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Legal Framework for digital therapeutics (DTx) in the European Union

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Summary: This paper examines the origins and limitations of EU medical device law. The main questions asked are whether EU medical device law defines the concept of medical purpose for software, whether the concept of medical purpose is understood as a medical service defined by national law, and whether it requires the involvement of medical professionals as users. Particular attention is paid to the aspect of Recital 8 of the Regulation (EU) 2017/745 on medical devices (MDR), alongside the general internal provisions of EU law and its sector-specific subsidiarity provisions. In practice, Member States have taken different legal approaches to address DTx-related challenges, creating legal uncertainty within the EU as to which DTx should be defined as a medical device.

Keywords: digital therapeutics, healthcare, medical device, public health, wellness application.

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1. Introduction

The cost of health care is skyrocketing in the European Union (the EU). In Estonia, the cost of delivery of healthcare has increased by 30% over past couple of years. The increase was trigged by the pandemic, overall increase of cost of living, aging society, higher expectations on high quality services, labour shortage and wage pressure. Implementation of personalised medical approach has been seen as one of the cost-effect solutions, which includes the clinical treatment and the self-managed treatment, so-called digital therapeutics (DTx).

DTx are considered as medical devices designed by the manufacturer for human use. Unlike drugs, they do not have any pharmacological, metabolic and/or immunological effects, but mainly have a physical one. It should be noted that software, such as, for example, a medical application, can also be a medical device if it is intended to be used for therapeutic or diagnostic purposes for humans. At the same time, DTx should be distinguished from so-called fitness applications, which, for example, record daily steps or count calories and are practically unregulated. Since such fitness applications usually do not have specific diagnostic or therapeutic benefits in a narrower medical sense, they are usually not medical devices, and therefore less stringent requirements are imposed on them.

DTx for preventing or treating disease is expected to become a new pillar in providing care to patient – beyond the traditional ambulatory and clinical healthcare.[1] It is a patient facing software application that helps to treat, prevent, or manage a medical order or disease, and has a proven clinical effect.[2] For instance in oncology, DTx's functions are based on medical guidelines and best practices aimed at prevention, monitoring, management, and treatment of symptoms of cancer and corelated disease, or for treatment optimization.[3] DTx is a software that may include a clinical decision-making technical feature and

[1] FÜRSTENAU, D.; GERSCH, M.; SCHREITER, S. Digital Therapeutics (DTx). *Business & Information Systems Engineering*. 2023, vol. 65, no. 3, pp. 349–360. DOI: https://doi.org/10.1007/s12599-023-00804-z

[2] Digital Therapeutics (DTX). *European Data Protection Supervisor*. [online]. Available at: <https://www.edps.europa.eu/press-publications/publications/techsonar/digital-therapeutics-dtx_en>

[3] AAPRO, M., BOSSI, P., DASARI, A., FALLOWFIELD, L., GASCÓN, P., GELLER, M. A., JORDAN, K., KIM, J. W., MARTIN, K., PORZIG, S. Digital health for optimal supportive care

as well a supportive care technical feature. Also, information that have medical purpose and others such as lifestyle improvement purpose.

The functioning of the EU is a market-oriented ecosystem focusing on what to do that the ecosystem would rapidly respond to market opportunities. Whereas in practice, e.g., the pathway of products to become a medical device in the EU is lengthy and, on some occasion, impede citizens from innovative health care solutions. For instance, Apple passed lately administrative process in the US[4] and now its watches are not anymore just luxury products on users' wrist that supports healthy lifestyle but also medical accessories. In US, users of an Apple Watch can benefit from innovative healthcare service as their device is a part of a treatment process, providing opportunities to its users to use his or her device for diagnoses of medical conditions.[5] Namely, the watch records and processes data about irregular heart rhythm that appears to be atrial fibrillation (AFib). It is recognised that "When left untreated, AFib is one of the leading conditions that can result in stroke, the second most common cause of death around the world."[6]

In the EU, however, many important medical opportunities based on software are not considered as a medical device. On the Apple's product description, e.g., it is stressed that "temperature sensing feature is not a medical device"[7] and as a result should not intended for use in medical diagnosis, treatment, or for any other medical purpose. The main question in this domain is why?

Through this paper we will examine EU law jurisprudence and assess the way in which the recognition of a digital therapeutics as a medical device takes place. It must be admitted that the paper covers only the first step of a long journey. Namely, analysing what is the role of EU law in medical device market? When a software could be qualified as a medical device? Which software is excluded from the scope of EU medical devices law? Secondary questions that we will examine are:

How EU law defines software in terms of medical device?

in oncology: benefits, limits, and future perspectives. *Supportive Care in Cancer*. 2020. vol. 28, no. 10, pp. 4589–4612. DOI: 10.1007/s00520-020-05539-1.

4 APPLE. *Using Apple Watch for Arrhythmia Detection.* [online] Available at: <https://www.apple.com/healthcare/docs/site/Apple_Watch_Arrhythmia_Detection.pdf>

5 COSSIO, M. *The power of wearable health Technology: The approval process for the Apple Watch as a Class II medical device*. 2023. [online] Available at: <https://www.linkedin.com/pulse/power-wearable-health-technology-approval-process-apple-manuel-cossio/>

6 APPLE. *ECG app and irregular heart rhythm notification available today on Apple Watch*. [online] Available at: <https://www.apple.com/mg/newsroom/2019/03/ecg-app-and-irregular-rhythm-notification-on-apple-watch-available-today-across-europe-and-hong-kong/>

7 APPLE. *Apple Watch – Compare models.* [online] 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->

Which are different approaches taken by Member States to define the concept of 'medical purpose'?

Which software EU law does not consider as to be a medical device?

To answer these questions, we will relay to on text, guidelines, case-law of EU law, and pre-existing literature in the field of EU healthcare law and policies. Since the EU medical device legal framework is relatively new and there is not enough case law, many questions unfortunately will stay with definite answers. Therefore, we will also address some specific legal questions in the field that are relevant to more detailed and further discussion.

