021, electronic version of the document: https://qbdgroup.com/en/blog/samd-mdsw-difference/ (accessed: 22 December 2022).
[26] https://www.imdrf.org/ (accessed: 22 December 2022).
[27] In relation to the objectives indicated, the IMDRF is the direct successor to the Global Harmonization Task Force on Medical Devices, which operated between 1993 and 2012.
[28] European Commission, https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/international-cooperation_pl (accessed: 22 December 2022).
[29] *Software as a Medical Device (SaMD): Clinical Evaluation,* 21 September 2017, electronic version of the document: https://www.imdrf.org/documents/software-medical-device-samd-clinical-evaluation (accessed: 22 December 2022), *Software as a Medical Device (SaMD): Application of Quality Management System*, 02 October 2015, electronic version of the document: https://www.imdrf.org/documents/software-medical-device-samd-application-quality-management-system (accessed: 30 November 2022), *Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations*, 18 September 2014, electronic version of the document: https://www.imdrf.org/documents/software-medical-device-possible-framework-risk-categorization-and-corresponding-considerations (accessed: 22 December 2022), *Software as a Medical Device (SaMD): Key Definitions*, 18 December 2013, electronic version of the document: https://www.imdrf.org/documents/software-medical-device-samd-key-definitions (accessed: 22 December 2022).

purposes without being part of a hardware medical device"[30]. Although IMDRF guidance is not legally binding, it frequently provides the foundation for regulatory frameworks in individual countries, which are subsequently supplemented at the national legislative level. A similar approach to the regulation of SaMD has been adopted by the US Food and Drug Administration (hereinafter: FDA), which has issued its own guidance on SaMD[31]. A detailed analysis of the FDA's regulation of SaMD falls outside the scope of this publication. Nevertheless, it is worth outlining the general scope and approach to the regulation of SaMD and comparing them with the regulatory framework governing MDSW.

It follows from the above definition of SaMD that the physical location of the software determines its regulatory status. Where hardware constituting a medical device requires software to fulfil its medical purpose because that software controls the device or influences its use, such software is not considered SaMD[32]. Under the MDR, however, software which drives a medical device (hardware) or influences its use is considered MDSW, provided that the software itself has or fulfils a medical purpose. If such software does not have or fulfil a medical purpose, it is not classified as MDSW; nevertheless, it remains within the scope of the MDR as an accessory to a medical device within the meaning of Article 2(2) of the MDR[33]. Accordingly, the insulin dose calculation software which controls an insulin pump to ensure that it administers the calculated dose, cited above as an example of MDSW, would not qualify as SaMD[34].

In accordance with the definition of a medical device set out in Article 2(1) of the MDR, medical devices also include "devices for the purpose of contraception or promotion of conception". Consequently, software, and mobile applications in particular, designed to identify fertile days and assist in preventing pregnancy are considered MDSW[35]. By contrast, the

[30] Software as a Medical Device (SaMD): Key Definitions, point 5.1, electronic version of the document: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf (accessed: 22 December 2022).
[31] P. Baird, K. Cobbaert, *Software as a medical device. A comparison of the EU's approach with the US's approach*, p. 4, electronic version of the document: https://www.bsigroup.com/globalassets/meddev/localfiles/fr-fr/whitepapers/md-wp-software.pdf (accessed: 22 December 2022).
[32] Ibid.
[33] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 5, electronic version of the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).
[34] A.S. Grell, *SaMD versus MDSW: what's the difference between Software as a Medical Device and Medical Device SoftWare?*, 1 September 2021, https://qbdgroup.com/en/blog/samd-mdsw-difference/ (accessed: 22 December 2022).
[35] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 28, electronic version of

definition of SaMD developed by the IMDRF covers only devices intended for contraception[36]. It should be emphasised that the regulatory provisions proposed by the IMDRF are not always adopted unchanged in national legislation. Accordingly, in the case of a mobile application similar to the one described above, the FDA determined that it was intended to prevent pregnancy and that its placing on the market required prior approval[37].

Another example of a difference in the scope of the concepts of SaMD and MDSW concerns software used in clinical management. In the United States, software intended for use by healthcare professionals which requires them to independently verify and analyse the recommendations provided by the software is not considered SaMD, provided that it does not acquire, process or analyse signals or images. By contrast, a considerably wider range of applications supporting clinical decision-making by healthcare professionals may be classified as MDSW[38]. One example is applications designed to check drug–drug interactions, which are used as part of medication prescribing software[39].

### 2.2 Placing SaMD on the market

Differences between the EU and the United States in the regulation of the subject matter of this publication are not limited to the scope of the concept of software as a medical device itself. Equally significant is the different approach adopted in the two jurisdictions to regulating its market authorisation. The FDA has issued a number of guidance documents concerning software. Certain types of software have been classified as SaMD, while others, despite falling within the product category under discussion, have not been made subject to the relevant

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the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).

[36] *Software as a Medical Device (SaMD): Key Definitions*, point 5.2.1, electronic version of the document: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf (accessed: 22 December 2022).

