The Motion Damian Müller: Would greater room for maneuver in the procurement of medical devices lead to higher risk for patient safety?

A Comparison of Medical Device Regulations in the USA and Switzerland.

Master thesis submitted to the University of Bern

Supervisor: **Prof. Dr. Rudolf Blankart**

Kompetenzzentrum für Public Management

Schanzeneckstrasse 1

CH-3001 Bern

By:

Lukas Stickroth

Heidelberg, Germany

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Abbreviations

21 CFR	21 Code of Federal Regulation
AIMDD	Active Implantable Medical Device Directive
BFARM	German Federal Institute For Drugs and Medical Devices
CE	Conformité Européenne
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
DSF	Device Software Function
EU	European Union
EUDAMED	European Database for Medical Devices
FDA	U.S. Food and Drug Administration
FD&C ACT	Federal Food, Drug, and Cosmetic Act
FOPH	Federal Office of Public Health
HRA	Federal Act on Research involving Human Beings (Human Research Act)
IMDRF	International Medical Device Regulators Forum
InstA	Institutional Framework Agreement
ISO	International Organization for Standardization
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR / EU-MDR	Medical Device Regulation
MDSW	Medical Device Software
MedDO	Medical Devices Ordinance
MMA	Mobile Medical Application
MRA	Mutual Recognition Agreement
PACS	Picture Archiving And Communication System
QMS	Quality Management System
SaMD	Software as a Medical Device
SiMD	Software in a Medical Device
SFC	Switzerland's Federal Council
SMEs	Small and medium-sized enterprises
TF	Technical Files
TPA	Federal Act on Medicinal products and Medical Devices (Therapeutic Products Act)
USA	United States of America

Management Summary

This master thesis analyzes the possible consequences for patient safety of introducing medical devices from third countries into Switzerland.

First, the introduction lays out the basic problem of the current situation and how it came about. Due to deficiencies in medical devices, the countries of the European Union adopted a new Medical Device Regulation, which provides for stricter procedures for declaring the conformity of medical devices, as well as higher risk class ratings for medical devices. Switzerland subsequently adapted its Medical Devices Ordinance to the Medical Device Regulation. At the same time, negotiations on the Institutional Framework Agreement between Switzerland and the European Union were broken off and the Mutual Recognition Agreement was not updated. The latter led to Switzerland now being considered a third country by the European Union.

For Switzerland, one consequence of this was that declarations of conformity that had been clarified by the Designated Bodies in Switzerland were no longer recognized by the European Union. The stricter rules of the Medical Device Regulation also led to a bottleneck of available medical devices. This prompted Damian Müller, a member of the Council of States, to call on the Federal Council to recognize medical devices from third countries. Despite concerns of the Swiss Federal Council, this motion was accepted and must now be implemented.

In this master thesis, the current regulations of Switzerland are first compared with those of the United States of America. The basic differences of the regulations, such as the conformity assessment procedures in Switzerland and the European Union, are compared to the Premarket Notification 510(k) and other procedures of the United States of America.

The focus is then placed on patient safety, and it becomes clear that the term patient safety is not easy to define; in addition to the risks posed by the medical devices themselves, the range of medical devices and innovations are also decisive factors.

Subsequently, two health applications, which are approved as medical devices according to Medical Device Regulation, are analyzed and their functions are compared with possible evaluation decisions of the U.S. Food and Drug Administration. This is done using non-legally binding guidelines provided to manufacturers by the regulatory agency of the United States of America.

In the presentation of the results, as well as the subsequent discussion of their significance for patient safety, the author concluded that it cannot be affirmed that the introduction of products from third countries such as the United States of America will lead to a direct impairment of patient safety. Rather, standardization and international collaboration will lead to improvements in patient safety.

The low availability of information on the exact functions of medical devices as well as the limitation to individual products lead to a lack of generalizability of these results.

1. Introduction

Due to scandals in the field of medical devices in the European Union (EU) (e.g., the PIP scandal: manufacturers used industrial instead of high-purity medical silicone to produce silicone breast implants), the Medical Device Directive (MDD), which was introduced to harmonize laws in the EU, was superseded by the Medical Device Regulation (MDR). The MDR came into force in 2017, and as of May 26, 2021 no products can be placed on the market under MDD (European Union 2023).

The Mutual Recognition Agreement (MRA) of 2002 served to reduce technical trade barriers and achieve mutual recognition of medical devices in Switzerland (CH) and the EU. However, this has not been updated to MDR approved products, which is why the security of supply from medical devices in Switzerland is at risk. In the absence of an update, Switzerland is thus considered a third country from an EU perspective. Consequently, Switzerland no longer has access to the European Database for Medical Devices (EUDAMED) to report incidents rapidly. This means, for example, that Switzerland can neither report incidents to EUDAMED nor direct measures to protect patients, as reports handed out by EUDAMED will not be received by the relevant agencies in Switzerland. As no agreement between the EU and Switzerland regarding the Institutional Framework Agreement (InstA) has yet been reached, there will be no updated MRA for the time being.

In anticipation of an updated MRA, the Swiss Federal Office of Public Health (FOPH), which subordinate to the Federal Department of Home Affairs and responsible for the national health

policy in Switzerland, comprehensively revised its Medical Devices Ordinance (MedDO) in close correlation with the MDR as of 26 May 2022. The FOPH justifies this revision as it is intended to dampen negative effects for a limited period of time, as Swiss authorities no longer have access to EUDAMED and cooperation regarding market surveillance is limited (BAG 2021, p. 4). These measures did not yet lead to the desired results regarding the supply of medical devices to Switzerland, as the revision lead to the same restrictions and prerequisites for medical devices from the EU in Switzerland and vice versa.

The revised MedDO leads to third countries as from the EU requiring a Swiss authorized representative (Article 51 MedDO) within the transition period (Article 104a MedDO). If producers do not register in time, necessary products cannot be imported in an "ordinary way" and supply might be at risk. In the EU, the transition period for producers and their medical products needed to be extended already to keep supply steady.

The new stricter rules for regulation under MedDO and the MDR can lead to delayed placing of innovative products on the market.

