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AI-DRIVEN WEARABLES IN HEALTHCARE: RETHINKING THE LEGAL FRAMEWORK FOR SMARTWATCHES

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Abstract: *The increasing use of wearable technologies like smartwatches has revolutionised personal health tracking, offering features such as heart rate monitoring and atrial fibrillation detection. Despite their advanced health-monitoring capabilities, these devices are still classified as consumer electronics rather than medical devices within the legal frameworks of the European Union and Slovakia. This legal distinction poses significant challenges related to user safety, device reliability, and regulatory oversight. Current regulations, including the European Union's Medical Devices Regulation, impose strict standards on medical devices that smartwatches, as wellness products, are not required to meet. This paper examines the legal rationale behind the non-classification of smartwatches as medical devices and highlights the gaps in regulatory frameworks. Through a comparative analysis of Slovak and European laws, the study reveals the challenges in regulating AI-driven wearables and suggests the need for legal reforms to better integrate these technologies into healthcare, ensuring a balance between innovation, safety, and accountability.*

Key words: *Information Technology Law; Medical Device Regulation; AI-Driven Wearables; Health Monitoring; Technologies in Healthcare*

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1. INTRODUCTION

The fast development of smart wearable technologies (hereinafter referred to as the "**smart wearables**" or the "**wearables**") over the last years has significantly influenced the way people monitor their health and overall well-being. Smart wearables are defined as a subset of the Internet of Things (Moshawrab et al., 2022). A good example of this trend is **smartwatches**, which have transformed from a simple time-keeping accessory into a multifunctional device capable of measuring vital signs, tracking fitness parameters, monitoring pulse or oxygen saturation, and even detecting potential health risks such as irregular heart rhythms (Hudock et al., 2024). These devices often **incorporate artificial intelligence** (hereinafter referred to as the "**AI**") which enables them to process health data and provide users with an interpretation of various outcomes (Hosseini et al., 2023). To illustrate, we can mention a smartwatch developed by the American company Apple, which integrates electrocardiogram functionality (hereinafter referred to as the "**ECG**") allowing users to monitor heart rhythms and detect anomalies that could indicate conditions like atrial fibrillation.[1] Nevertheless, despite offering functions that closely align with those of medical devices, smartwatches are not classified as medical devices, as they are not intended for medical purposes (Ribeiro,

[1] Apple Inc. has conducted multiple clinical trials to validate its wearable health features, including the ECG app and Irregular Rhythm Notification, demonstrating their effectiveness in detecting atrial fibrillation (Apple Heart Study, 2018).

2023). This criterion forms one of the defining characteristics of a medical device under the legislation, which will be further discussed below in this paper.

The European Union (hereinafter referred to as the "**EU**") adopted Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices[2] (hereinafter referred to as the "**Medical Devices Regulation**" or "**MDR**") that prescribes **safety requirements** ensuring that products marketed for medical purposes are clinically tested, reliable, and effective. Among its most important provisions is the obligation of a **clinical evaluation**, which Article 2(4) MDR defines as a systematic and planned process of generating, collecting, analysing, and assessing clinical data in order to verify a device's safety, performance, and clinical benefit for its intended use. The Medical Devices Regulation also provides a **legal definition of a medical device**[3] that is closely tied to its specific intended medical purpose.

In practice, however, smartwatches are marketed as tools for **consumer purposes** rather than explicit medical use, which excludes them from the legal category of medical devices (Ribeiro, 2023). Consequently, unlike certified medical devices, smartwatches are not subject to demanding conformity assessments, which leaves a regulatory gap and creates the question of whether the current legal framework should be re-evaluated to reflect the increasing medical potential of AI-driven wearables (Bouderhem, 2023).

Manufacturers such as Fitbit, Garmin, and Apple have successfully capitalised on rising consumer interest in accessible and affordable health-monitoring tools (Pekas et al., 2023). While these products undoubtedly offer valuable insights into users' daily activity, heart rate, or sleep quality, their ability to provide clinically actionable information remains disputed (Alzahrani et al., 2025). Apple and Fitbit have actively sought regulatory clearance for their ECG and irregular rhythm notification features through a process, which ensures that these features meet safety and effectiveness standards similar to other legally marketed medical devices. For example, consumer-grade wearable devices produced by Apple and Fitbit have been cleared by the United States Food and Drug Administration for pre-diagnostic detection of atrial fibrillation, indicating that these health-related functions have undergone regulatory review to ensure safety and effectiveness comparable to that required for traditional medical devices (Jamieson, 2025).

This paper studies why smartwatches are not legally classified as medical devices. It shows gaps in the current legislation and considers what reforms could be needed. The core of the study is the issue of whether smartwatches and other AI-driven wearables should be considered medical devices, since they are becoming increasingly important in health monitoring.

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices which amends Directive 2001/83/EC, Regulation (EC) No. 178/2002, and Regulation (EC) No. 1223/2009, and repeals Council Directives 90/385/EEC and 93/42/EEC.

[3] Article 2(1) of the MDR: Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The starting point is the assumption that EU regulations do not have the same speed as technological change. Current definitions and legal frameworks do not fully reflect the functions smartwatches now have, especially when AI is involved.