2. The role of EU law: market for medical devices

The medical device market in the EU is currently regulated by two EU regulations: Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic devices (IVDR)). The aim of these regulations is "to create a safe EU market in medical devices, to ensure that the trade within the EU is not impeded by tariff barriers and to respond to developing global medical devices markets".[8] Namely, the medical device market regulates the arrangements for supplying medical devices to health system, where traditionally the main purchasing role within the health system was not performed directly by individual patient[9].

In 2015, Sepah et al. first mentioned the term "digital therapeutics" and expressed that DTx are "evidence-based behavioral treatments delivered online" that can increase healthcare accessibility and effectiveness5. However, the life is changing and developments in the DTx solutions are good example on how e.g., individuals will directly decide whether to use traditional solutions or digital ones for taking care of their health. Such approach is also supported by the European health data space initiative (the EHDS Proposal)[10], and provides solutions and benefits to natural person from innovative treatments.

It must be stressed that the legal framework of medical devices base on the EU Regulations is quite young, and still goes through its challenging implementation process. Despite all this, one thing is clear – the legal framework creates a 'rule-based risk classification' scheme[11] that is derived from Global Harmonization

[8] HERVEY, T. K., McHALE, J. V. *European Union Health Law: Themes and Implications*, Cambridge: Cambridge University Press, 2015, p. 367.

[9] Ibid.

[10] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final

[11] Class I, Class IIa, Class IIb and Class III.

Task Force (the GHTF) guidance.[12] Accordingly, the stipulated legal obligations on manufactures are proportionate to the risk of the device.

However, before any classification, one should make sure whether a product qualifies as a medical product or not. It is not an easy task since the EU Regulations based medical device market, regarding software as DTx, is designed by taking account, among others, Member States' differences in performance accountability and culture, which will be described in more details in the Section 4 of this research.

2.1. Is software a medical device within the EU?

As a rule, within the EU, a software is qualified as a medical device (MD) if it is intended by the manufacturer to be used, alone or in combination, for human beings for at least one specific **medical purpose**.[13] Like a software-based diagnoses assistant tools for doctors. Also, a software or system that is intended by the manufacturer to be used in vitro (IVD), alone or in combination, for the examination of specimens, including blood and tissue donations, derived from human body, solely or principally for the purpose of providing information on one or more certain concerns, such as related to defining or monitoring therapeutics measures, should be qualified as a medical device.[14] "In vitro diagnostic medical devices are generally tests used on biological samples to determine the status of a person's health. There is a broad range of in vitro diagnostics (IVDs), from self-tests for pregnancy and blood glucose tests for diabetics, to sophisticated diagnoses performed in laboratories."[15]

The MDR and the IVDR entered into force on 26 May 2017 and are applicable since 26 May 2021. On 15 March 2023, the EU extended the MDR and the IVDR transition periods for legacy devices[16]. Namely, because at the beginning of the year, there was still over 21 thousand medical device certificates that

[12] HERVEY, T. K., McHALE, J. V. *European Union Health Law: Themes and Implications*…p. 374.

[13] Art 2(1) MDR.

[14] Art 2(2) IVDR.

[15] EUROPEAN COMMISSION. *Questions and Answers on the progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation.* 2021. [online] Available at: <https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_5210>

[16] Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices [2023] OJ L 80; Read more: EUROPEAN COMMISSION. *European Health Union: Supporting the transition to the new medical device framework.* 2023 [online] Available at: <https://health.ec.europa.eu/system/files/2023-01/mdr_proposal_factsheet_0.pdf>

were not renewed according to a new medical device regulatory framework because of the lack of notified bodies.[17] Legacy devices in that sense are devices, which were placed on the market after the MDR's date of application (26 May 2021) whereas certain conditions were fulfilled.[18] The extension of deadline was granted to prevent the lack of availability of medical devices on the EU market.[19]

The overall approach of the EU Regulations is to harmonize fragmented legal requirements and demonstrated claims of the manufacturer that a product complies with minimum product safety and performance requirements. It creates a special, sector-specific version of the CE mark system – a product safety certification – a process governed in general in the EU by the 'General Product Safety Regulation'.[20] As Hervey and McHale restated the CE acts as "a passport for the product, allowing it to be placed on the EU market and to circulate freely within in it".[21] In fact, "[a]ffixing the CE mark to a product is only legal after a conformity assessment has been performed"[22], which must have been carried out in accordance with the MDR and the IVDR. A medical device bearing a CE certification is presumed to meet general safety and performance requirements provided in Annex I of the MDR:

Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

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17 HÖLLE, K. Current developments on the MDR transition periods. *TaylorWessing*. 2023 [online] Available at: <https://www.taylorwessing.com/en/insights-and-events/insights/2023/03/aktuelle-entwicklungen-zu-den-ubergangsfristen-der-mdr>

18 EUROPEAN COMMISSION. *Extension of the Mdr Transitional Period and Removal of the 'Sell Off' Periods.* 2023, part I, point 1. [online] Available at: <https://health.ec.europa.eu/system/files/2023-07/mdr_proposal_extension-q-n-a.pdf>

19 Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices, COM(2023) 10 final.

20 HERVEY, T. K., McHALE, J. V. *European Union Health Law: Themes and Implications*… p. 369; Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety [2023] OJ L 135/1.

21 HERVEY, T. K., McHALE, J. V. *European Union Health Law: Themes and Implications*… p. 369.

22 KEUTZER, L., SIMONSSON, U.S.H. Medical device apps: an introduction to regulatory affairs for developers. *JMIR mHealth and uHealth*. 2020, vol. 8, no. 6, e17567, pp. 1–2. DOI: 10.2196/17567.