The Motion 20.3211 by Damian Müller addressed a possible solution to keep the supply steady.

Damian Müller demanded that products certified by non-European regulatory systems with similar requirements should also be admitted. The Federal Council recommended the rejection of this Motion, pointing to the possibilities for exemption and the major differences between the different regulations of medical devices in the EU and the United States of America (USA). At this time, the Federal Council might have expected the issues around the InstA and MRA to be resolved soon., the Motion was adopted by the Council of States on May 30, 2022, and by the National Council on Nov. 28, 2022.

As explained in the statement of the Federal Council of 02.09.2020, there are major differences in the regulatory systems of the USA and Switzerland. It is now necessary for politicians to assess whether and to what extent the approval according to the rules of the U.S. Food and Drug Administration (FDA) differ from the Swiss standards.

Switzerland and the USA differ substantially in the process of bringing medical devices to the US or Swiss market respectively. The USA has an authority, the FDA, which decides on the approval of medical products, whereas manufacturers in the EU declare the conformity of their medical products themselves but must undergo a conformity assessment procedure.

Since this paper focuses on the regulatory level and certification of medical devices at the product level, the author will not compare the risk and quality systems of the USA and Switzerland at the company level.

2. Background

In this chapter, the author will describe the different systems for regulation of medical devices in Switzerland, with reference to the EU, and the USA.

For this comparison, the author analyzed laws, regulations and other legal documents from Switzerland, the EU, and the USA. For the Result-chapter, these legal contexts from different countries were compared and for the Discussion-chapter, the consequences for patient safety through implementing products from the USA in Switzerland will be identified.

Based on these findings, the author will identify consequences for the Swiss market and challenges which need to be addressed.

a. Comparison Regulation in Switzerland and the USA

Switzerland

Legislative Background

In Switzerland, medical devices are regulated under the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) and the Federal Act on Research involving Human Beings (Human Research Act, HRA). Medical devices fall under the scope of the Medical Device Ordinance (MedDO). Furthermore, the Ordinance on In Vitro Diagnostic

Medical Devices (IvDO) is an important ordinance for the regulation of medical devices, but it is not in scope of this research paper.

The TPA regulates the marketing of medicinal products and medical devices in Switzerland. It has been in force since January 1, 2002. In addition to medical devices, the TPA also governs the regulation of medicinal products and the control of narcotics traffic. Swissmedic is the central supervisory authority and is subordinate to the Federal Department of Home Affairs.

The HRA applies to research concerning human diseases and the structure and functioning of the human body, where its purpose is to protect the dignity, privacy and health of human beings involved in research. (Art.1, Art.2 HRA).

Especially relevant for this master thesis is the MedDO, which regulates medical devices in Switzerland on an ordinance-level. To ensure conformity with the EU-MDR, the MedDO refers in Article 5 directly to the EU-MDR.

Therefore, this research paper will refer to the EU-MDR (also referred to as MDR in this paper), when necessary.

The MedDO and MDR refer to a wide range of medical devices for human use, including instruments, implants, software, and diagnostic equipment. Both introduce a risk based classification system for medical devices (I, IIa, IIb, III) (Article 15 MedDO; Article 51 MDR), establish requirements for conformity assessments of medical devices (Chapter 3 Section 1 MedDO; Article 52 MDR) and lay down provisions clinical evaluation (Article 46 MedDO referring to Article 61 MDR) as well as post-market surveillance (Chapter 7, Section 1 MedDO; Article 83-85 MDR) and vigilance (Chapter 7, Section 5 MedDO; Chapter VII, Section 2 MDR).

Additionally, Switzerland and the EU both issue guidance documents to assist in the implementation of the guidelines.

Role of Swissmedic

Swissmedic is the central regulatory authority in CH for medicinal products and is, as mentioned, an agency within the Federal Department of Home Affairs.

The organization's core competencies include the approval of drugs, operation permits for manufacturing and wholesale, inspections, market surveillance of medicines and medical products, criminal prosecution, clinical studies, laboratory analysis of drug quality, standard setting, information dissemination, and national and international collaboration.

Swissmedic is involved in the entire lifecycle of a medical device. Responsibilities cover authorizing necessary clinical trials, issuing manufacturing licenses, evaluating applications for drug approval based on international criteria for quality, safety, and efficacy, and continuous monitoring of safety and quality once the drug reaches the market.

Classification of medical devices

"[1] Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks" (Article 15 MedDO).

Provisions for the classification follow rules 1 to 22 from Annex VIII MDR (Article 15 MedDO). These consider whether a device is invasive, has measuring functions, if these are vital parameters or if it has diagnostic functions which can lead to a risky surgery. In case the device is an implant, the duration (more or less than 30 days) inside the body has an impact on the classification of the medical device (Annex VIII, Chapter III Rule 1 to 22 MDR).

The risk for patient's health is defined as a low risk for Class I devices, a low to medium risk for Class IIa devices, a medium to high risk for Class IIb devices and a high risk for Class III devices.

Designated Bodies (in the EU called Notified Bodies)

Designated Bodies are organizations designated by the respective state to assess the conformity of medical devices before being placed on the market. As the MRA is not updated, Designated Bodies in Switzerland can no longer assess conformity on medical devices for the EU-market, therefore, the Designated Bodies from the EU play a s significant role in the CE-Marking (Conformité Européenne) process also for Switzerland.

Designated Bodies in Switzerland are regulated under Chapter 5 MedDO and asses the conformity of medical devices before manufacturers can place them on the Swiss market.

Most important aspects regarding Designated Bodies in the MedDO are the requirements for Designated Bodies (Article 33 MedDO; Annex VII MDR) including the assessment procedure (Article 34-36 MedDO).

The work of Designated Bodies is not limited to the conformity assessments of medical devices. Instead, Designated Bodies are also involved in clinical evaluation (Article 63 MedDO), post-market surveillance (Article 57 and Article 62 MedDO) and Audits (Annex IX Article 3.4 MDR)

Conformity Marking

Art. 13 MedDO states that medical devices placed on the market in Switzerland or made available on the Swiss market must either bear a conformity marking as presented in of Annex 5 MedDO or Annex V MDR. Furthermore, exclusions from the marking are listed in this article as well as the necessity to fix the identification number to the conformity marking.