The research is based on an analysis of Slovak and EU laws on medical devices. It reviews legislation, regulations, and relevant case law to see how medical devices are defined and how smartwatches are placed within those definitions. Based on this study, the paper asks whether the legislation should be updated so that smartwatches and other similar devices are considered medical devices. In conclusion, the paper suggests ways in which the law could be changed to address innovation, aiming to balance safety, accountability, and the opportunities.

2. THE USE OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE

There is no doubt that artificial intelligence has become important in health care. It is not just clinical diagnosis and treatment, but also the managing of health data and improving patient care. To the extent that AI-driven tools are more widely utilised, it is clear that legal and ethical guidelines are essential to their safe and transparent use (Al Kuwaiti et al., 2023). The health data area focuses on the management and analysis of the overabundance of health data produced by wearables, but it raises ethical data use, and privacy questions. Transparency and accountability here are crucial for keeping the users´ trust and keeping this industry growing in a responsible manner (Radanliev, 2025).

In May 2024, the European Union adopted the Artificial Intelligence Act[4] (hereinafter the "**AI Act**"), a set of rules to harmonise AI regulation with the aim of promoting the development and use of safe and reliable AI in the European market, maintaining the protection of fundamental rights. According to Article 3(1) of the AI Act , AI systems are defined as a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.

Artificial intelligence is now an important element for health care, especially in connection with e-Health and telemedicine. These institutes provide unique opportunities for remote health monitoring, with patients being able to gain and transfer their own physiological measurements to healthcare professionals. Smart wearables, such as smartwatches, can instantly detect human physiological signals and act as a bridge between patients and doctors. But despite their effectiveness, they are not well-regulated and are in a grey zone between wellness and medical devices (Fong et al., 2011).

The current regulatory system, including the EU system, lags behind the passage of AI technology into health care, especially in the world of wearables, and is featured in several recent analyses (Brönneke et al., 2021). This regulatory deficit has been recognised, with laws evolving more slowly than technology, resulting in ambiguous oversight of AI-powered wearable devices, particularly concerning data privacy, security, and interoperability (Iqbal and Biller-Andorno, 2022).

[4] Regulation no. 2024/1689 of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

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The most significant developments in this space involve AI systems used for diagnosis, treatment planning, and surgery. The applications of AI in healthcare services are broad and are expected to assist, automate, and augment several healthcare services. Like any other emerging innovation, AI in healthcare also comes with its own risks and requires regulatory controls (Palaniappan et al., 2024).

3. REMOTE HEALTH MONITORING

One of the primary capabilities of AI in telemedicine is remote monitoring, which is also called **self-monitoring**. This approach allows patients to log information about their health in a nonmedical setting, giving them independence and control over their own health care. This data can then be shared with doctors so that early detection is possible, as well as continuous care and decision-making based on data. Research shows that many wearables with AI improve efficacy and accuracy while making health care more personal (Shaik et al., 2023).

Wearable technologies, such as smartwatches, equipped with **heart rate monitors and ECG capabilities**, or chest straps that measure **pulse rates**, exemplify the possibilities of AI in remote health monitoring.[5] AI-driven wearables have revolutionised patient monitoring, providing real-time health insights that enable earlier diagnosis and intervention (Bohr and Memarzadeh, 2020). **Mobile applications** available on smartphones, often connected to smartwatches, further improve patients´ ability to collect and transmit health-related data, improving the accessibility of health management tools (Li, 2019).

One of the major challenges of monitoring through wearable technologies, in the area of health care, is the seamless integration of the data they collect into electronic health records (hereinafter referred to as the "**EHR**") (Canali et al., 2022). The lack of standardised data formats, shared protocols, and interoperability means that wearable-generated health data often cannot be uploaded to electronic health records or clinical databases (Canali et al., 2022). To adequately integrate wearable technologies into the existing health record systems, it is crucial to address both the technical interoperability and the legal frameworks that govern data sharing and patient privacy (Tong, 2018).

In Slovakia, according to § 5(4) of Act No. 153/2013 Coll. on the National Health Information System (hereinafter referred to as the "**NHIS Act**"), while patients can manually enter basic data into their **electronic health book**[6], the system currently does not support uploading files such as Portable Document Format (PDF), which creates a technical gap in the integration of wearable-generated data directly into the EHR.[7] This type of communication might be beneficial in monitoring the patient's health in the long term or in dealing with various chronic conditions.

Other than the technical obstacles, one of the biggest issues is the **legal definition of wearable devices**. In the EU, the Medical Devices Regulation describes criteria for defining medical devices, including requirements for testing, certification, and compliance with safety standards. However, wearable technologies often occupy a grey area, being marketed primarily as wellness products rather than medical devices, despite their growing role in remote health monitoring. As the line between wellness wearables and medical devices becomes more difficult to distinguish, a single wearable device can already monitor a collection of different medical risk factors (Piwek et al., 2016).

[5] Devices with ECG measurement capabilities record electrical signals from the heart, providing healthcare professionals with critical information on heart rhythms and potential anomalies, such as atrial fibrillation.
[6] Section 5 (1) d) of the NHIS Act.
[7] Own research made by accessing electronic health book.