[37] U.S. Food & Drug Administration (10 August 2018), *FDA allows marketing of first direct-to-consumer app for contraceptive use to prevent pregnancy*, https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-app-contraceptive-use-prevent-pregnancy (accessed: 22 December 2022).

[38] P. Baird, K. Cobbaert, *Software as a medical device. A comparison of the EU's approach with the US's approach*, p. 5, electronic version of the document: https://www.bsigroup.com/globalassets/meddev/localfiles/fr-fr/whitepapers/md-wp-software.pdf (accessed: 22 December 2022).

[39] Ibid.

regulations through the exercise of enforcement discretion[40,41]. The choice of the pathway for obtaining market authorisation for SaMD in the United States is also characterised by flexibility. For class I medical devices, i.e. those presenting the lowest risk, registration of the medical device, together with the submission of an appropriate application to the FDA, is sufficient. In such cases, it is not necessary to identify another device that is substantially equivalent to the device covered by the application[42]. For lower-risk devices, namely those belonging to class I and, predominantly, class II, the 510(k) procedure may be used, under which SaMD must be notified to the FDA. In this case, however, it is necessary to demonstrate that the SaMD is substantially equivalent to software that has already been authorised for marketing, which provides the basis for the FDA to grant market authorisation. The identification of reference devices is facilitated by databases made available by the FDA[43]. Devices belonging to the highest risk class, class III, generally require FDA approval for marketing following the completion of the device evaluation procedure (Pre-Market Approval, hereinafter PMA)[44]. For devices without an equivalent that has already been authorised for marketing, the appropriate procedure is either the PMA procedure or the de novo procedure, which applies to new types of devices presenting a low level of risk that have not previously been classified[45]. It is worth noting here the particularly interesting FDA pilot programme aimed at developing an additional market authorisation pathway, namely Digital Health Software Precertification. This pathway is intended exclusively for medical software and envisages the assessment of the manufacturer rather than the product, which constitutes a significant *novum* in the context of the assessment preceding the placing of a medical device on the market. The aim of this procedure is to ensure the rapid introduction to the market of

[40] The FDA's exercise of enforcement discretion applies where the risk to the patient associated with a given product is assessed as low and the product belongs to a product group identified by a product code for which marketing authorisation has already been granted. During the COVID-19 pandemic, this procedure made it possible to place on the market unverified medical devices which, nevertheless, were essentially equivalent to medical devices already authorised for marketing. The purpose of this approach was to ensure continuity of supply for patients and users. A. Clark, *FDA guidances for medical device regulation after enforcement discretion and EUA expiration*, 23 May 2022, electronic version of the document: https://www.raps.org/news-and-articles/news-articles/2022/5/fda-guidances-for-medical-device-regulation-after (accessed: 22 December 2022).

[41] Author's own translation. [This footnote refers to a translation from English to Polish made in the original version of the article – editor's note].

[42] U.S. Food & Drug Administration, *How to register and list*, https://www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list (accessed: 22 December 2022).

[43] For the 510(k) procedure: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (accessed: 22 December 2022).

[44] U.S. Food & Drug Administration, *PMA Review Process*, https://www.fda.gov/medical-devices/premarket-approval-pma/pma-review-process (accessed: 22 December 2022).

[45] U.S. Food & Drug Administration, *De Novo Classifcation Request*, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request (accessed: 22 December 2022).

software developed by manufacturers who, through their excellence and organisational culture, as well as their ability to monitor and oversee software after it has been placed on the market, are capable of ensuring its safety and effectiveness[46].

Against this background, the regulatory framework governing MDSW under the MDR appears to be more general in nature and may therefore give rise to uncertainties in its practical application[47]. The market authorisation pathway depends on the risk class to which the device belongs. The involvement of a notified body in the process of placing a medical device on the market is required not only for higher-risk classes, namely Classes IIa, IIb and III, but also, pursuant to Article 52(7) of the MDR, for devices placed on the market in a sterile condition, devices with a measuring function and reusable surgical instruments, all of which belong to the lowest risk class, class I. The classification rules for MDSW, set out in Annex VIII to the MDR, should themselves be regarded as complex. Without anticipating the detailed discussion of MDSW classification in the subsequent part of this publication, it should merely be noted that these rules will, in the vast majority of cases, result in MDSW being classified in a risk class higher than class I. In this context, it is worth mentioning that, pursuant to Article 61(1) of the MDR, clinical evaluation is mandatory for medical devices of all classes, while the obligation to conduct clinical investigations applies, as a general rule, to all implantable devices and class III devices.

The above observations lead to the conclusion that the regulation of software as a medical device under the MDR does not constitute a revolutionary change, either from a historical or an international perspective. The MDD had already regulated standalone software, while the concept of MDSW, even taking into account its broader scope, does not differ fundamentally from that of SaMD. The significance of the changes introduced by the MDR in relation to software as a medical device should therefore be sought primarily in the criteria governing its qualification and classification, rather than in the granting of medical device status to standalone software.