Conformity Assessment

The process for conformity assessment is regulated in (Article 23 MedDO), referring to the relevant Articles and Annexes from the MDR.

In Switzerland and the EU conformity of medical devices with the MedDO or MDR is not declared or checked by a government authority. Instead, manufacturers declare conformity with the regulations themselves. Depending on the risk classification of the medical device, a Designated Body must be involved in the conformity procedure (Article 24 MedDO; Article 52 MDR). Though it is stated in the recital 60 of the MDR, that, as a general rule, Class I devices should be carried out under the sole responsibility of the manufacturer and declare conformity themselves, not via a Designated Bodies.

Several possibilities for manufacturers to declare conformity are given in the MDR. Which procedure to choose, also depends on the risk classification of the medical device. In the following, the eligible conformity assessments will be shown according to each device class:

Annexes from the MDR that are important for all medical devices and are therefore not always explicitly mentioned below:

- General Safety and performance Requirements (Annex I)
- Technical Documentation (Annex II)
- Technical Documentation on Post Market Surveillance (Annex III)
- EU Declaration of Conformity (Annex IV)
- UDI – Unique Device Identification (Annex VI)
- Classification Rules (Annex VIII)

Class I

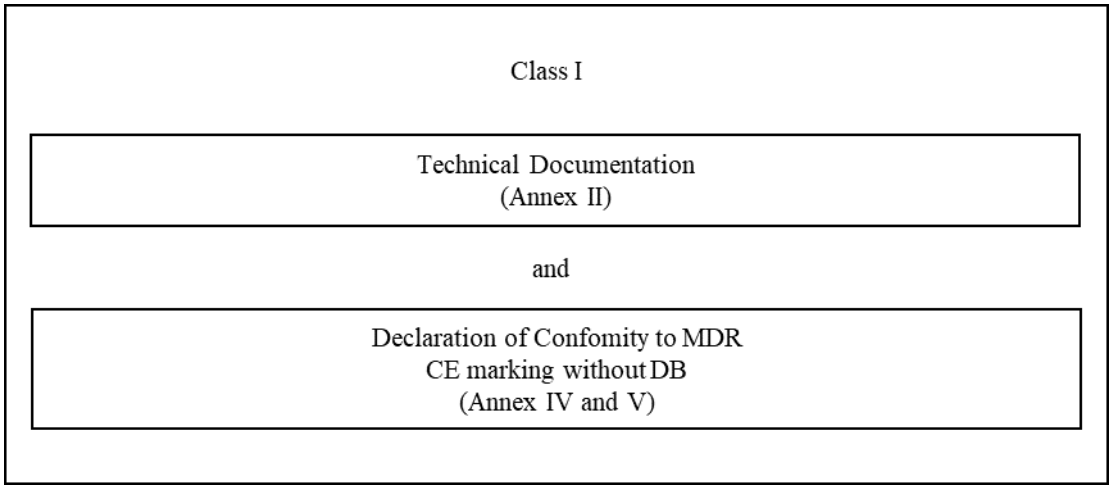

Figure 1: Class I Declaration of Conformity

Devices of Class I do not need the involvement of a Designated Body. The implementation of the technical documentation is sufficient.

*Class I** (sterile devices, devices with measuring function and reusable instruments)