Moreover, all medical devices, other than custom-made and investigational devices, must be identifiable.[23] The EU Regulations require medical devices to have a Unique Device Identification (UDI) in order a product to be traced through the supply chain from manufacturer to patient. UDI means a series of numeric or alphanumeric characters that is created through an internationally accepted device identification and coding standards.[24]

Since the MDR and the IVDR are regulations and therefore directly applicable, one could state that there is a EU's regulatory structure for medical devices. It is half true as actually there is not a centralized single market authorization body in place. The market for medical devices in the EU does not operate under centralized system. In undertaking the task of whether a product constitutes a medical device, as it is stressed on the preamble of the MDR[25], is conferred to Member States. The regulation refers to legal powers of the Member States to decide on case-by-case bases whether a product falls within the scope of the EU Regulations. This has its effects in context of proper and fair functioning of the EU. Mainly because different Member States could have miscellaneous opinions. This may lead manufacturers on the one hand to 'forum shopping' by choosing a Member State which is less stringent in its approach as anyhow "[m]arketing authorizations given by individual Member State must be mutually recognized and taken into account in the other Member States".[26] On the other, this could potentially have implications for internal market law and its detailed provisions. Namely, without common decision-making body the implications on novel digital therapeutics solutions will come to light through the adversarial process of litigations, where there is a high degree of unpredictability of outcomes. As a result, one could ask whether the EU and Member States really prefer the court room approach to decide on the politics in medical settings?

2.2. Marketing Authorisation

Soon, the EU medical device market will be arranged by the EDAMED – the European database on medical device. The EUDAMED is integral part of the implementation of the two Medical Device Regulations, an IT system that is structured around interconnected modules and a public website – Actors registration; UDI/Devices registration; Notified bodies and Certificates; Clinical Investigations and performance studies; Vigilance and post-market surveillance;

[23] Art 27(1) MDR.
[24] Art 2(15) MDR.
[25] Recital 8 MDR.
[26] HERVEY, T. K., McHALE, J. V. *European Union Health Law: Themes and Implications*... p. 371.

Market Surveillance; and EUDAMED public. However, the use of EUDAMED is not yet mandatory nor required. It will be 6 months after the entire EUDAMED is declared fully functional.[27] Currently, there are already three out of six modules functioning. The general purpose of the database, among others, will be to adequately inform the public about devices placed on the market, the corresponding certificates issued by notified bodies and about relevant economic operators.[28]

Despite the EU Regulations and the EUDAMED, the backbone of medical device market relies still on national agencies. They are the so-called gatekeepers of the medical device market in the EU. In case of Estonia, the Republic of Estonia Health Board[29] (the Health Board) decides on behalf of the Member State whether a product qualifies as a medical device. The Health Board's Regulation[30] lays down its status as a competent governmental authority, which enacts according to Health Service Organisation Act[31]. The role of the Health Board is to implement the EU and the national public health related policies related to, among others, in the field of high-quality health care protection and the healthcare services.[32] The governmental authority reports to the Ministry of Health[33] and the framework of implemented measures are governed by Art 168 TFEU.

The notified bodies, so-called conformity assessment bodies designated accordance with the MDR, are more like supportive organs. "Notified bodies are nationally based, are under the oversight of a national 'competent authority,' and are certified by Member States."[34] They determine whether the medical device meets certain 'essential requirements', as specified in the Regulations.[35] Mostly they are for-profit organizations and will independently monitor whether device comply with the safety and performance requirements before certain medical devices reach the EU market. Contrary to pharmaceutical products where licensing is undertaking by public body like the European Medical Agency (the EMA) and other national agencies, the scrutiny of medical devices is undertaken by

27 EUROPEAN COMMISSION. *Public Health: Medical Devices – EUDAMED.* [online] Available at: <https://health.ec.europa.eu/medical-devices-eudamed/overview_en>

28 Art 33(1)(a) MDR.

29 In Estonian languga Terviseamet.

30 Terviseameti põhimäärus [Statute of the Health Board], RT I, 29. 12. 2022, 72. [online] Available at: <https://www.riigiteataja.ee/akt/129122022072>

31 Tervishoiuteenuste korraldamise seadus [Health Services Organisation Act], RT I 2001, 50, 284. [online] Available at: <https://www.riigiteataja.ee/en/eli/508012018001/consolide>

32 Terviseameti põhimäärus [Statute of the Health Board], RT I, 29. 12. 2022, 72... § 6(1)

33 Terviseameti põhimäärus [Statute of the Health Board], RT I, 29. 12. 2022, 72... § 4

34 HERVEY, T. K., McHALE, J. V. *European Union Health Law: Themes and Implications*... p. 369.

35 Ibid.

private companies.[36] Across the EU, as Tamara K. Hervey et al. note "[t]hey vary in their approach and capacity".[37] For instance, in Estonia, there does not exist any notified bodies for medical devices at all.[38] In general, it is expected to have certain control over their designation and functioning at the EU level[39], it does not in itself mean that the discretions on the market regarding medical devices based on national context will disappear. Namely, the notified bodies are still required to follow e.g., the principle of Art 168(1) TFEU, which, among others, states that in proving public health, preventing physical and mental illness and diseases, and obviating source of danger to physical and mental health, EU law only compliments entity based national policies.

Criticism on conferred powers in healthcare often stresses the challenges in common understandings of Member States on which product qualifies as a medical device and which not. In practice, one of the problems in determining whether a software qualifies as a medical device actually turns on deciding what is a medical device software and what is a wellness/lifestyle software. For instance, does a digital pain diary or a self-reporting cancer treatment software qualify as a medical device or a wellness/lifestyle software? Answers to these questions requires legal assessment on under which conditions does the MDR and IVDR apply on a product? Also, it requires understanding on how to interpret Art 168(1) in terms of lack of centralised decision-making body with the aim to promote proper functioning of internal market in terms of digital therapeutics as a medical device.

The life is changing faster than one could imagine. The health care setting and related jurisprudence is part of the evolution as well. As this article is not designed as a crystal ball gazing exercise, we provide here an account of the EU regime as it impacts on health at the time on writing in 2023. Future developments are for future articles.

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[36] GREER, S. L., ROZENBLUM, S. (eds.). Chapter 5: The EU market shaping health. In: GREER; ROZENBLUM (eds.). *Everything you always wanted to know about European Union health policies but were afraid to ask*. Third, revised edition. World Health Organization. Regional Office for Europe, 2022, pp. 183–219. [online]. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK590173/>

[37] HERVEY, T. K., McHALE, J. V. *European Union Health Law: Themes and Implications*... p. 370.

[38] EUROPEAN COMMISSION. *Single Market Compliance Space: Notified bodies (NANDO)*. [online] Available at: <https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies>

[39] Recital 50 MDR.