It should nevertheless be emphasised that the rules governing the placing of SaMD on the market in the United States appear to be more flexible and transparent than those applicable to MDSW. This not only places entities operating in the US market in a more favourable position

[46] U.S. Food & Drug Administration, *Digital Health Software Precertification (Pre-Cert) Pilot Program*, https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program (accessed: 22 December 2022).

[47] The MDR still contains relatively few provisions specifically intended to regulate software, apart from the rules used for classification purposes.

and may determine the choice of that jurisdiction as the preferred one for placing software as a medical device on the market. More importantly, it may also affect patients' access to modern diagnostic and treatment methods, which often depend precisely on the availability of appropriate software. It is worth noting that the solutions developed by the FDA in this area are also recognised in other countries, such as Australia[48] and Switzerland[49], which are introducing far-reaching facilitations for the placing on the market of medical devices previously authorised by the FDA.

### 3. Qualification and classification of software under the MDR

The discussion of the qualification and classification of software as MDSW should be preceded by an explanation of why the proper conduct of both processes is of such great importance, including from the perspective of commercial activity. Pursuant to Article 6(1) of the MDR, the provisions of the Regulation apply to devices offered by means of information society services[50] to a natural or legal person established or residing in the Union. This means that the personal scope of application of the MDR is exceptionally broad. For example, a mobile application provider established in India which offers its application through an online platform enabling a natural person residing in the EU to download it will also be required to comply with the requirements arising from the MDR, provided that the application is classified as MDSW within the meaning of the MDR. Furthermore, the online platform referred to in this example will be required to obtain a declaration of conformity from the application provider, since, pursuant to Article 6(2) of the MDR, an entity offering a device to a natural or legal person established or residing in the EU is obliged to make a copy of the declaration of conformity available at the request of the competent authority.

[48] Therapeutic Goods Administration, *Use of market authorisation evidence from comparable overseas regulatory bodies for medical devices*, https://www.tga.gov.au/resources/resource/guidance/qa-use-market-authorisation-evidence-comparable-overseas-regulatory-bodies-medical-devices (accessed: 22 December 2022).

[49] Swiss Medical Technology Association, *Politicians decide in favour of patient care*, https://www.swiss-medtech.ch/en/news/politicians-decide-favour-patient-care (accessed: 22 December 2022).

[50] Pursuant to Article 1(1)(b) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, 'service' means any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services. For the purposes of this definition: (I) 'at a distance' means that the service is provided without the parties being simultaneously present; (II) 'by electronic means' means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and is entirely transmitted, conveyed and received by wire, radio, optical means or other electromagnetic means; (III) 'at the individual request of a recipient of services' means that the service is provided through the transmission of data on individual request.

It would appear, however, that the most severe consequence of the incorrect qualification and classification of a medical device for an individual entrepreneur is the imposition of penalties, the regulation of which has been entrusted to the Member States pursuant to Article 113 of the MDR. In Poland, the relevant provisions are set out in Chapter 16 of the Medical Devices Act. With regard to administrative financial penalties associated with the incorrect qualification and classification of a medical device, particular attention should be paid to sections 1 and 2 of Article 74 of the aforementioned Act. The former regulation provides for a financial penalty ranging from PLN 20,000 to PLN 5,000,000 to be imposed on an entity placing on the market or putting into service devices that do not meet the general safety and performance requirements laid down in Annex I to the MDR. Since these requirements apply to all medical devices, placing on the market a product incorrectly classified as not being a medical device, and consequently not meeting the requirements set out in Annex I to the MDR, may result in an obligation to pay a financial penalty within the aforementioned limits. Incorrect classification of a medical device, for example, as a class I device, may in turn result in a conformity assessment being carried out without the involvement of a notified body. Consequently, the manufacturer may conduct the conformity assessment in a manner contrary to Annexes IX–XI to the MDR and, pursuant to Article 74(2) of the Medical Devices Act, be subject to a financial penalty of up to PLN 500,000.

### 3.1 Qualification of MDSW

The starting point for qualification as MDSW is the determination that the product in question constitutes software. In the absence of a definition of software in the MDR itself, recourse should be made to the definition proposed in the MDCG guidance, according to which software is "a set of instructions that processes input data and creates output data"[51]. The same guidance defines MDSW as "software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a «medical device» in the medical devices regulation or in vitro diagnostic medical devices regulation"[52]. Accordingly, the intended purpose of the software, as determined by the manufacturer, is of fundamental importance for its qualification as MDSW[53]. It may therefore be concluded that software will be classified as MDSW if, in accordance with

[51] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 28, electronic version of the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).
[52] Ibid., p. 6.
[53] Ibid.

the intended purpose specified by the manufacturer, it fulfils purposes falling within the definition of a medical device set out in Article 2(1) of the MDR[54].