Wearable products can be broadly defined as mobile electronic devices that can be unobtrusively embedded in the user's outfit as part of clothing or an accessory. Unlike conventional mobile systems, they can be operational and accessed with little or no hindrance to user activity. To this end, they can model and recognise user activity, state, and the surrounding situation, a property referred to as context sensitivity (Lukowicz et al., 2004). This specificity, however, further complicates their legal classification, as they do not easily fit into traditional regulatory categories. The absence of clear legal definitions and classifications of such devices under **standard diagnostic, treatment, or therapeutic procedures** raises questions about their regulatory status and creates an obstacle to their being approved by doctors, healthcare providers, including insurance companies, which in turn limits their integration into formalised health care systems.

Smartwatches have the potential to transform patient care by providing continuous data streams, however, their regulatory oversight lags behind, raising questions of safety and efficacy in medical contexts (Matheny et al., 2019). Some authors also see other issues, such as concerns about system interoperability and patient data overload that pose a challenge to the adoption of wearables by healthcare providers (Dinh-Le et al., 2021). Additionally, concerns over **data security** and **patient privacy** must be addressed to ensure compliance with EU regulations, particularly those found in the General Data Protection Regulation (GDPR)[8] (Yigzaw et al., 2022).

The inclusion of AI-driven wearables in healthcare requires the re-evaluation of existing laws to ensure these technologies meet the required safety, accuracy, and accountability standards (Fong et al., 2011).

4. LEGAL FRAMEWORK FOR MEDICAL DEVICES: FOUR ARGUMENTS FOR APPLYING IT TO AI-DRIVEN WEARABLES

In the context of legislation, it is crucial to thoroughly examine the legal definition of medical devices at both the European Union and the Slovak Republic levels. At the EU level, **the key legal instrument is the Medical Devices Regulation**, which describes a medical device as any product, whether physical or software-based, intended by the manufacturer to be used for human beings with a defined medical function. These functions may include, for instance, the diagnosis, prevention, or monitoring of diseases; the treatment or compensation of injuries or disabilities; or the examination, modification, or replacement of physiological or anatomical processes. Importantly, the regulation clarifies that such devices achieve their principal intended effect without relying on pharmacological, immunological, or metabolic mechanisms, although these may assist the device's function. In vitro diagnostic purposes, such as analysing samples from the human body to provide relevant medical information, also fall within the scope of this definition.[9] Additionally, the regulation includes certain products under the category of medical devices, such as devices intended for the control or regulation of conception, and products specifically designed for cleaning, disinfecting, or sterilising medical devices.[10]

[8] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
[9] Regulation of the European Parliament and the Council (EU) no. 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 17.8/2002 and Regulation (EC) No. 1223/2009 and on the repeal of Council Directives 90/385/EEC and 93/42/EEC.
[10] Regulation of the European Parliament and the Council (EU) no. 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 17.8/2002 and Regulation (EC) No. 1223/2009 and on the repeal of Council Directives 90/385/EEC and 93/42/EEC.

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At the Slovak national level, Act No. 362/2011 Coll. on medicines and medical devices and on the amendment of certain laws (hereinafter referred to as the "**Medicines Act**"), further differentiates between in vitro[11] diagnostic medical devices, single-use[12] medical devices, custom-made[13] medical devices, and medical devices intended for clinical trials.[14] This legislation defines medical devices in ways closely aligned with the EU regulation but introduces provisions linked to transitional circumstances such as the COVID-19 pandemic. For example, Section 143(k) of the Slovak Medicines Act defines the core legal concepts applicable to medical devices. According to this provision, a medical device encompasses a wide range of products, such as instruments, apparatuses, materials, devices, computer programs, or other products intended by the manufacturer to be used on humans for a defined medical objective. These objectives include diagnostic, preventive, monitoring, or therapeutic purposes; mitigating the effects of disease or injury; supporting or compensating for anatomical or physiological functions; or controlling human reproduction.[15] Importantly, the primary intended function of such devices must not rely on pharmacological, immunological, or metabolic mechanisms, although these may support the device's operation. The legal definition also extends to accessories specifically designed to be used in conjunction with a medical device.[16] The relevant amendment to the Medicines Act was introduced via Act No. 165/2020 Coll., which amends Act no. 362/2011 Coll. on medicines and medical devices and on the amendment of certain laws and amends certain laws, which introduced provisions regulating essential terms for the field of medical devices. These provisions encompass online distribution, manufacturer registration, clinical testing, market entry, procedures for missing or incorrect CE marking, safety and health protection measures, confidentiality obligations, and the recording of accidents, malfunctions, or failures of a

[11] **In vitro diagnostic medical device** is a medical device that is a) a reagent, reagent product, calibration material, control material, or their set, tool, device, or system used alone or in combination, intended by the manufacturer for in vitro evaluation of samples originating from the human body, including donated blood or tissue, in particular for the purpose of providing information 1. relating to a physiological or pathological condition, 2. relating to a birth defect, 3. enabling the determination of safety and tolerability for a possible recipient, 4. enabling the control of therapeutic measures, 5. enabling self-diagnosis by non-experts in the home environment, or 6. enabling evaluation of the functionality of the diagnostic medical device in vitro, b) a container for samples, regardless of whether it is of the vacuum type or not, specifically designated by the manufacturer for the direct collection of a sample originating from the human body, and for its storage for an in vitro diagnostic test, c) a product intended for general use in the laboratory, if, due to its characteristic properties, it has been specifically designated by the manufacturer for in vitro diagnostic tests, d) an accessory of an in vitro diagnostic medical device, which is specifically intended by the manufacturer for use together with an in vitro diagnostic medical device in accordance with its intended purpose, except for invasive medical devices intended for sampling and medical devices coming into direct contact with the human body, intended for obtaining a sample.
Section 2 (19) of the Medicines Act.