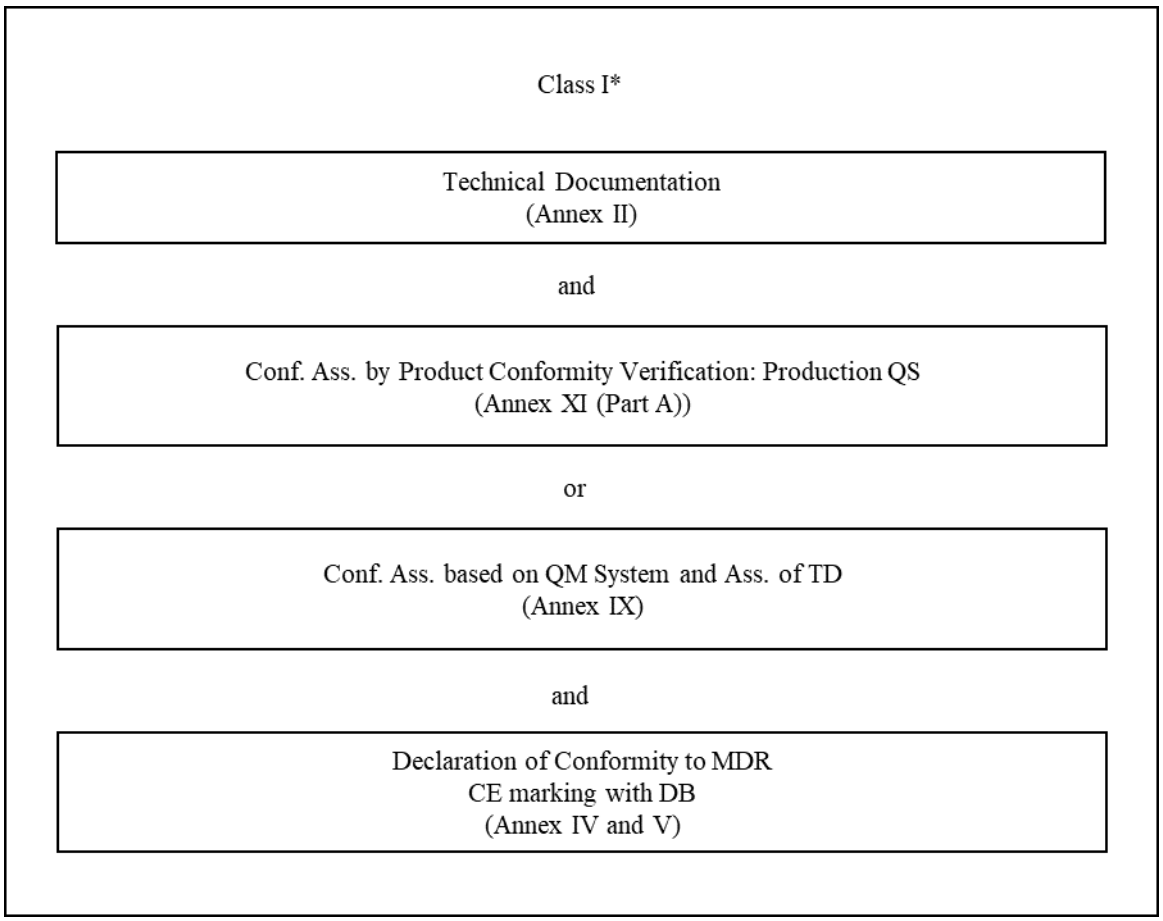

Figure 2: Class I Declaration of Conformity*

For these specific devices of Class I, conformity can be assessed by a product conformity verification (Annex XI MDR) through the procedure of production quality assurance (Annex XI, Part A MDR).

Alternatively, conformity can be declared through assessment based on a quality management system (Annex IX, Chapter I MDR) and assessment of technical documentation (Annex IX, Chapter II MDR).

Class IIa

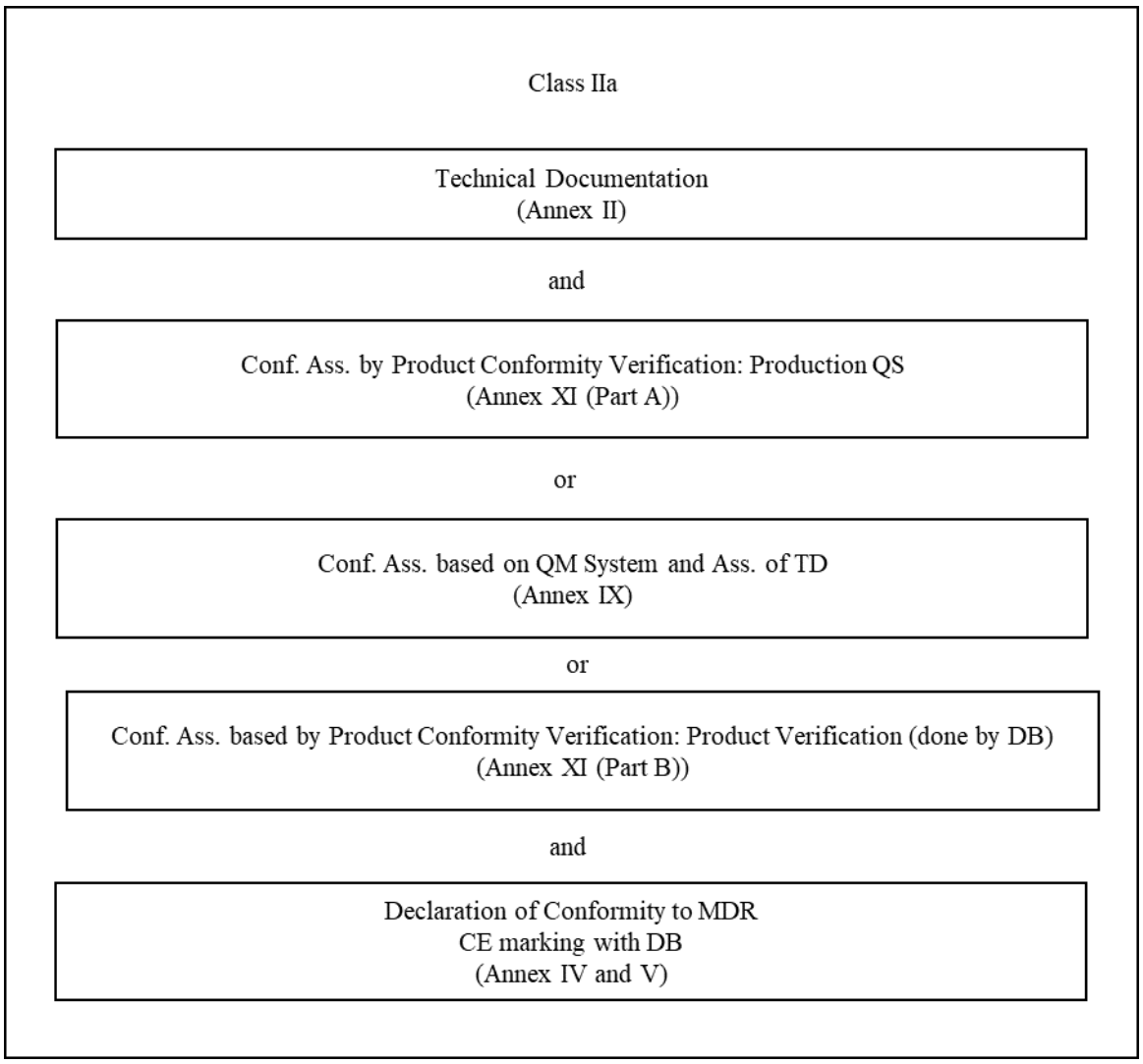

Figure 3: Class IIa Declaration of Conformity

Devices of class IIa can be assessed through three pathways. The first pathway is the assessment based on a quality management system (Annex IX, Chapter I MDR) and assessment of technical documentation (Annex IX, Chapter II MDR).

The second way is an assessment based on product conformity verification through the procedure of production quality assurance Annex XI, Part B MDR.

The third option is to go through the assessment based on product conformity verification through product verification as shown in (Annex XI, Part A MDR).