It should nevertheless be emphasised that the intended purpose of a product as specified by the manufacturer constitutes only the subjective element in the qualification of a medical device. In its judgement of 22 November 2012, the CJEU ruled that the manufacturer's intention that an object be used for medical purposes is a necessary condition for its recognition as a medical device[55]. However, the manufacturer's discretion in this respect does not mean that it is free to classify a product as a medical device at will[56]. As follows from the Opinion of the Advocate General in the aforementioned case, "any product which, by its very nature, is clearly intended to be used solely for a purpose of a medical nature will have to be regarded as a medical device, even if the manufacturer does not describe it as such"[57]. Consequently, where a product is placed on the market without being classified by the manufacturer as a medical device, despite clearly serving the medical purposes set out in the definition of a medical device, the consequence should be that the product is recognised as a medical device that has been improperly placed on the market, potentially giving rise to corresponding administrative liability on the part of the manufacturer, to be determined *ad casum*. The fulfilment of a medical purpose specified in the definition of a medical device therefore constitutes an objective and necessary element of qualification as MDSW.

Qualification of software as MDSW is independent of the location of the software. It may be hosted in cloud computing infrastructure, on a computer or mobile phone, or incorporated as an additional functionality into another medical device in the form of hardware[58]. It is worth noting here that the MDR moves away from the concept of standalone software, since its location is irrelevant to its qualification and classification as MDSW[59]. Similarly, the method of connection between the software and the device (via cable, wirelessly or through Bluetooth) is not relevant to qualification as MDSW[60]. Furthermore, the qualification process is unaffected

[54] See p. 5.
[55] Judgement of the CJEU of 22.11.2012, C-219/11, paragraph 33.
[56] See J. Prütting, T. Wolk, *Software unter dem Regime der europäischen Medizinprodukteverordnung (2017/745/EU)*, "Medizinrecht" 38 (2020), p. 360.
[57] Opinion of Advocate General Paolo Mengozzi of 15 May 2012, case C-219/11, paragraph 63, electronic version of the document: https://eur-lex.europa.eu/legal-content/PL/TXT/HTML/?uri=CELEX:62011CC0219&from=EN (accessed: 22 December 2022).
[58] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 7, electronic version of the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).
[59] Ibid., p. 3.
[60] Ibid., p. 16.

both by whether the software is intended for use by healthcare professionals or laypersons and by the level of risk to patients and users arising from its use[61].

When analysing the circumstances that are not decisive for the qualification of software as a medical device, it is essential to refer to the CJEU judgement of 7 December 2017, which is of fundamental importance for determining whether software may be recognised as a medical device. According to the position expressed by the CJEU in that judgement, "the EU legislature intended to focus, in order to classify software as a medical device, on the purpose of its use and not the manner in which the effect it is capable of producing on or in the human body is likely to materialise"[62]. It is therefore not necessary for a product to act directly within or upon the human body in order to be recognised as a medical device. It should be emphasised that adopting a different position would effectively preclude the possibility of recognising software as a medical device[63]. By defining the scope of the concept of a medical device broadly, the aforementioned judgement also contributes to ensuring a high level of health protection[64].

As mentioned *supra*, software that drives a medical device or influences its use may also qualify as a medical device, provided that the software itself has or fulfils a medical purpose, or itself provides information for one or more of the medical purposes specified in the definition of a medical device[65]. Software that does not meet this condition cannot be classified as a medical device. It will be regarded as an accessory to a medical device (Article 2(2) MDR), to which the provisions of the MDR apply pursuant to Article 1(4) MDR. Examples of such accessories include software that operates, modifies the state of, or controls a medical device through the device's interface or operator, or provides output data relating to the functioning of a medical device[66]. At the qualification stage, the practical significance of the distinction between software that drives a medical device or influences its use while itself having or fulfilling a medical purpose, and software that does not have or fulfil such a purpose, is limited. However, this distinction plays a significant role at the classification stage.

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[61] Ibid., p. 7.
[62] Judgement of the CJEU of 7.12.2017, C-329/16, paragraph 29.
[63] Ibid., paragraph 28.
[64] S. Majkowska-Szulc, *Ramy prawne certyfikacji wyrobów medycznych na przykładzie oprogramowania wspomagającego przepisywanie leków. Glosa do wyroku Trybunału Sprawiedliwości z 7 grudnia 2017 r., C -329/16*, "Gdańskie Studia Prawnicze" 2021, vol. 49, no. 1, p. 142.
[65] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 8, electronic version of the document:
https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 20 December 2022).
[66] Ibid.

It is also necessary to consider whether software containing a module that fulfils a medical purpose can qualify as MDSW. It may be the case that only one module fulfils a medical purpose, whereas the functionalities of the remaining software modules do not fall within the scope of the definition of a medical device. This raises the question of whether the presence of a single module that fulfils a medical purpose determines whether the entire software, including its 'non-medical' modules, is recognised as MDSW. The MDCG guidance provides the answer: modules falling within the scope of the MDR must meet the requirements applicable to medical devices and bear the CE marking. The remaining modules are exempt from these obligations. In such cases, however, the manufacturer is required to clearly distinguish the modules that constitute MDSW from the other modules. In addition, the software as a whole, comprising modules classified as MDSW as well as other modules, devices and accessories intended to operate together, must be safe and ensure that the functioning of modules regulated by the MDR is not adversely affected. This requirement also applies to the way in which the individual modules are connected[67]. The position outlined above should be endorsed. Adopting a different approach would lead to a legal fiction whereby software comprising different modules would be recognised as a medical device, even though, considered as a whole, it would not provide grounds for classification as MDSW. At the same time, this would make it more difficult to place non-medical modules on the market, thereby limiting access to the functionalities they offer as components of the software.