[12] **A single-use medical device** is a medical device intended for single use for one patient.
Section 2 (29) of the Medicines Act.

[13] **A custom-made medical device** is a medical device individually manufactured according to a medical order, which was prescribed by a doctor with the required specialisation under his responsibility and who determined the characteristic properties of the medical device and the purpose of its use only for the given patient, clearly identified by name, surname, or birth number.
Section 2 (30) of the Medicines Act.

[14] **A medical device intended for clinical testing** is a medical device intended for clinical testing by a doctor with the required specialisation or another person with professional competence to conduct clinical testing in a medical facility.
Section 2 (31) of the Medicines Act.

[15] Act No. 362/2011 Coll. on Medicines and Medical Devices and on the amendment of certain laws.

[16] Act No. 362/2011 Coll. on Medicines and Medical Devices and on the amendment of certain laws.

medical device after its release into the market. These regulations were in force from May 26, 2020, to May 25, 2021.[17]

While the Medical Devices regulation remains the primary legal framework governing medical devices, it is not the only regulation relevant to AI-driven wearables.

Recently enacted as the AI Act, it represents the European Union's first horizontal regulation focusing on the applications of artificial intelligence. Moreover, AI-driven wearables use algorithms to monitor health, classify, and predict different needs of the user. Hence, it is also necessary to analyse their inclusion in the scope of the AI Act. Its **approach is risk-based**, defining AI systems based on the potential harm they might cause to humans (health and safety) or their fundamental rights. A remarkable condition for the AI system to be classified as high-risk in this context is that it must either form a safety component of a wider product, or itself be treated as an autonomous product, and that such product be covered by one of the existing EU harmonisation acts listed in Annex I. In both cases, and only then, could it be deemed high-risk if said product must undergo a conformity assessment conducted by an independent third party before being able to legally become available on the EU market or be put into use. This regulation mechanism guarantees that AI systems employed in critical applications (like medical devices) meet the established safety and performance requirements before entering the market.[18]

Devices equipped with artificial intelligence are likely to be categorised as high-risk AI systems under the EU AI Act (Mesarčík, Gyurász et al., 2024). If such products provide real-time health recommendations, detect medical conditions, or influence treatment decisions, they align with AI systems that pose significant risks to health and patient safety (Fraser et al., 2023). However, we believe that not all AI-driven wearables are automatically deemed high-risk.

Article 6 (3) of the AI Act allows AI systems listed in Annex III to be excluded from being classified as high-risk in cases where they do not pose a greater level or type of risk, provided that the risks to health and safety or fundamental rights of individuals are insignificant and there is no significant effect or material change as a result of using the system, which mainly affects decision-making. This provision includes general wellness products such as pedometers or basic heart rate monitors. Generally, these systems are intended for well-being rather than medical applications and therefore do not meet the high-risk criteria. The difference is whether the AI features in these wearables have a direct impact on medical decision-making or health outcomes (Aboy et al., 2024).

The cross-reading of the Medical Devices Regulation and the AI Act reveals how AI-driven wearable technologies represent a regulatory limbo, where the existing legal frameworks are not able to fully understand nor to satisfactorily cover their dual nature, which combines medical features with a consumer-friendly approach and autonomous capabilities, and makes classic definitions unclear (Mennella et al., 2024).

The legal framework of the debated issue also comprises the **Regulation of the European Health Data Space** (hereinafter referred to as the "**EHDS**")[19] which aims to empower citizens with unobstructed access to and control over their electronic medical records, to secure cross-border free flow of health data in the European Union for individual care as well as for secondary purposes, and to promote a unified digital health

[17] Act No. 165/2020 Coll., amending Act no. 362/2011 Coll. on medicines and medical devices and on the amendment of certain laws and amending certain other laws.
[18] Article 6 (1)(a) and 6 (1)(b) of the AI Act.
[19] Regulation of the European Parliament and the Council (EU) no. 2025/327 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

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system.[20] Through implementing the EHDS, the European Union has established a harmonised legal framework for access, use, and exchange of electronic health data across member states.

No direct reference to wearables is made in the EHDS, but it could be interpreted that these are included by reading the definitions used within. For instance, the definition of an *electronic health data access service*[21] would include mobile applications that provide people with the ability to access their own electronic health data, which is something typically realised through wearable interface devices. Also, by way of the regulation, the EHDS defines an *electronic health record system or EHR system*[22] as a system, including hardware, software, or a combination, that can be used by healthcare providers or patients to store, process, or view priority categories of personal electronic health data.

As many of these wearable technologies are meant to gather and transmit such information for use by the patient or for inclusion in healthcare services, their role clearly falls within the scope of the EHDS framework.