Class IIb

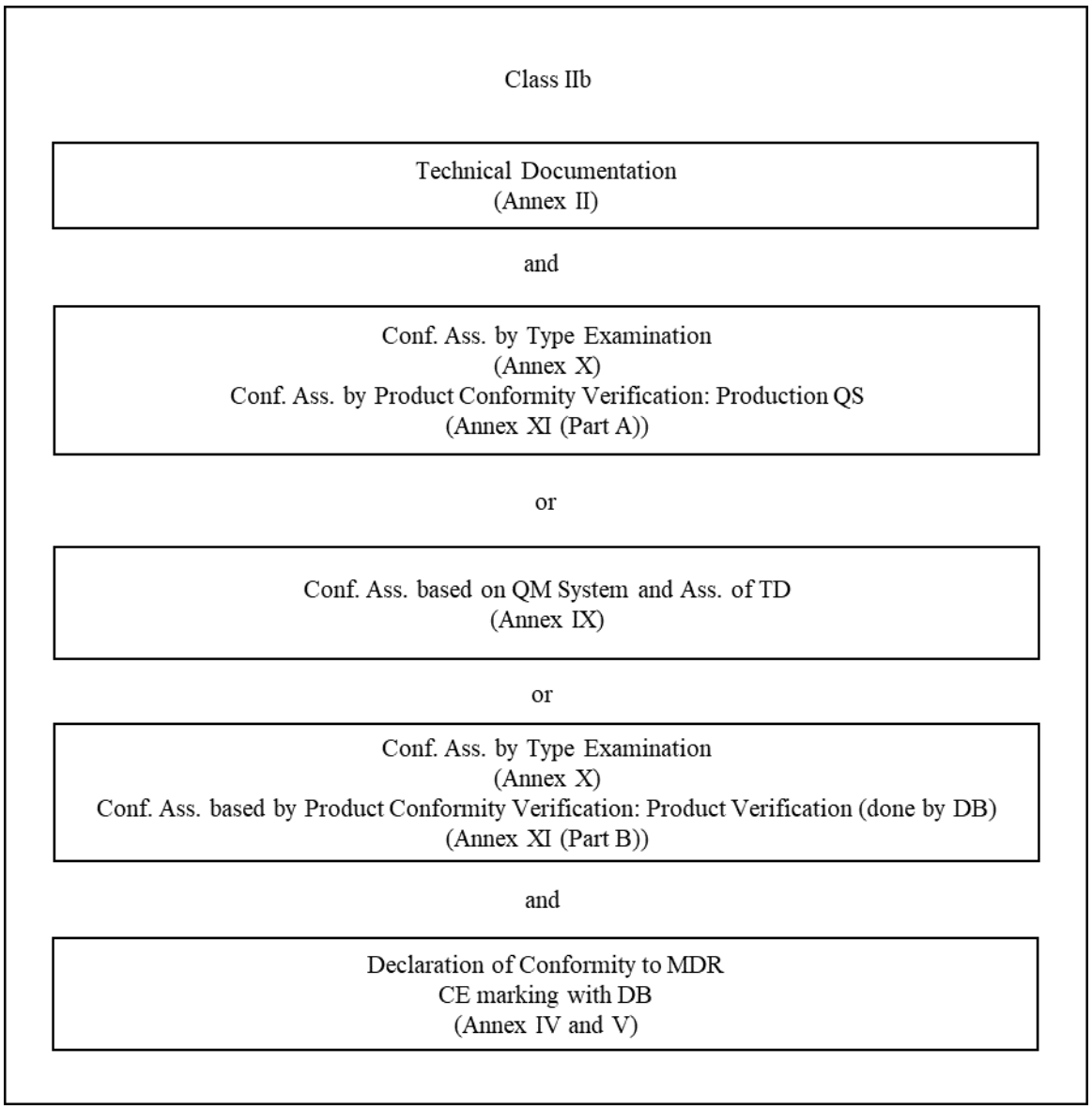

Figure 4: Class IIb Declaration of Conformity

For Class IIb devices, conformity can be declared through assessment based on a quality management system and assessment of technical documentation (Annex IX, Chapter IMDR and Annex IX, Chapter IIMDR).

The second option is to assess conformity based on type-examination (Annex X MDR) in combination with a conformity assessment based on production quality assurance (Annex XI, Part B MDR).

The third option is to assess conformity based on type-examination (Annex X MDR) in combination with a conformity assessment based on product conformity verification (Annex XI, Part A MDR).