3. Software as a medical device in the EU

The qualification system in the EU provides that if software has a medical purpose on its own, it is qualified as a medical device software (MDSW) and "in order to be qualified as a medical device, the product must first fulfil the definition of a software" provided by Art 2(1) of the MDR.[40] In case of "to be qualified as an in vitro diagnostic medical device software, the product must additionally fulfil the definition of an in vitro diagnostic medical device" stipulated by Art 2(2) of the IVDR.

3.1. Is your product a software according the MDR and IVDR?

The MDR[41] provides that medical device means any software 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.[42] The wording defines a software by focusing on the aim of the software – it must have a medical purpose on human beings. The provision presents closed list of activities that should be referred as a medical purpose while does not clarify how the medical and non-medical purpose is defined. Nor does so the MDR or the IVDR. Namely, should the software be used in service that is provided only by a professional? Or is it enough if the software follows only some medical protocols? Without having answer to these questions, it is difficult to decide on whether e.g., a predictive headache software must be qualified a medical device or wellness/lifestyle software.

[40] MDCG 2019-11, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, p. 6.

[41] In order to be qualified as In vitro medical device, a product must first qualify as a medical dice in the context of the MDR.

[42] Art 2(1) MDR.

3.2. Medical Device Coordination Group (the MDCG)

The Medical Device Coordination Group (the MDCG), an EU's body, which provides advice to the Commission and assist the Member States, explains that „a set of instructions that process input data and creates output data"[43] can be qualified as a medical device. The approach reflects a software in technical means via two components – 'data' and 'set of instructions'. The MDCR elaborates that "[a]ny data provided to software in order to obtain output data after computation of this data can be considered as input data".[44] Also, "[a]ny data produced by a software can be considered as an output data".[45] The MDCG does not underline any requirements on how the data should be provided nor on how or to whom the data should be displayed. Accordingly, in terms of the purpose in question, processing of data does not require any particular type of data such as a personal data or health related data or must have a demonstrable access for professionals in order to fall under the definition of a software in terms of medical device. The data in question is rather understood broadly and has effect in technical terms relating to specific information management practices – as an aspect of the purpose.

Continuedly, the concept of 'set of instructions' is not explained by the MDCG. In the context of general understanding, the set of instructions[46] are as written form of a computer program, which is based on "the so-called high-level languages (HLL) that bear a certain resemblance to literary language and have their own rules of syntax and grammar".[47] It is a computer program that can be expressed by source code and object code. Since the aim in question is to define a set of instructions in terms of software, at the heart of this discussion is the source code. The code, which is written and designed by the programmer. Namely, in case of digital therapeutics, the set of instructions are defined by evidence-based approach and commands to execute are written by a programmer. Consequently, these commands are translated or complied into version that can be 'understood' by a computer/phone/device (object code) – "a series of '0's and '1's reflecting the presence or absence of an electrical pulse".[48] Without going any deeper, a hasty conclusion is that a software in its literary form is not readily understood other than by a person skilled in that programming language that the

[43] MDCG 2019-11, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, p. 5.

[44] Ibid.

[45] Ibid.

[46] Also known as a module.

[47] ROWLAND, D., KOHL, U., CHARLESWORTH, A. *Information technology law*. London: Routledge, 2017, p. 447.

[48] ROWLAND, D., KOHL, U., CHARLESWORTH, A. *Information technology law.* London: Routledge, 2017, p. 448.

software is written[49] and in case of digital therapeutics, it is an expression of ides (medical protocols) with the aim to prevent, manage, or treat a medical disorder or diseases, or wellbeing.

In terms of legal clarity, there would be desirable to have reference in the MDCG guidelines regarding 'set of instructions' that they should reflect in respect of schemes, rules, and methods for performing mental acts in medical treatment, surgery, therapy and diagnostics methods practised on the humans. This would help to distinguish the aspects of which product should be qualifies a medical device and which, for instance, wellness/lifestyle software. However, since it is not the case, the 'set of instructions' should be currently understood broadly and thus have its effect on any set of instructions. In shortly, the definition given by the MDCG on a software, without the context of general understanding, could be slightly misleading. Addition to above, lack of clear references on whether processing of data or data itself must exist in digital means, may rise questions regarding the actual scope of the MDR. However, since a software can exist only by digital means and the guidelines by their nature are not legal sources, in this article, the authors take the approach that the data defined in this question should be presented and is processed only in digital means.

3.2.1. CJEU: Snitem and Philips France case

The latest case which reveals the MDR's provision on how to define a medical device is *Snitem and Philips France*[50] case. The Court of Justice of European Union (the CJEU or the Court) held that for a computer program to be regarded as a medical device, it must satisfy two conditions cumulatively – **the objective pursued** and **the action resulting therefrom**.[51] With this in mind, the Court explains that in order to a product be qualified as a medical device, it is not sufficient that software can be **used in medical context**. It is also necessary that the intended purpose, defined by the manufacturer, is **especially medical** (judgement of 22 November 2012, Brain products, C-219/11, EU:C:2012:742, paragraphs 16 and 17). For instance, a software must be qualified as a medical device if it cross-references patient-specific data with the drugs that the doctor is contemplating prescribing, and is thus able to provide the doctor, in an automated manner, with an analysis intended to detect, in particular, possible contradictions,

[49] ROWLAND, D., KOHL, U., CHARLESWORTH, A. *Information technology law.* London: Routledge, 2017, p. 448.

[50] Case C-329/16 ECR Syndicat nationel de l'industrie des technologies médicales (SNITEM), Philips France v Premier minister, Ministre dea Affaires sociales de la Santé [2017] ECLI:EU:C:2017:501.

[51] Ibid, point 22.

drug interactions and excessive dosages, is used for the purpose of preventing, monitoring, treatment or alleviation of a diseases, and therefore pursues a specifically medical objective, should be qualified as a medical device. The Court however does not reveal in its explanations the concept of 'especially medical', nor does so the MDR or IVDR. Thus, it remains unanswered the question whether the concept is synonym of the notion of the health service in the EU, or not? This means, in order to a product be qualified as a medical device does it require involvement of a health care professional or having instead only medical effect on humans? Or both?