### 3.2 Classification of MDSW

The fundamental changes introduced by the MDR in relation to MDSW concern, above all, the classification of MDSW, i.e. the assignment of a medical device to a particular risk class. The correct classification of a medical device is of great importance at every stage of its life cycle and affects, among other things, the content of the technical documentation, the quality management system, clinical evaluation and the level of cybersecurity. Above all, however, it determines whether the involvement of a notified body is required as part of the conformity assessment of the device. The rules for the classification of medical devices, including those specifically concerning MDSW, are set out in Annex VIII to the MDR. An analysis of these rules should, however, be preceded by a brief reference to the classification rules applicable before the MDR. As explained *supra*, software that drives a device or influences its use was automatically assigned to the same class as the device. As a general rule, however, standalone

[67] Ibid., p. 18.

software, being an active device, was classified as class I pursuant to Rule 12 of Annex IX to the MDD. Most MDSW placed on the market in accordance with the MDD also belongs to this risk class.

### 3.2.1 Classification rules under the MDR

It should be noted that, under the MDR, MDSW is still regarded as an active device, i.e. a device whose operation depends on a source of energy[68]. Accordingly, Rules 9–13 and 22 of Annex VIII apply to MDSW. In practice, however, the relevance of Rules 9, 10 and 12 to MDSW will be very limited, as these rules classify devices intended to fulfil diagnostic and therapeutic purposes and devices intended to exchange energy or substances between the body and the device[69].

Rules 3.3 and 3.5 of Annex VIII to the MDR are of particular importance for the classification of software. Under the former, software that is independent of other devices should be classified separately. By contrast, software that drives a device or influences its use is classified in the same class as that device. If one relies solely on a literal interpretation, the interpretation of this provision gives rise to certain doubts. The main question is whether the distinction made at the qualification stage between software that drives or influences the use of a medical device and itself has a medical purpose, and software that does not have such a purpose, should also be reflected in the classification. Since having a medical purpose determines whether software is recognised as MDSW, whereas the absence of such a purpose results in its being recognised as an accessory to a medical device, it is reasonable to limit the application of the first sentence of Rule 3.3 precisely to software constituting an accessory to a medical device[70]. Such a distinction is *novum* in comparison with the MDD. Under the latter, any software that drove a device or influenced its use was automatically assigned to the same class as the device, irrespective of whether it had or fulfilled a medical purpose[71].

At the same time, the MDCG guidance expresses the view that Rule 3.3 should also serve to establish the minimum class to which software that drives a medical device or influences its use

[68] See Article 2(4) of the MDR.
[69] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 12, electronic version available at: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).
[70] Ibid.
[71] See Section 2.2 of Annex IX to the MDD.

should belong[72]. This means that, even where such software itself fulfils a medical purpose, its risk class should not be lower than that of the medical device (hardware) which it drives or whose use it influences. This view should be assessed negatively. Not only does it lack any basis in the provisions of the MDR, but it is also inconsistent with the assumption adopted above. If software that drives a medical device or influences its use and itself has a medical purpose is granted the status of a separate medical device (MDSW), then the lower limit of its classification should likewise not be restricted by the risk class of another medical device (hardware). Accordingly, it seems reasonable to conclude that the classification of such software should be independent of, and unrestricted by, the risk class of the medical device (hardware).

In analysing the classification rules, two further rules of an organisational nature should also be noted. The first of these, Rule 3.5, provides that where several rules or several sub-rules apply to the same device on the basis of its intended purpose, the strictest rule or sub-rule, resulting in its classification in a higher class, shall apply. It may be assumed that Rule 3.5 will further support the application of Rule 11. Given its broad scope of application, Rule 11 may frequently conflict with other rules and, as it leads to classification in higher risk classes, will take precedence in its application. Rule 13, in turn, applies to active devices and therefore to all MDSW. Under this rule, where the other rules concerning active devices, i.e. Rules 9–12, do not apply, the device will fall within class I.

### 3.2.2 Rule 11 and its consequences

Rule 11 of Annex VIII to the MDR, which had no equivalent under the MDD, is of central importance for the classification of MDSW[73]. The wording of this provision – "software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa" – has two consequences. First, Rule 11 does not distinguish

[72] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 12, electronic version of the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).

[73] Rule 11: "Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause: death or an irreversible deterioration of a person's state of health, in which case it is in class III; or a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.
Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.
All other software is classified as class I."

between who will take the diagnostic or therapeutic decision. The scope of this rule is therefore not limited to information provided for the purpose of a diagnostic or therapeutic decision taken exclusively by a human being. Such decisions may be taken and subsequently implemented by the software itself[74]. Secondly, the nature of the decisions in question means that, in practice, the vast majority of MDSW will fall within class IIa. Furthermore, under Rule 11, software intended for monitoring physiological processes must also belong to at least risk class IIa. It should be noted, however, that Rule 11 applies exclusively to software that monitors the functioning of a medical device (hardware) for medical purposes[75]. MDSW not used for the above purposes, or for their risk-qualified forms, will be classified as belonging to class I.