Class III / certain Class IIb devices

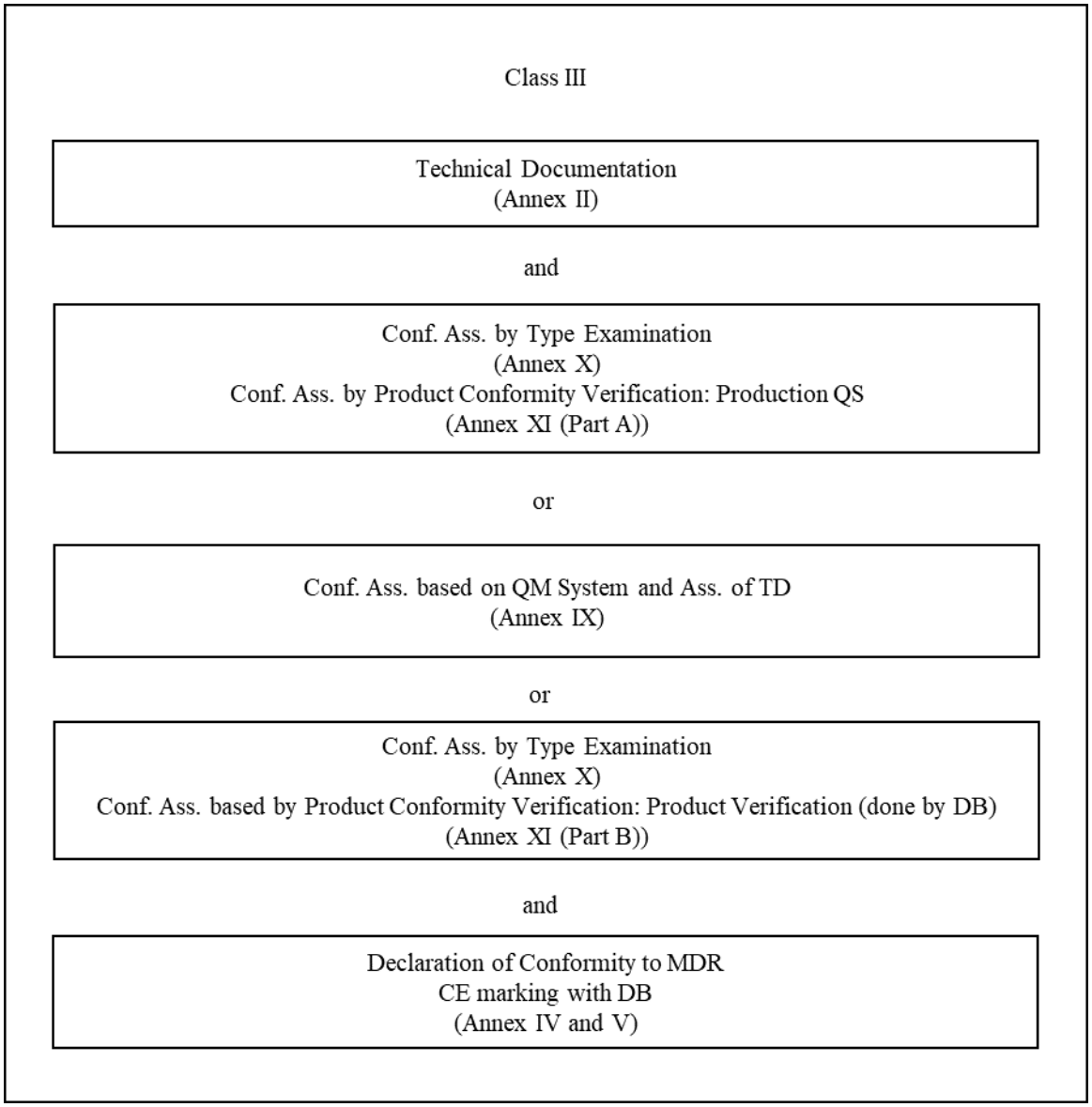

Figure 5: Class III / certain Class IIb devices Declaration of Conformity

For Class III and certain Class IIb devices, conformity can be declared through assessment based on a quality management system and assessment of technical documentation (Annex IX MDR and Annex IV, Paragraph 4MDR).

The second option is to assess conformity based on type-examination (Annex X MDR) in combination with a conformity assessment based on production quality assurance (Annex XI, Part B MDR).

The third option is to assess conformity based on type-examination (Annex X MDR) in combination with a conformity assessment based on product conformity verification (Annex XI, Part A MDR).

For certain devices, such as implantable devices of Class III or certain Class IIb active devices, additional clinical evaluation consultation procedures exist (Article 54, Paragraph 1 and Annex IX, Section 5.1 MDR).

Quality Management

Even though not specifically mentioned in the MDR, the ISO 13485:2016 (International Organization for Standardization) is a recognized standard for Quality Management Systems (QMS) in the EU and Switzerland. As it does not substantially differ from the recognized standards in the USA, the author will not further focus on this topic.

Clinical Evaluation and Trials

Clinical evaluations are required to verify the safety and performance of certain medical devices under the MDR. These evaluations are based on systematic and methodologically sound processes to analyze clinical data relevant for the respective medical device. In some cases, existing clinical data is not sufficient to prove safety and clinical trials must be conducted.

As this paper focuses on conformity assessment, the author will not further investigate clinical trials under the MDR.

United States of America

Legislative Background

In the USA, the Federal Food, Drug and Cosmetic Act (FD&C Act) is the primary legislation for governing medical devices. It provides a legal framework for the oversight, safety, effectiveness, and labeling requirements of medical devices.

Furthermore, the 21 Code of Federal Regulations (21 CFR) is a set of regulations issued by the FDA providing detailed requirements for manufacturing, labeling, marketing, and post-market surveillance of medical devices, also covering quality system regulations, and post-market reporting.

Role of the FDA

The Food and Drug Administration (FDA) is the primary regulatory authority responsible for ensuring safety and efficacy of medical devices, drugs and more. The basis for the FDA's authority is the FD&C Act from 1938, which has been updated by the Food and Drug Administration Modernization Act (FDAMA) of 1997 and the Food Safety Modernization Act (FSMA) in 2011.

The FDA has a central role in the pre-market review and approval process for medical devices. The most important pathways to bring medical devices on the market in the USA are the 510(k) Clearance, also known as Premarket Notification and the Premarket Approval (PMA). Furthermore, the FDA enforces quality control standards and monitors medical devices on the market to ensure their safety. The FDA is also authorized to ensure compliance with regulatory requirements through inspection.

Classification of Medical Devices

Classification of medical devices is regulated within the sections under 21 CFR 2023 Part 860, "Medical Device Classification Procedures". Important sections regarding classification herein are the "Subpart B – Classification", which regulates classification for "preamendments

devices", devices which were in commercial distribution before May 28, 1976 (21 CFR 2023 860.84). As well as the "Definitions", which include the definition of the three classes for medical devices (I, II and III) and their respective controls (21 CFR 2023 860.3).

The classification of a medical device represents their risks for patients and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. The FDA differences between three risk classes: Class I (low risk), Class II (Medium risk) and Class III (High risk).

Procedures for placing medical devices on the market

In the USA, the FDA approves medical devices under the FD&C ACT. The three primary procedures for approval, depending on their classification, are laid down in their corresponding section of 21 CFR.

The most frequently used procedure is the Premarket Notification (also called 510(k)). Medical devices of Class I and II can be brought on the market via the 510(k) procedure and Class III devices only when exceptions are applicable. The manufacturer has to demonstrate a substantial equivalency to a medical device which is legally marketed in the USA and not subject to a premarket approval (PMA) (21 CFR 2023 Part 807 Subpart E).

Class III devices must undergo the most stringent type of device marketing application under FDA-regulation before being placed on the market in the USA. The premarket approval (PMA) requires sufficient scientific evidence to assure that the device is safe and effective (21 CFR 2023 Part 814).

If no predicate device exists, manufacturers can bring novel medical devices, for which general controls alone or general and special controls may provide sufficient assurance of safety and effectiveness, via De Novo Classification on the market. This classification is intended for Class I and Class II devices, which otherwise would have been classified as Class III (21 CFR 2023 Part 860 Subpart D).