The uncertainty is mostly created by effects that the EU's explicit competencies are still limited in the field of health care. The health care settings are viewed as "an economic priority and EU policies are designed around European integration and harmonisation, anchored in what is referred to as the 'European Social Model'"[52] and underlined by the European Pillar on Social Rights. Since the EU is driven and shaped predominantly by market forces the health care in the EU is thereby "being framed in terms of rights and values in a European market for health".[53] This is emerged from the obligation of the Union to promote high level of protection of human health[54], meantime having no power to define the scope and application of health-care-related services.[55] Therefore, the concept of health service is defined by nation laws in different Member States and as a result the question regarding medical purpose may vary in different Member States. Mainly in questions related to predictive and wellness or lifestyle software, and predictive and lifestyle tests.

3.3. Existing risks and vulnerabilities of DTx legal regulation: examples of Estonia and Germany

3.3.1. 'Medical purpose': example of Estonia

In Estonia, according to paragraph 2(1) of the Health Service Organisation Act[56] (the Act), health services are the activities of health care professionals for the prevention, diagnosis or treatment of diseases, injuries or intoxication in order to reduce the malaise of persons, prevent the deterioration of their state of health or development of the disease, and restore their health. The exact list of services

[52] GRAEME. L., HARMON; S., DOVE, E. *Mason and McCall Smith's Law and Medical Ethics*. Oxford University Press, 2019, p. 41.

[53] Ibid.

[54] Article 9 TFEU.

[55] See Art 6(a) and Art 168 TFEU.

[56] Tervishoiuteenuste korraldamise seadus [Health Services Organisation Act]. RT I 2001, 50, 284 [online]. Available at: <https://www.riigiteataja.ee/en/eli/508012018001/consolide>

that fall under this paragraph is established by the minister responsible for the domain. Accordingly, the Act defines what constitutes a health service and how the list of services is defined but does not reveal what should be understood by means of medical purpose. Is the notion of medical purpose synonym of the health service in Estonia? Can we state that this requires involvement of a health care professional or having instead only medical effect on human's body? Nor the national Medical Device Act[57] gives a clear answer to that.

Admittedly, medical jurisprudence is composed by medical law and bioethics.[58] The core of these two fields is medical practice – "with its emphasis on the one-to-one relationship between doctor and patient within the confine of the home, surgery, or hospital".[59] The Hippocratic Oath is an integral part of it, which provides the statement of practitioners: "I will share my medical knowledge for the benefit of the patient and the advancement of healthcare".[60] On the axel of medical jurisprudence, the legal challenges which medical law tries to regulate in Estonia are therefore on the close proximity to a doctor/a person who is treating and to a patient/a person who is receiving the treatment.[61] As Ants Nõmper et al. stated: medical law covers topics that have a smell of the white coat.[62]

In Estonia, medical activities amount to services and fall under § 758 -773 of the Law of Obligations Act[63] (the VÕS) and Art 57 TFEU. These provisions provided by the VÕS apply to all health care related services and requires that such service should be offered only as a professional activity. Accordantly, a lawful medical activity can take place only if service is provided by a professional. Apart of that, § 758(1) the VÕS stipulates that these provisions on health care services should apply particularly:

by examining the patient in the interest of his or her health and observing the rules of medical, by consulting and treating the patient of offering obstetrical care to the patient, and by informing the patient of his or her state of health and the progress and results of his or her treatment.

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57 Meditsiiniseadme seadus [Medical Devices Act]. RT I 2004, 75, 520 [online] Available at: <https://www.riigiteataja.ee/en/eli/515032023005/consolide>

58 GRAEME. L., HARMON; S., DOVE, E. *Mason and McCall Smith's Law and Medical Ethics*..., p. 2.

59 GRAEME. L.; HARMON; S.; DOVE, E. *Mason and McCall Smith's Law and Medical Ethics*..., p. 3.

60 Ibid.

61 NÕMPER, A., SOOTAK, J. *Meditsiiniõigus [Medical Law]*. Tallinn: Juura, Õigusteabe AS, 2007, p. 14.

62 NÕMPER, A., SOOTAK, J. *Meditsiiniõigus [Medical Law]*. Tallinn: Juura, Õigusteabe AS, 2007, p. 14; The white coat is a dressing wered by doctors.

63 Võlaõigusseadus [Law of Obligations Act] RT I 2001, 81, 487. [online] Available at: <https://www.riigiteataja.ee/en/eli/524032023004/consolide>

These are services that includes the aspects of 'medical purpose' in Estonia and admittable there is a strong influence by the understanding that medical activities should be provided by professionals. Namely, VÕS § 758(2) provides that qualified doctors, dentists, nurses, and midwifes are responsible for their actions in duty.[64] As a result, in the context of Estonia, it presumed that the medical purpose notion has a smell of a white coat. However, since there are no clear guidelines issued by the Member State nor any case law which actually provides understandings how the topic is regulated in the light of the DTx but there exist awareness that medical devices are used in beaty salons, the actual approach is rather on the fact it should have only medical effect on humans.

3.3.2. The German approach as a "leading" pathway for EU Member States

In December 2019 the German Digital Service Law ("Digitale-Versorgung-Gesetz") was adopted. This innovation-friendly law has been recognized as a groundbreaking step forward to providing digital-enabled patient care.[65] Its main goal was to provide patients with broad access to low-risk digital medical applications and to stimulate innovation in this area. The specified law introduced the general right to provide and reimburse digital medical applications (DiGA) for insured persons within the framework of compulsory medical insurance in Germany. In particular, the DVG provided doctors with the opportunity to prescribe DTx to patients, while at the same time guaranteeing reimbursement through the State Insurance Mechanism (GKV). In order to be discharged and therefore reimbursed, DTx must be included in a special DiGA list after a positive assessment by the German regulatory authority – the Federal Institute for Drugs and Medical Devices (BfArM).

It should be noted that Germany has taken an innovative step forward to comprehensive care for patients with digital support in connection with the adoption of the German Digital Service Law (DVG). In particular, in order to obtain permission to reimburse expenses in accordance with DVG requirements, the manufacturer must prove that the medical application meets the requirements of security, functionality and quality, as well as data protection requirements. Besides, the manufacturer must show that the application has a positive impact on patient care, which, in turn, must be confirmed by a comparative study demonstrating the benefits of using the application, as opposed to not using it.