The inclusion of wearable-derived data in the EHDS strengthens fundamental principles like the protection of data, transparency, and interoperability. AI-driven wearables also process sensitive personal data, bringing serious questions of data privacy, interoperability, and security to the fore. The electronic health record, which exists in the digital space, represents a risk in terms of its vulnerability to the disclosure of highly sensitive data. The digital age brings new ways of compromising privacy, but technologies can be used to improve and protect privacy. The application of an encryption system should contribute to this (Nastič, 2021).

Because of the nature of these devices, as many collect and analyse real-time biometric data, including heart rate, blood oxygen levels, and electrocardiogram readings, it is important that they conform to EU rules designed to protect individuals' data. AI-driven wearables additionally support the development of third-party applications, which can thereby gain access to the data collected by these devices.[23]

In doing so, such data collected through wearables should be processed lawfully, fairly, and in a transparent manner in accordance with the **General Data Protection Regulation** (hereinafter referred to as the "**GDPR**")[24], which represents the EU leading regulatory framework for personal health data. The GDPR sets out several key principles and obligations that have a direct impact on the use of AI-driven wearables in healthcare and personal health monitoring, such as lawfulness, fairness and transparency, purpose limitation, data minimisation, data security and protection measures, user control and data access rights, accountability and compliance obligations.

The balancing act of the Medical Devices Regulation, the AI Act, and the GDPR leads to a challenging labyrinth for compliance concerning AI-driven wearables, as some safety requirements for devices are covered in one framework, while governance of AI is captured by another, and data privacy with yet another:

- The Medical Devices Regulation determines whether **an AI-driven wearable is a medical device** that must adhere to safety and effectiveness criteria.

[20] Recital 1 of the EHDS.
[21] Article 2 (1)(h) of the EHDS.
[22] Article 2 (1)(k) of the EHDS.
[23] Article 29 Data Protection Working Party: Opinion No. 8/2014 on the Recent Developments in the Internet of Things.
[24] Regulation of the European Parliament and of the Council (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

- The AI Act regulates the **risk classification of AI in wearables** and imposes additional regulatory obligations with respect to high-risk AI applications.
- The GDPR **ensures the lawful and secure processing of personal health data** from AI-driven wearables, providing fundamental rights for users to have control over their biometric and health record information.

Medical device classification and smartwatches

One of the questions that's rightly been asked is whether smartwatches or other AI-driven wearables could be considered medical devices in the existing legal system.

The following are some of the most relevant criteria derived from the MDR that can be part of an analysis framework:

a) The nature of the device
b) The intended user of the device
c) The specific medical purpose of the device
d) The negative definition concerning the principal effect of the device

4.1 The Nature of the Device

To qualify as a medical device, the product must fall within one of the various categories stated in Article 2(1) of the Medical Devices Regulation, such as an **instrument, apparatus, appliance, software, implant, reagent, material, or other article** intended by the manufacturer to be used, alone or in combination, for human beings.

Before the consideration of the qualification of smartwatches under this criterion, a discussion on "software" is in order. Regulations on medical healthcare do not define what software is, but we can refer to EU documents, as in the case of guidelines regarding the Medical Devices Regulation. Although healthcare legislation does not specifically define software, this is now clarified by secondary guidelines enacted under the Medical Devices Regulation, such as MDCG 2021-24[25], which clarify that software can be considered an active medical device if it is designed for monitoring or diagnosing medical conditions.[26]

From a technical standpoint, software can be described as a structured set of programmed instructions designed to process input data and generate corresponding outputs.[27] In regulatory terms, the relevant EU guidelines frequently refer to the Medical Devices Regulation, particularly Annex VIII, which classifies certain software as active devices when they are intended, either independently or as part of a system, to acquire information for the purpose of identifying, diagnosing, monitoring, or treating physiological or pathological states, including congenital anomalies.[28] Artificial intelligence may form part of a medical device or, in the case of autonomous control, constitute standalone software, which has functions distinct from ordinary data archiving or storage (Mesarčík and Gyurász, 2020; cf. Kamanjasevic and Biasin, 2020). In this context, the judgment of the European Court of Justice in the SNITEM case[29] provides important clarification regarding the classification of software as a medical device. The

[25] MDCG 2021-24 Guidance on classification of medical devices.
[26] MDCG 2021-24 Guidance on classification of medical devices. 2021, p. 11.
[27]MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, 2019, p. 5.
[28] Regulation of the European Parliament and the Council (EU) no. 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 17.8/2002 and Regulation (EC) No. 1223/2009 and on the repeal of Council Directives 90/385/EEC and 93/42/EEC.
[29] For a more detailed analysis of the decision, see: Minssen, Mimler and Mak (2020).

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court emphasised that it is not necessary for the software to exert a direct or indirect effect on the human body to fall under the scope of the Medical Devices Regulation. Rather, the decisive criterion is the manufacturer's stated intention: if the software is specifically designed for a medical purpose as defined in the applicable legislation, it may qualify as a medical device regardless of whether it physically interacts with the patient.[30] Conversely, the MEDDEV 2.1/6 guideline on the qualification and classification of standalone software (hereinafter referred to as the "**MEDDEV 2.1/6 guideline**") used in healthcare specifies that software cannot be considered a medical device if it merely stores, archives, or compresses data without any loss, or if it simply facilitates data retrieval. Software functioning as an electronic database, which allows searching of metadata without altering or interpreting it, does not fulfil the requirements to be classified as a medical device.[31]

MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR lists examples of **software that, in itself, meets the definition of a medical device**. These include, for instance, **smartwatch applications** whose medical purpose is to send alerts to a physician upon detecting abnormalities in physiological parameters. In the case of software available on wearable devices, it typically involves software designed to be used in combination with specific hardware. For instance, Apple clarifies that certain components of the Series 7 Apple Watch, such as the electrical heart sensor and ECG app, have been approved as medical devices, while others, like the blood oxygen (SpO_2) sensor, are not. According to Apple's official documentation, measurements from the Blood Oxygen app are not intended for medical use, including self-diagnosis or medical consultations, and are designed solely for general fitness and wellness purposes.[32]

By contrast, the ECG feature is classified as a medical device and comes with explicit limitations: it mandates the latest versions of watchOS and iOS, should not be used by users under 22 years old, and is unsuitable for people previously diagnosed with atrial fibrillation. SpO_2 results serve as personal wellness indicators without diagnostic value, while the ECG app has specific clearance to detect atrial fibrillation activity (Scheid et al., 2023).

Now that it has been made clear when software should be deemed to constitute a medical device, the question arises: When does this apply to smartwatches?

Smart wearables, such as smartwatches, therefore trigger interesting questions regarding which category they would belong to in Article 2 (1) of the Medical Devices Regulation. From a regulatory standpoint, such devices can be classified as instruments or appliances based on their hardware features, such as sensors, processors, and communication modules that are intended for monitoring and relaying physiological information. Meanwhile, the performance of such devices is mostly determined by operating software programs that process the accumulated data and produce medically useful information or outputs (for example, alerts or diagnostic impressions). With these two sides considered, smart wearable devices may fall into more than one device

[30] Decision of the Court of Justice of the EU of 7 December 2017 in case C -329/16, Syndicat national de l'industrie des technologies médicales (Snitem), Philips France v Premier ministre, Ministre des Affaires sociales et de la Santé , Santé decision.

[31] MEDDEV 2.1/6 – Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices. 2016, p. 3.

[32] Which Apple Watch Is Right for You? Available at: https://www.apple.com/watch/compare/?afid=p238%7CsNZgeoZeS-dc_mtid_1870765e38482_pcrid_601516710177_pgrid_99322576784_pntwk_g_pchan__pexid_30368077007_&cid=aos-us-kwgo---slid-gsi8KLF7--product- (accessed on 14.07.2025).

category in Article 2 (1) of the Medical Devices Regulation. Therefore, it can be concluded that they meet the first requirement to qualify as a medical device, which is being one of the designated types of products.

4.2 The Intended User of the Device

The second characteristic that should be considered concerns the identification of the **user** of the medical device **for whom it is intended** and, in line with Article 2(1) of the Medical Devices Regulation, that user must be **only a human being**. All the smart wearables discussed, including smartwatches and other AI-driven wearables, are clearly intended for human use.

However, neither existing legislation nor European Commission guidelines provide an explicit definition of "human usability". As such, only pragmatic interpretations and *a contrario* arguments can be applied.

The MEDDEV 2.1/6 guideline provides insight into activities that do and do not fall under the scope of software for the benefit of individual patients. An example of software for the benefit of individual patients is software intended to be used for the evaluation of patient data to support or influence the medical care provided to that patient. Examples of software that are not considered as being for the benefit of individual patients are those that aggregate population data, provide generic diagnostic or treatment pathways, scientific literature, medical atlases, models, and templates, as well as software for epidemiologic studies or registers.[33]

In conclusion, AI-driven wearables used to monitor and analyse health data specific to an individual and potentially influence personal healthcare decisions are more likely to fall within the regulatory scope of medical devices, provided that other definitional criteria are also met. The health and safety monitoring function of wearable devices is mainly used for older adults, children, pregnant women, and patient groups (Lu et al., 2020).

4.3 The Specific Medical Purpose of the Device

The third criterion is more precisely defined in Article 2(1) of the Medical Devices Regulation, as it concerns the requirement that the medical device must be intended for **one of the specific medical purposes** exhaustively listed in the relevant legislation.[34]

In the Medical Devices Regulation, the term "monitoring" is not defined expansively but is limited, in Article 2(1), to the monitoring of a disease, injury, or disability. As such, this difference is important, as not all devices worn on the body are designed for these purposes. For example, a general smartwatch that monitors fitness data, such as step count or calorie intake, is not, in our view, medical monitoring. On the other hand, an

[33] MEDDEV 2.1/6 – Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices. 2016, p. 12.

[34] Medical purposes are part of the definition of a medical device:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation, or compensation for an injury or disability;
- investigation, replacement, or modification of the anatomy or of a physiological or pathological process or condition;
- the provision of information by means of in vitro examination of specimens derived from the human body, including blood and tissue donations, provided that the principal intended action of the device is not achieved by pharmacological, immunological, or metabolic means, although such means may assist in its function.

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instrument able to detect atrial fibrillation or to monitor blood oxygen levels in chronically ill patients, does fulfil this criterion.

Secondly, the notion of medical purpose in the Medical Devices Regulation implies that it includes activities typically involving a medical skill or professional experience. This raises the question of whether the legislation applies mainly to devices for healthcare professionals or if it also applies to wearables developed for self-monitoring by lay users. In this regard, the Medical Devices Regulation definition of "user"[35] is pertinent to note. This implies that medical devices should not only be designed for exclusive healthcare professionals but also for patients at home.