More procedures exist under the 21 CFR, such as the Investigational Device Exemption (21 CFR 2023 Part 812) or Humanitarian Device Exemption (21 CFR 2023 Part 814 Subpart H) but are not relevant to this research and therefore will not be addressed further.

As this research paper focuses on devices which came onto the market through a premarket notification, only this procedure will be further examined.

Premarket Notification (510(k))

As the most frequently used process for marketing a medical device, the premarket notification will be examined further.

1. Firstly, it is necessary, to check whether a premarket notification is required. Some Class I or II devices may be exempt from 510(k) requirements (21 CFR 2023 807.85), therefore it is necessary to check whether the 510(k) is suitable or maybe even a PMA is necessary, which is most of the time required for Class III devices (21 CFR 2023 807.81).

2. Second step is to identify a predicate device which is a "comparable type in commercial distribution" (21 CFR 2023 807.87 lit. f). This device shall be comparable in terms of intended use, technological characteristics, or both. (21 CFR 2023 807.92 lit. a)

3. The manufacturer must show by comparison with the predicate device, that is medical device is safe and effective to use. Therefore, one must submit a 510(k) submission, including the necessary information and documentation (21 CFR 2023 807.87).

4. After the 510(k) was submitted, the FDA will review the documents and determine, whether the device is substantially equivalent. Eventually, the FDA will request additional documents (21 CFR 2023 807.87, 807.90 and 807.100).

5. After the FDA granted clearance to market the device in the USA, the manufacturer must register its establishment and list their device (21 CFR 2023 Part 807 Subpart B).

Quality Management

The Quality System Regulation (QSR) is regulated under (21 CFR 2023 Part 820). It contains the requirements for a sufficient QMS in the USA. As the requirements are comparable, yet not fully equivalent, to the requirements in Switzerland and the EU, the author will not further examine the QSR. Additionally, on 23 February 2022, the FDA published a call for comment on further alignment of the QSR with international standards (FDA 2022a).

Clinical Evaluations and Trials

Most medical devices are cleared through the premarket notification (510(k)) process which requires manufacturers to demonstrate that their device is substantially equivalent to an existing and legally marketed device, the predicate device, in terms of safety and effectiveness. Exceptions exist, such as the use of new technology or indication for use or significant differences in technological differences occur.

Premarket Notifications (PMA) on the other hand require extensive reviews of clinical data by the FDA.

As this paper focuses on the 510(k), the author will not further examine clinical evaluations and trials.

Interim results of the Comparison

Between Switzerland and the USA there are several noticeable differences regarding the regulation of medical devices.

The legal basis of Switzerland is not only their own legislation but also EU legislation, to which the MedDO refers directly to the EU-MDR to ensure conformity, adopting various articles and annexes. The USA applies primarily its own legislation as a basis for regulation.

Furthermore, the roles of the central regulatory authorities of the respective countries differ substantially. In Switzerland, Designated Bodies play a significant role in assessing conformity of medical devices before manufacturers can place them on the market. In the USA, the FDA is the authority for pre-market approval and clearance processes. Thus, the USA has a centralized and Switzerland (as well as the EU) a decentralized approval of medical devices.

Switzerland separates four risk classes (I, IIa, IIb, III), whereas the USA only categorizes into three risk classes (I, II, III).

Quality management in Switzerland and the USA do not differ substantially. Switzerland recognizes QMS following the ISO 13485:2016 as sufficient and the USA pursues an alignment with international standards such as the ISO 13485:2016.

In Switzerland, clinical evaluation and trials are required in the conformity assessment processes for most risk classes. In the USA, clinical evaluation and trials are required as well, but within the 510(k) process, only if there is a substantial difference or difference in the intended use of the device.

Comparison Medical Device Software – Switzerland and the USA

In this section, the approach of the FDA will be compared with the chosen approach in the MDR-framework regarding software functions and medical device classifications.

The "Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR" specifies Medical Device Software (MDSW) as "… software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a 'medical device' in the medical devices regulation or *in vitro* diagnostic medical devices regulation" (MDCG 2019, p. 6).

The definition of medical purpose is given in Article 2(1) of the MDR. The guidance document includes a graphic to assist in assessing, whether the software is covered by the medical device regulation.

The IMDRF, which the FDA follows closely in this regard, defines Software as a Medical Device (SaMD) as follows: "The term 'Software as a Medical Device' (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device" (IMDRF 2013, Article 5.1).

The FD&C Act describes a medical device in Section 201(h) as a device, tool, machine, or similar item, including its parts or accessories, designed to diagnose, treat, or prevent disease in humans.

Therefore, the term SaMD is not corresponding to the definition of MDSW, as MDSW includes driving or influencing a medical device (MDCG 2019, pp. 7–8).

According to FDA guidance, a software driving or influencing a medical device would be referred to as Software in a Medical Device (SiMD). A medical device software running on a mobile platform can be referred to as a "Mobile Medical App (MMA)", which belongs to SaMD. All these types of devices can be referred to as "Device Software Functions (DSF)" (FDA 2022a, p. 1).

The following illustration shows the different types of software devices according to the FDA.

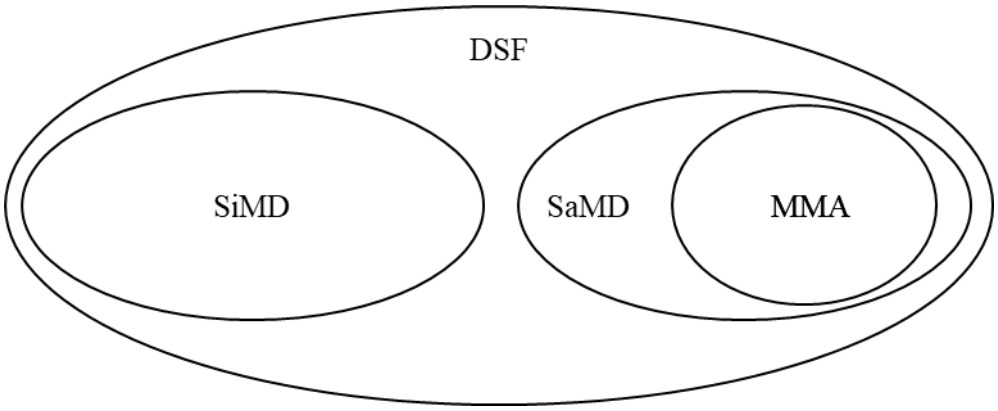

Figure 6: Software Device by function (USA)

Therefore, FDA's term DSF is closest to the MDCG guidance document's term MDSW.