[64] Ibid.

[65] GROENE, N., SCHNECK, L. Covering digital health applications in the public insurance system: how to foster innovation in patient care while mitigating financial risks – evidence from Germany. *Frontiers in Digital Health*. 2023, vol. 5, 1217479 DOI: 10.3389/fdgth.2023.1217479.

Such a study should generally be retrospective and not necessarily constitute a genuine clinical trial. Valid concepts are epidemiological studies or studies using methods from other scientific fields, such as health research. Moreover, with the implementation of the EU Digital Content Directive (Directive (EU) 2019/770) in the German Civil Code (*Bürgerliches Gesetzbuch* – "BGB"), the German legislator has also reinforced consumer protection in this area of law. So it means that where digital medical applications are marketed to consumers, manufacturer obligations under these provisions may even go beyond the general regulatory obligations under the MDR.

However, in this area of law, proper regulation regarding data protection is still required in order to ensure optimal protection of the medical data of data subjects "to achieve a balance between protecting the patients' fundamental rights of autonomy and confidentiality of their health data on the one hand, and creating digital health services and a high level of work efficiency across the health sector on the other hand".[66] Indeed, one of the key challenges of digital healthcare is the processing of patient data (including sensitive data), the widespread use of which has significant value for research and development, but at the same time is limited by a number of local and national regulations, as well as EU regulations, including EU Regulation 2016/679 (General Data Protection Regulation – "GDPR"). Moreover, DTx also allows the collection of patient-level data that can be used to reassess their safety and effectiveness in real-world settings and to study the quality of life of patients by collecting the results reported by patients. In this framework, the exponential growth in the volume of data related to individual patients raises some legal concerns about the quality and safety of the data collected.[67] Thus, the growing use and development of data sharing technologies implies the need to define a legal framework capable of protecting human privacy, while ensuring transparent data exchange for research purposes, therefore it is important to create systems for collecting real data, ensuring data quality and respecting patient data protection. Moreover, where digital medical products and services require the transfer and processing of personal data (including sensitive health data), data protection authorities also monitor the market, while failure to comply with data protection requirements can lead to severe sanctions such as an injunction to stop processing and/or imposition of huge fines. This means that the harmonization of regulatory processes in the field of data protection is a crucial issue, since the

[66] Ibid.

[67] GOPAL, G. V., SUTER-CRAZZOLARA, C., TOLDO, L., EBERHARDT, W. Digital transformation in healthcare – architectures of present and future information technologies. *Clinical Chemistry and Laboratory Medicine*. 2019, vol. 57, no. 3, pp. 328–335. DOI: 10.1515/cclm-2018-0658.

lack of specific regulations guaranteeing the safety and quality of these devices is another obstacle to the development of DTx.[68]

At the same time, the German law does not define "digital health" specifically and the term can be interpreted broadly in its law-enforcement practice. In particular, digital health is a general term for the new markets in which the providers of such digital medical products and services as telemedicine servies, medical software applications for smartphones and other medical devices including artificial intelligence and others are active. The term "digital health", similar to "e-health", is symbolic of the rapidly advancing digitisation of the German healthcare sector. And even if the German law has been widely recognized as forward-looking and a driver of digital health innovation, it also entails certain risks for the public healthcare system and due legal classification of digital health technologies (including DTx) as medical devices in the legal practice.[69] Thus, In accordance with German law, DTx is recognized as a new category of medical devices, but there are currently no relevant case-law on liability in this area of law. In legal practice this means that the manufacturers themselves should critically analyze whether certain functions of their digital (medical) product can lead to its classification as a strictly regulated medical product (medical device) from the point of view of the German law. In addition, for the possible liability of the manufacturers whose DTx will be classified as medical devices, the question of which specific risk class these products should be classified is essential. On the other hand, convincing clinical evidence on the therapeutic benefits of digital therapy and strict compliance with MDR requirements, including data protection and security requirements, can minimize liability risks. Nevertheless, new issues of liability in connection with DTx, which have so far been little discussed in judicial practice, require a specific analysis of possible risks and appropriate insurance on an individual basis.

Simultaneously, the progressive digitalization in the healthcare sector is already opening up space for many new business areas. As N. Groene and L. Schneck point out: "Countries seeking to introduce similar innovation-friendly legislation might therefore refer to Germany to understand the mechanics of the legislation, its related risks and how these risks have empirically unfolded to derive implications for their national policies".[70] Indeed, Germany has become

[68] RASSI-CRUZ, M.; VALENTE, F.; CANIZA, M.V. Digital therapeutics and the need for regulation: how to develop products that are innovative, patient-centric and safe. *Diabetology & Metabolic Syndrome.* 2022, vol. 14, no. 1, pp. 1–7. DOI: 10.1186/s13098-022-00818-9.

[69] GRIEB, J., TSCHAMMLER, D., FÄRBER, C., WOITZ, S. Digital Health Laws and Regulations Germany 2023-2024. *International Comparative Legal Guides International Business Reports*. 2023. [online] Available at: <https://iclg.com/practice-areas/digital-health-laws-and-regulations/germany>

[70] GROENE, N., SCHNECK, L. Covering digital health applications in the public insurance system: how to foster innovation in patient care while mitigating financial risks—evidence from Germany. *Frontiers in Digital Health*. 2023, vol. 5., 1217479 DOI: 10.3389/fdgth.2023.1217479.

a leader in the regulation of the DTx market, becoming a "reference point" for other EU Member States in this area of law. In turn, other EU Member States, such as, for example, Latvia, France or Belgium, are also taking steps in this direction.[71] However, it should be noted that the EU medical device law is still immature. In this regard, we believe that only the progress of law enforcement practice in this area of law will show the real practical obstacles and problems in classifying various digital medical applications (medical devices) as DTx at both national and European levels, taking into account the constant development of digital technologies. In other words, it is the further development of legal practice that will allow us to show the real vulnerabilities and shortcomings of the legal regulation of the DTx market (including the problems of their classification in the context of developing digital technologies). And here the legal experience of the leading EU Member States and, first of all, Germany, can become a significant point for such a development of the European DTx market. We expect other EU Member States to adopt the "German approach" in the near future, as the largely similar standards in all Member States will make the EU a particularly attractive place for DTx innovators.[72]