We therefore think that wearables allowing individuals to analyse their own state of health cannot be automatically withdrawn from the scope of medical devices only because they are employed by lay users.

As with the previous characteristic, existing European case law can further clarify this requirement. In particular, the Court of Justice of the EU (hereinafter referred to as the "**CJEU**") in Brain Products GmbH established that if a manufacturer did not design its product for medical purposes, it cannot be required to be certified as a medical device. A product is only classified as a medical device when it is specifically intended for a medical purpose. The subject of the dispute was a device called ActiveTwo, manufactured by BioSemi and others, used for measuring physiological signals. The company Brain Products claimed that the device fulfilled the definition of a medical device. Since it lacked the CE marking, which is mandatory for placing medical devices on the market, Brain Products sought to prohibit its commercialisation. In response, BioSemi and others argued that the ActiveTwo device was not intended for medical purposes and therefore did not fall within the scope of the medical device definition. The German national court made a reference for a preliminary ruling to the CJEU, inquiring whether the medical purpose defined by the manufacturer is an essential characteristic of what constitutes a medical device. The CJEU held that the intended medical purpose of the manufacturer is indeed a central element in ascertaining whether a given product should be classified as a medical device. This view was not only borne out by the wording of the respective rules, but also by their intention, that is, to guarantee unrestricted movement of medical devices in the EU while ensuring a high level of protection for patients' health. The Court stressed that such a freedom could be infringed only to protect public health. Moreover, the CJEU stated that if the manufacturer of a product has not intended its use for one (or more) of the medical purposes provided for by the Medical Devices Regulation, such a product cannot be subject to certification obligations. The Court gave the example that different sports equipment, which are also able to measure the operation of some human organs (in a non-medical context), could not instantly be judged to be medical devices. If they were, that would be an arbitrary way of imposing certification guidelines without a rational reason.[36]

At present, **health-monitoring features in smartwatches appear to be supplementary** rather than their primary function, often presented as wellness tools rather than medical devices (Devine et al., 2022). Problematic in the context of smart wearables is the intended use component of the definition: any device that could fulfil these purposes and may be used in such a way, but is not intended to do so, does not fall under the legal definition of a medical device and therefore falls under only minimal

[35] "User" means any healthcare professional or lay person who uses a device.
Article 1(37) of Medical Devices Regulation.
[36] Decision of the Court of Justice of the EU of 22 November 2012 in case C-219/11, Brain Products GmbH v. BioSemi VOF, Antonius Pieter Kuiper, Robert Jan Gerard Honsbeek, Alexander Coenraad Metting van Rijn, pp. 6-10.

regulation. With the variety, quantity, and easy availability of these technologies to patient-consumers versus more experienced and trained healthcare professionals, patient-consumers may be prone to use devices in ways not approved by the manufacturer (Iqbal and Biller-Andorno, 2022). This raises the question of whether the current definition of a medical device is sufficiently flexible to accommodate emerging trends in wearable health technologies. A reconsideration of regulatory criteria may be necessary to ensure that the potential health benefits of these technologies are adequately recognised within the legal framework.

4.4 The Negative Definition Concerning the Principal Effect of the Device

A medical device is characterised, under Article 2(1) of the Medical Devices Regulation, among other aspects, by the fact that it achieves its main intended action in or on the human body **by means other than pharmacological, immunological, or metabolic mechanisms.** These mechanisms may support the device's function, but they must not be the primary mode of action.

Importantly, this does not mean that a medical device must act directly on or within the body in a physical sense, it only requires that its effect is not mediated through chemical or biological processes.[37] This distinction is fundamental when differentiating medical devices from medicinal products[38] (Manellari et al., 2022). For instance, glucometers and insulin pumps comply with this definition because their principal effect, which is monitoring and delivering insulin, respectively, is not achieved through pharmacological action.

Accordingly, wearable technologies can be seen as satisfying this final requirement for classification as a medical device.

To summarise, we agree that for smartwatches to be classified as medical devices, manufacturers must navigate complex regulatory frameworks that were not originally designed to address AI-driven health technologies.

5. SUGGESTIONS

Smart wearables are the most prominent trend in fitness. But, commercial AI-driven wearables, such as smartwatches, are no longer just basic fitness trackers. Today, their functionality extends well beyond some of the more fundamental features, like counting steps and monitoring location using GPS. By contrast, they are **technologically advanced tools** that include a wide range of features designed to **monitor the user's health and physical activity**. The crossover of functionalities in practice leads to **uncertainty** about what information wearables can collect for medical purposes and what they cannot. It also gives rise to further challenges related to the **legal classification** of such technologies (Scheid et al., 2023).

[37] Decision of the Court of Justice of the EU of 7 December 2017 in case C -329/16, Syndicat national de l'industrie des technologies médicales (Snitem), Philips France v Premier ministre, Ministre des Affaires sociales et de la Santé , Santé decision.

[38] According to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Article 1(2) medicinal product shall mean any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

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A more precise legal definition would clarify the ambiguity concerning the classification of wearable health devices. In particular, the current Medical Devices Regulation might be amended to provide a clearer and explicit definition of AI-driven wearables designed for health monitoring. This would mean that all devices offering substantial health monitoring capabilities, even data-driven devices, could be subject to strict standards as well as safety, accuracy, and certification regimes.