Under the wording of Rule 11 quoted above, virtually all MDSW providing information for diagnostic or therapeutic purposes will, in practice, belong to at least class IIa. The implications of this situation are of fundamental importance, since the conformity assessment of MDSW belonging to Class IIa or higher classes would have to involve a notified body authorised to do so under the MDR. It should be emphasised that the number of notified bodies authorised to carry out conformity assessments under the MDR is limited[76]. When assessing the availability of these bodies, account should be taken not only of their lower number compared with the number of notified bodies authorised to carry out conformity assessments under the MDD[77], but also of the fact that, in view of the above observations concerning the classification of MDSW, demand for their services will increase under the MDR. The conclusions drawn from the experience of applying the MDR to date indicate that the problem is not limited to a shortage of notified bodies. Significant obstacles may also include the excessive time required for certification under the MDR and the lack of certainty regarding the regulations applicable to the placing of medical devices on the market[78]. The consequences of these difficulties and

[74] E. Vollebergt, *Enriched MDR and IVDR*, 2021, p. 676.
[75] Ibid., p. 677.
[76] At the time this article was completed, there were 39 notified bodies across the EU, of which only two were notified bodies operating in Poland. https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=bodyTypeId:3,legislationId:34 (accessed: 14 July 2023).
[77] A total of 55 notified bodies were authorised to carry out conformity assessments under the MDD: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.pdf&refe_cd=93%2F42%2FEEC&requesttimeout=900 (accessed: 22 December 2022).
[78] According to a MedTech Europe report, the certification process under the MDR takes an average of 13–18 months. To date, only an average of 14% of all medical devices placed on the market have been certified in accordance with the MDR. However, the consequences of the changes to the certification rules resulting from the MDR are borne primarily by small and medium-sized enterprises. In their case, only 7% of the devices placed on the market have been certified in accordance with the MDR. Unfortunately, the MDR also appears to be unfavourable to innovative products, which undoubtedly include MDSW. Only approximately 10% of the certified products are new products, while the remaining 90% are products that were already part of manufacturers' portfolios. Among the reasons identified for this situation are, inter alia, the fact that MDCG guidance documents

constraints are particularly severe for MDSW manufacturers. In software development in particular, the time between the emergence of a product concept and its introduction to the market may determine the success or failure of a given product and, ultimately, the survival of the undertaking concerned[79]. Start-ups, which are numerous among software developers, generally have limited financial resources until their software is placed on the market. The burdens associated with preparing extensive technical documentation and meeting other regulatory requirements at the product development stage will therefore be particularly onerous for this group of undertakings[80]. All the circumstances described above may not only significantly restrict patients' and users' access to innovative medical software, but also adversely affect the position of software manufacturers in the medical device industry.

### 3.2.3 Attempts to address the consequences of applying Rule 11

The Medical Device Coordination Group seeks to mitigate the consequences for the classification of MDSW arising from the application of Rule 11 by indicating in its guidance that this rule is intended to reflect the SaMD classification principles developed by the IMDRF[81]. Classification based on the IMDRF guidance involves taking into account a combination of the significance of the information provided by the software for making a medical decision and the specific clinical situation or health condition of the patient. Applying this combination of assessment criteria, in accordance with Annex 3 to MDCG 2019-11, would significantly alleviate the effects of applying Rule 11 by allowing MDSW to be classified in lower risk classes. It nevertheless seems problematic that the MDCG seeks to achieve the above objective, which is otherwise sound and justified, on the basis of non-binding guidance, while referring to classification principles established by the IMDRF, which are even less binding within the EU. Subsequent guidance concerning the classification of all medical devices does

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are not drafted in clear terms and are sometimes directly contradictory to the wording of the MDR. Guidance documents concerning classification, namely MDCG 2021-24, were singled out for criticism. *MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 June 2022*, electronic version of the document: https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf (accessed: 22 December 2022).

[79] M. Berensmann, M. Gratzfeld, *Anforderungen für die CE-Kennzeichnung von Apps und Wearables*, "Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz" 2018, no. 61, p. 319.

[80] Ibid., p. 320.

[81] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 14, electronic version of the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 22 December 2022).

not fundamentally alter this picture either[82]. It indicates that, when classifying MDSW, consideration should be given to its intended purpose, the context of its use, the information it provides and the decisions taken on the basis of that information. In essence, this corresponds to the aforementioned criterion for assessing the risk associated with the use of a given MDSW. The approach presented in the MDCG guidance does not resolve two fundamental problems.