3.4. Digital healthcare services

As it was stressed above, in Estonia, there does not exist a special legal framework for digital healthcare services. The existing e-health system (Health Information System)[73], which is governed by the state, is created, and currently functioning based on the Basic Regulation of the health information system[74]. The aim of this regulation is to stipulate the rules for processing health related data by the Health Information System but does not set actual requirements for digital healthcare services in Estonia. The so-called rulebook could be seen as an extension of Art 6(2) GDPR, allowing Member States to introduce more specific provisions for processing data related to health. The Basic Regulation just clarifies some GDPR rules such as who are authorized representatives in certain cases and some technical aspects of processing data but does not create the scope of digital service in health care.

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71 BROWN, D. *Digital Therapeutics Regulation: 3 Leading Countries (inc. FDA, MDR, & DiGA).* 2021 [online] Available at: <https://www.smartpatient.eu/blog/fda-mdr-digital-therapeutics-regulation-leading-countries>

72 Ibid.

73 TERVISEPORTAAL. *Sinu värav terviseteenustesse [Your gateway to health services].* [online] Available at: <https://www.digilugu.ee/login>

74 Tervise infosüsteemi põhimäärus [Health Information System Statutes] RT I, 06. 12. 2016. 11 [online]. Available at: <https://www.riigiteataja.ee/akt/112032019034>

Contrary to Estonia, Germany has adopted the Digital Supply Law (the DWG), which came in force 9 December 2019. The law does not only focus on technical aspects of data processing but also on aspects of digital service requirements, in order to be qualified as a digital healthcare service. Accordingly, patents in Germany are now in position to use health apps that help them ee.g., to document their blood sugar level and get benefits from other DTx solutions. The Apps are tested by the Federal Institute for Drugs and Medical Devices (BfArM) for safety, functionality, quality, data security and data protection.[75] As a result, the notion of 'medical purpose' in the means of DTx is covered, among other understandings, by the DWG.

4. Exclusion: not a medical device

As it was shown in previous chapter, there is no clear regulative base for understanding how the notion 'medical purpose' is defined in Estonia. As a result, it is tricky to assume that the context is same as in Finland, in Spain or in France. Therefore, one could say that the notion of 'medical purpose' may be differently understood in different Member States, for instance, for certain predictive and lifestyle tests. This all affects directly whether a pain diary or a self-reporting symptoms tool should be considered as a medical device or not.

Despite the fact that at the EU level, there does not exist a clear and easily followed guidelines for notion of 'medical purpose', there are some pinpoints which will help to understand and follow the EU's approach. For instance, the MDR stipulates that products which achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, are not medical devices.[76] These products are regulated by other means. Also, " " [s]imple search", which refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information does not qualify as a medical device software (e.g. library functions)".[77] Additionally software, which has the sole purpose of archiving, collecting and transmitting data, like patient medical data storage software, the function of which is limited to indicating to the doctor providing treatment the name of the generic drug

[75] BUNDESMINISTERIUM FÜR GESUNDHEIT. *Ärzte sollen Apps verschreiben können [Driving the digital transformation of Germany's healthcare system for the good of patients]*. 2020. [online] Available at: <https://www.bundesgesundheitsministerium.de/digitale-versorgung-gesetz.html>

[76] Art 2(1) the MDR.

[77] MDCG 2019-11, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, p. 6.

associated with the one he plans to prescribe, or software intended to indicate the contraindications mentioned by the manufacturer of that drugs in its instructions for use, is not qualified as a medica device.

Provided these examples and the *Philips France*[78] case, it shows that if a software cannot imitate the work of the brain of a doctor (being able to take decisions regarding human's health) and only displays data from different sources it should not be considered as a medical device. Accordingly, a digital pain diary which collects data from its users and matches it with recommended publicly available information to manage the pain may not be qualified as a medical device. Whereas, for instance, a software which collects data from its users, processing it by using medical diagnoses or treatment protocols from the domain, which are designed in the source code, could be qualified as a medical device. This should also apply to a self-reporting tool on cancer symptoms, whether its functions are e.g., linked to protocols of doses assessment of the chemotherapy or not.

Importantly, it must be noted that the MDR and the CJEU follows the understanding that software is comprised by modules. According to Art 1(3) MDR, devices with both a medical and non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose. In practice this means that software can have sever 'set of instructions', or modules. If one module is considered to fall under the MDR regulation, other modules must as well fulfil the requirements stipulated by the regulation.

4.1. Software as a wellness/lifestyle application

In practice, in the matter in question can be determine also by using exclusion methodology – if a software does not qualify as a medical device, it is qualified as a wellness/lifestyle software. Adding here the unique feature of EU law, one could among other challenges, overcome the national interpretation of 'medical purpose'. Namely, "EU law enjoys supremacy or primacy over contradictory national law".[79] This requires Member Sates' courts e.g., to "set aside any such contradictory national law and apply EU law in its place".[80]

Development of wearable technology is a good example of mainstreamed use of activity trackers and fitness watches. New generation of such devices

[78] Case C-329/16 ECR Syndicat nationel de l'industrie des technologies médicales (SNITEM), Philips France v Premier minister, Ministre dea Affaires sociales de la Santé [2017] ECLI:EU:C:2017:501.

[79] MOSSIALOS, E. (ed.). *Health systems governance in Europe: the role of European Union law and policy*. Cambridge University Press, 2010, p. 93.

[80] MOSSIALOS, E. (ed.). *Health systems governance in Europe…* p. 93.

have several health- and wellness-related capabilities. In practice, they can track health/wellbeing and medical information, for example, "counting steps, physical activity minutes, sitting time, heart rate, sleep duration, body temperature, oxygen saturation (SpO2), irregular heart rhythms, and more".[81] In the EU, like in Estonia, there is no specific legal framework for wellness or lifestyle software or applications. These type of software are generally regulated, among others, by Regulation (EU) 2016/679 on the protection of natural persons with regarding to the processing of personal data and the free movement of such data (the GDPR)[82], Regulation (EU) 2022/2065 on a Single Market For Digital Services (The Digital Service Act)[83] and Regulation (EU) 2022/1925 on contestable and fair markets in the digital sector (the Digital Market Act)[84].