Another such concept is a **stratified certification system** that would classify wearables depending on their functionality and medical benefit. For instance:

- **Tier 1**: Devices offering general wellness and fitness information
- **Tier 2**: Devices that can monitor vital health metrics (e.g., heart rhythm monitoring)
- **Tier 3**: Devices with predictive diagnostics, which should be considered a medical device.

This tiered approach allows flexibility, such that highly advanced gadgets, like smartwatches with medical potential, can receive the right amount of regulation while not stifling innovation for consumer products.

New studies highlight the **complexity of regulating** wearable technologies that blur the line between wellness products and medical devices (Hosseini et al., 2023). Researchers and regulators argue that the current legal frameworks may not be fully prepared to handle the nuances of these devices, especially as they become more integrated into healthcare systems. For example, while smartwatches can monitor vital signs and alert users to potential health risks, they are not designed to replace traditional diagnostic tools used by healthcare professionals (Hosseini et al., 2023); (Pekas et al., 2023). This leaves **a grey area**: if smartwatches fail to detect a serious condition, who is at fault? Moreover, the validity of health data recorded by wearables has been challenged, since several devices do not adhere to similar standards required for medical devices (Pekas et al., 2023). That is not ideal for users who may be using smartwatches as a health monitor without really understanding that they are limited devices. Legislation should be introduced to provide **certainty around legal liability for smart wearables** that fail to detect or report serious health conditions. That may involve ensuring that companies clearly disclose limitations of their devices and providing legal avenues for consumers to seek redress if a device fails them.

Besides these safety aspects, **the privacy issues** associated with AI-driven wearables for healthcare must also be considered, since such devices deal with sensitive personal health data and thus demand more stringent standards of data privacy protection to prevent misuse or abuse of users' health information. Smartwatches are used to gather huge amounts of sensitive personal health information that often is processed by third-party companies (Peres da Silva, 2023). This has significant implications in terms of data security and how personal health data could be abused.[39] However, the GDPR only partially addresses AI regulation, being focused on the processing of personal data and ensuring the protection of data subjects. It is not suitable for full protection against other AI systems (Meszaros et al., 2022). Thus, the regulatory framework will need to develop accordingly to safeguard individual´s health data and enable the adoption of novel healthcare technologies. Perhaps the answer is to update

[39] Wearables, such as Fitbit and Apple, have been involved in data breaches, exposing millions of users' sensitive health data. One notable incident involved an unsecured database containing over 61 million records from fitness trackers, raising concerns about data privacy and the security of personal health information. More details about this case are available at:
https://www.fiercehealthcare.com/digital-health/fitbit-apple-user-data-exposed-breach-impacting-61m-fitness-tracker-records (accessed on 18.01.2025).

the GDPR legislation or to develop new legislation more tailored to AI-driven wearables regarding what constitutes appropriate data collection, processing, and storage of health data. Such changes would better ensure **more robust and effective consent options for users** who wish to provide access to their sensitive health-related data, improved protocols surrounding data sharing between providers and third-party manufacturers, and increased penalties for those who fail to keep health information secure.

6. CONCLUSIONS

In recent years, there has been an exponential increase in smart wearables, especially smartwatches, that capture and process health data or provide users with practical information about their health metrics.

However, these technologies currently **lack sufficient legal support**, as they do not fully qualify as medical devices under existing regulations. Innovation in the medical sector of medical devices is often driven by start-ups, which have great ideas but lack experience in the development of medical devices in accordance with relevant regulations. Inexperience, together with difficulty in identifying the relevant regulations and translating them into technical requirements, results in the development of new innovative medical devices that are not always successful (Arandia et al., 2022).

This paper has examined a specific aspect of AI-driven wearables, **facilitated by artificial intelligence**, which **enables the monitoring of selected health attributes**, such as in home environments or non-clinical settings, and the provision of relevant health information. While smartwatches offer promising advancements for remote health monitoring, significant **legal** and **technical barriers** remain. A clearer definition of their legal status and the establishment of systems that permit safe connections between wearable data and national health records will be crucial. By filling in these gaps, the European Union would be much better placed to utilise AI tools and make significant improvements to patient care as well as modernising systems.

The results show that the current legal framework in Slovakia and the EU does not yet reflect the growing role of AI-driven wearables in health care. Obsolete definitions and regulations limit their potential and slow down their adoption in medical practice. For these technologies to be safely and properly used, the law will have to change to ensure standards of quality as well as safety for patients and healthcare professionals.

Thus, future studies need to consider several directions. One is the creation of clearer and more dynamic legislation that will be able to adapt to new technology as it evolves. Comparative studies among EU countries might demonstrate how different approaches function in practice.

And there is the technical dimension as well, centred around matters like data privacy, interoperability, and cybersecurity which are key for building trust (and linking wearables with healthcare professionals). Answering these questions will require interdisciplinary research, bringing together legal, medical, and technical knowledge.

Finally, cooperation between regulators and the private sector, consisting of medical device companies, must be highlighted. A clearer understanding of how these players interact could help convert promising ideas into dependable medical devices that stand to benefit patients and healthcare professionals alike.

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