First, insofar as Rule 11 classifies MDSW as class IIa, it does not take the risk factor into account. A literal interpretation of this provision leads to the conclusion that it establishes an automatic classification of software as class IIa, provided that the software supplies information used to take decisions for diagnostic or therapeutic purposes. Despite the unambiguous results of the literal interpretation, the particular role played by teleological interpretation in the interpretation of EU law should be taken into account when interpreting Rule 11[83]. The functions of teleological interpretation in EU law include promoting a particular objective, preventing undesirable outcomes and filling gaps[84]. Classifying software that meets the above criteria as belonging to at least class IIa, thereby requiring the involvement of a notified body in the conformity assessment process, undoubtedly serves to ensure a high level of protection of the health of patients and users. This, in turn, is an objective expressed in the Preamble to the MDR and prevents the placing on the market of devices that theoretically guarantee a lower level of safety, where conformity assessment is carried out by the manufacturer itself. It is also difficult to identify any regulatory gap in the aspect of Rule 11 under consideration. The risk posed by a medical device has been taken into account in the MDR at various stages of the product life cycle. Nor has this element been overlooked in the establishment of the classification rules under the MDR, including Rule 11 itself. This rule takes account of the risk posed by a given MDSW to life and health, but only at the stage of classification into higher risk classes. Teleological interpretation therefore also leads to the conclusion that MDSW providing information used for the above purposes is automatically assigned to class IIa, without the risk being taken into account at this stage. The MDCG guidance, partly by referring to IMDRF provisions and relying on risk assessment, produces classification outcomes that differ from those resulting from the MDR, without explaining or further developing the

[82] Medical Device Coordination Group 2021-24, *Guidance on classification of medical devices*, October 2021, electronic version available at: https://health.ec.europa.eu/system/files/2021-10/mdc-g_2021-24_en_0.pdf (accessed: 30 November 2022).
[83] J. Helios, W. Jedlecka, *Wykładnia prawa Unii Europejskiej ze stanowiska teorii prawa*, Wrocław 2018, p. 178, electronic version of the document: https://repozytorium.uni.wroc.pl/Content/89794/PDF/Wykladnia_prawa_Unii_Europejskiej_ze_stanowiska_teorii_prawa.pdf (accessed: 22 December 2022).
[84] Ibid., p. 180.

classification rules laid down in the MDR. Rather, it appears that the MDCG guidance in this respect replaces the MDR classification rules by adopting risk assessment criteria that lead to less stringent classification outcomes than those prescribed by the MDR. Attempts to replace the MDSW classification principles arising from a directly applicable Regulation should be assessed negatively.

Secondly, by changing the classification outcomes resulting from the MDR, which, in the author's view, is impermissible, the MDCG guidance does not effectively remove the main barrier to the availability of MDSW to patients and users and therefore fails to achieve its stated objective. The involvement of notified bodies in the conformity assessment procedure, particularly their availability, should be regarded as such a barrier. In effect, the MDCG guidance identifies only one type of software that belongs to class I and does not require the involvement of a notified body in the conformity assessment process[85]. Irrespective of the examples provided in the MDCG guidance, the number of types of software that could be classified as class I, even taking into account the modified classification rules introduced by that guidance, will be marginal.

In view of the above, as a *de lege ferenda* proposal, it is suggested that the European legislator should incorporate directly into the MDR a solution enabling MDSW to be classified as class I more easily. This proposal could be implemented by adding the following sentence to Rule 11 of Annex VIII to the MDR:

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, as well as software intended for monitoring physiological processes, is classified as class I if the risk associated with the use of the software to the life and health of the patient, user or another person, or to public health, is low.

The proposed wording would make it possible to classify software as class I on the basis of a risk criterion arising directly from the Regulation itself[86]. Once anchored in the MDR, this risk criterion could be further specified in the MDCG guidance. Importantly, the proposed solution would make it possible to classify software as class I on the basis of the degree of risk associated

[85] This refers to menstrual calendars for women that do not provide information for diagnostic or therapeutic purposes. MDCG 2021-24, *Guidance on classification of medical devices*, October 2021, p. 44, electronic version of the document: https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf (accessed: 22 December 2022).

[86] Cf. J. Prütting, T. Wolk, *Software unter dem Regime der europäischen Medizinprodukteverordnung (2017/745/EU)*, "Medizinrecht" 38 (2020), pp. 364 et seq.

with its use, even where its intended purpose currently determines its classification in at least class IIa.

### 3.3 Changes to MDSW

Changes made to MDSW after it has been placed on the market are an issue that requires separate consideration. Whereas, in the case of medical devices other than software, such changes or modifications are not the norm, the development of MDSW, and updates in particular, occur much more frequently. It is all the more surprising, therefore, that the MDR contains no specific provisions governing changes to MDSW. Under the general provisions concerning changes to a medical device that has already been placed on the market, set out in Section 4.10 of Annex IX to the MDR, such changes require approval by a notified body if they could affect the safety or performance of the device, or the conditions of use recommended for it. This raises the question of whether, owing to their specific characteristics, particularly their frequency and importance for ensuring software safety, changes to MDSW should be treated differently from changes to other medical devices. In seeking to answer this question, the MDCG guidance concerning the issue under consideration should first be taken into account[87]. According to this guidance, manufacturers should assess the impact of changes on the functions, intended purpose, essential design and production characteristics, as such changes may lead to modifications in the qualification and classification of the software. It is also indicated that the manufacturer must ensure the safety and performance of MDSW throughout the entire product life cycle by continuously evaluating it clinically and managing the associated risks. The MDCG guidance not only fails to answer the question of when changes to MDSW require approval by a notified body, but also provides no basis for drawing conclusions about any specific characteristics of changes to software that would justify treating them differently from changes to other medical devices.