However, the EU is currently creating a European health data space (the EHDS Proposal)[85], which among others, will lay down rules that have impact on wellness application. The wellness applications in the context of the EHDS are "any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles.[86] They are a software, which has the limited relevance for healthcare purposes[87] but can be useful for healthcare purposes. Despite the fact that the definition does not have any legal effect, it gives indications to which direction EU law is going. From technical point of view, this means that activity trackers and fitness watches may process two types of data simultaneously – health/wellness data and medical data, which are often difficult to differentiate. Which relevant to stress in the light of health care

[81] SCHEID, J. L., REED, J. L., WEST, S. Commentary: Is wearable fitness technology a medically approved device? Yes and no. *International Journal of Environmental Research and Public Health*. 2023. vol. 20, no. 13, p. 6230. DOI: 10.3390/ijerph20136230.

[82] 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) [2016] OJ L 119.

[83] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) [2022] OJ L 277.

[84] Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act) [2022] OJ L 265.

[85] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final.

[86] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final, Art. 2 (2) (o).

[87] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final, Recital.

is that "[h]ealth and wellness information should not be used to diagnose medical condition but rather it simply provides a real-time measurement of physical activity, sedentary time, and/ or sleep paraments".[88] This means that the notion of 'intended purpose' could help to define the EU's understanding of 'medical purpose'.

4.2. Intended purpose – Art 2(12) the MDR

The intended purpose concept draws the difference between a wellness/lifestyle software and a medical device software. Intended purpose means the use which for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.[89] Namely, the Implementing Regulation (EU) 2017/2185 (the Implementation Regulation) provides list of intended purposes which could be qualified as a medical device, such as software intended to be used for:

blood grouping, tissue typing, markers of cancer and non-malignant tumours, human genetic testing, determination of markers of infection/immune status, non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures, and more.

Indeed, the Implementation Regulation applies only Class IIa, Class IIb and Class III devices, leaving out medical devices of Class I. In this regard the approach is not perfect however it is presumed that taking into account the medical purpose approach, which requires for software to imitate a brain of a doctor in order to be qualified as a medical device, it would be challenging to get Class I certificate for any such software. Rather, due to their intended purpose they are seen at least as Class II device. For instance, Series 8 Apple watch, including measurements related to irregular heart rhythms (e.g., identifying episodes of atrial fibrillation AFib) is considered as a Class II medical device by the Food and Drug Administration (FDA).[90]

The MDCG explains that in its guidelines that "software which is intended to process, analyse, create or modify medical information may be qualified as a medical device software if the creation or modification of that information is

[88] SCHEID, J. L., REED, J. L., WEST, S. Commentary: Is wearable fitness technology a medically approved device? Yes and no. *International Journal of Environmental Research and Public Health*. 2023. vol. 20, no. 13, p. 6230. DOI: 10.3390/ijerph20136230.

[89] Art. 2(12) MDR.

[90] KAR, S. N. *Apple obtains FDA 510(K) clearance for a new AFib history feature for Apple Watch.* 2022. [online] Available at: <https://www.myhealthyapple.com/apple-obtains-fda-510k-approval-for-a-new-afib-history-feature-prior-to-wwdc/>

governed by medical intended purpose".[91] For instance, searching images for finding that support a clinical hypothesis as to the diagnosis or evolution of therapy.[92] Or a "software, which locally amplifies the contrast of the finding on an image display so that it serves as a decision support or suggests an action to be taken by the user".[93] The MDCG stresses that for instance, "cosmetic or compatibility purposes does not readily qualify the software as medical device software"[94] and means that "the risk of harm to patients, users of the software, or any other person, related to the use of the software within healthcare, including a possible malfunction is not a criterion on whether the software qualifies as a medical device"[95]. This creates un understanding that the 'smell of white coat 'is required also at the EU level as it is the case in Estonia.

5. Conclusion

To sum up, EU law provides that in order to a software to be qualified as a medical device it should be able to be used in medical context and the intended purpose must be especially medical. The notion of 'medical purpose' however is not clearly defined at the EU level. Mainly, it is due to the challenging conferred power system stipulated by the EU Treaties. Therefore, the pathway of a product to become a medical device in the EU is complicated and may vary within the Member States despite having common EU wide medical regulations in place.

For instance, in Estonia, the is not a special legal act for digital healthcare services. Therefore, in order to understand which software could qualify as a medical device require interpretation of several general health care laws. But it seems that in order software to be qualified as a medical device, the involvement of professionals as a user is rather required. In practice, this could mean that if DTx software cannot have demonstrable access for professionals or is not integrated with the existing Estonian Health Information System, a product may not be qualified as a medical device. In other words, if national professionals or/and a competent authority of the Health Information System do not accept a DTx as a component of a medical service, this may impede the use of beneficial tool as a medical device. Whereas in Germany, digital services in healthcare are regulated by special legal act, which among others, clarifies aspects on when

[91] MDCG 2019-11, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, p. 6.
[92] Ibid.
[93] Ibid.
[94] Ibid.
[95] Ibid, p. 7.

a software could be qualified as a medical device in terms medical digital services. However, it should be studied further whether German's approach also have some additional country-based challenges, which may impede harmonized implementation of the EU Regulations for DTx as a medical device.

Despite all this, what is clear is that the software must be able to imitate the work of the brain of a doctor – via being able to take decisions based on medical data in order to be qualified as a medical device, not only displaying data from different data sources. More precisely, the set of instructions defined by the software must follow medical protocols and have a 'intended medical purpose' that has a 'smell of white coat'. This requires professionals to be part of the use of a software in order a software to be qualified as a medical device. Everything which stays out of the mentioned scope would rather not to be qualified as a medical device and therefore is not intended for use in medical diagnosis, treatment, or for any other medical purpose even if there is a risk of harm to humans, including possible malfunctioning.

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