The issue of changes to software was also addressed in the European Commission's 2022 update of the Blue Guide[88]. The Blue Guide proves more helpful than the MDCG guidance in analysing the issue under consideration, stating that "a product should be considered as

[87] Medical Device Coordination Group 2019-11, *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR 2019-11*, p. 18, electronic version of the document: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (accessed: 30 November 2022).

[88] Commission Notice – The 'Blue Guide' on the implementation of EU product rules 2022, 2022/C 247/01, p. 18, electronic version of the document: https://eur-lex.europa.eu/legal-content/PL/TXT/PDF/?uri=CELEX:52022XC0629(04)&from=EN (accessed: 30 November 2022).

substantially modified by a software change where: (i) the software update modifies the original intended functions, type or performance of the product and this was not foreseen in the initial risk assessment; (ii) the nature of the hazard has changed or the level of risk has increased because of the software update; and (iii) the product is made available (or put into service where this is covered by the specific Union harmonisation legislation)"[89].

It should therefore be assumed that the decisive factor in assessing the significance of changes to software is the element of risk. An increase in risk or a change in its nature, not taken into account in the previous risk assessment, makes it possible to conclude that the change to the software was substantial. In view of the above observations, and with a view to guaranteeing patients and users access to up-to-date versions of MDSW, it seems reasonable to conclude that only a substantial change to MDSW, as understood above, should justify the need for approval by a notified body and may lead to a change in the qualification or classification of software already placed on the market.

**Conclusion**

The considerations presented provide grounds for concluding that the changes introduced by the MDR have varying implications for medical software. Such software could already have been recognised as a separate medical device, and the changes in this respect, including in comparison with other non-EU regulatory frameworks, are not revolutionary in nature. The changes introduced with regard to the classification of medical devices should be assessed quite differently. In this area, they primarily affect the legal and economic position of medical device manufacturers.

The analysis of the classification rules may be summarised as follows. Rule 11 of Annex VIII to the MDR determines that the placing on the market of the vast majority of MDSW will require the involvement of notified bodies. This fact, combined with the limited number of such bodies and the time required to complete the certification process, poses a risk of significantly restricting access to innovative software-based medical devices. The position of MDSW manufacturers is further complicated by the MDCG guidance, which independently reclassifies software in relation to the classification rules arising from the MDR in a manner that is not always consistent with, and sometimes directly contradicts, the MDR.

[89] Ibid., p. 18.

The stricter classification rules, combined with the MDCG guidance which, in the author's view, contradicts those rules in the cases identified above, may result in the market on which innovative software is first placed being one other than the European market, for example the US market. As explained *supra*, the latter also regulates the placing on the market of software that constitutes a medical device, while simultaneously taking into account the protection of patients and its users. The US legislator nevertheless demonstrates greater flexibility in allowing software to be placed on the market, thereby creating conditions for patients and users to enjoy better access to innovative medical solutions than is the case in the EU.

It should also be noted that the MDR does not regulate the significant changes introduced in relation to the provisions forming the basis for qualification as a medical device. The failure to take into account in the MDR the conclusions arising from the aforementioned judgement of the CJEU of 22 November 2012 should be assessed negatively. In the light of this judgement, the intended purpose specified by the manufacturer is not the sole criterion for qualification as a medical device, since, as a subjective element, it is corrected on the basis of the objective purpose of the device. Such a correction may result in software being recognised as a medical device despite a different intended purpose specified by the manufacturer. Clear regulation of this issue in the MDR, particularly in the context of the high financial penalties adopted in certain Member States (e.g. Poland) for placing on the market devices that do not meet the general requirements concerning safety and performance, would contribute to greater legal certainty in the market for this group of medical devices.

Ultimately, it should be concluded that the changes introduced by the MDR may disrupt the balance between guaranteeing a high level of protection of the life and health of patients and users of MDSW, and taking into account the interests of small and medium-sized enterprises operating in this sector, which are objectives of the Regulation. The new provisions do not sufficiently take into account the circumstances of the aforementioned groups of undertakings and make access to innovative medical technologies more difficult. It therefore seems reasonable to conclude that they conflict with at least one of the objectives of the MDR. At least one, since restricted access to innovative healthcare solutions will ultimately also have an adverse effect on the level of protection of patients' life and health. Intervention by the European legislator is therefore desirable, with a view to achieving both of the aforementioned objectives of the MDR more fully and restoring the balance between them. Such intervention could take into account the amendment to Rule 11 of Annex VIII to the MDR proposed in this article as part of the *de lege ferenda* proposal.

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