As other medical devices, MDSW is classified into classes I, IIa, IIb and III. To properly categorize the software device, Rule 11 from the MDR plays an important rule.

SaMD can be brought to the market via a 510(k) Premarket Approval (Class I and II), a Premarket Approval (PMA) (Class III) or De Novo, like other medical devices. Class I medical devices are generally considered low risk and therefore exempt from premarket submissions, but general controls apply.

To promote innovation, especially regarding Mobile Medical Apps, the FDA published a list of software functions, which could classify a device as a medical device, but the FDA will not

enforce regulations on these functions (FDA 2022b, pp. 13–15). Switzerland and the EU do not have such discretion.

If the software device is covered by the MDR, it is necessary to assess the risk classification of the device.

For the risk-based approach from the MDCG guidance, a comparison to the International Medical Device Regulators Forum (IMDRF) was made to help manufacturers in assessing the proper risk class. Software devices considered to be risk Class I are not included in the table.

		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
State of Healthcare situation or patient condition		**High** Treat or diagnose *~ IMDRF 5.1.1*	**Medium** Drives clinical management *~ IMDRF 5.1.2*	**Low** Informs clinical management *(everything else)*
	Critical situation or patient condition *~ IMDRF 5.2.1*	**Class III** *Category IV.i*	**Class IIb** *Category III.i*	**Class IIa** *Category II.i*
	Serious situation or patient condition *~ IMDRF 5.2.2*	**Class IIb** *Category III.ii*	**Class IIa** *Category II.ii*	**Class IIa** *Category I.ii*
	Non-serious situation or patient condition *(everything else)*	**Class IIa** *Category II.iii*	**Class IIa** *Category I.iii*	**Class IIa** *Category I.i*

Table 1: Classification Guidance on Rule 11 (MDCG 2019, p. 26)

This table is a guidance to help manufacturers determine the risk class of their software device based on Rule 11 of the MDR. The risk assessment under FDA regulation can differ substantially, as the results of the case study in Section 3 of this thesis will show.

The above descriptions show the main differences regarding Medical Device Software between Switzerland and the USA.

The MDR's approach for MDSW software is not differentiating between standalone software or software implemented in a medical device unlike the FDA. The risk-based approach in the MDR leads to a higher classification of MDSW software, as Rule 11 is not very specific.

FDA uses enforcement discretion to encourage innovation and create a distinction between regulated medical devices and SaMDs with low patient risk.

b. Patient Safety as a Measurement

In his Motion, Damian Müller refers to experts considering the new regulations to be too ambitious and who assume that it will take several years for the MDR and IVDR to be operational. Therefore, there is no guarantee that the Swiss population will be supplied with sufficient quality-tested medical devices in the coming years.

In his response statement from 02 September 2020, Switzerland's Federal Council (SFC) still assumed the MRA to be in place in short to medium term future. The SFC furthermore refers to the possibility for Swissmedic to authorize the placing on the market of a specific medical device upon justified application (Müller 2020).

It is debatable, whether Swissmedic has the capacity to check and authorize the placing of specific medical devices on the market on such a large scale, that it would dampen possible lack of devices in Switzerland.

This chapter provides a literature review of various aspects of patient safety. First, accessibility to medical devices is discussed in view of the new regulations in Switzerland and the EU. Subsequently, clinical trials and post-market surveillance with respect to recalls are discussed in relation to patient safety.

Accessibility of medical devices

MedTech Europe conducted a survey on the potential impact of the MDR on the medical device industry. In this study, producers were asked, among other things, whether they will stop distributing some products because of the new regulations. In this study, producers were asked about potential problems caused by the new regulations. The main issues reported were a significant increase in MDR recertification costs, general MDR maintenance costs, problems with clinical evidence for existing products, and lack of capacity on the part of Notified Bodies (in Switzerland called Designated Bodies) (MedTech Europe 2022, p. 14).

Producers anticipate constraints on continuation in all product categories and expect serious limitations on the health care system (MedTech Europe 2022, p. 7). This is also evident from the fact that over 50 percent of producers expect reductions in their portfolio and 33 percent of them are already discontinuing certain products (MedTech Europe 2022, p. 3). According to experts, it is also expected that me-too products and so-called own-brand labels will also not be continued (Shatrov and Blankart 2022, p. 1236).

It is also expected that the prices for medical devices will rise due to the new requirements, which will ultimately be borne by the healthcare system. In the short to medium term, the new regulations will create problems for healthcare. Products from manufacturers that have not been certified under the MDR will be frozen in the status of May 2021, as no significant innovations to software and hardware may be made. This ultimately also poses a risk to patient safety (Malvehy et al. 2022, p. 363).

Notified Bodies

Notified bodies already existed in the MDD but must undergo reapproval under the MedDO. The requirements for this are listed in Chapter 5, Section 1, Article 33 of the MedDO, which refers to Annex VII MDR. This reassessment led to a reduction in the number of Notified Bodies, thus limiting the capacity for certification and recertification (Bretthauer et al. 2023, p. 3; Shatrov and Blankart 2022, p. 1237).

This limitation of capacities is already noticeable. Under the MDD, certifications for medical devices took an average of 9 months. Due to the increased requirements for medical devices

and Notified Bodies, the duration for certifications increased to 18 months (Bretthauer et al. 2023, p. 4; MedTech Europe 2022, p. 6). With some manufacturers experiencing certification timelines more than 24 months (MedTech Europe 2022, p. 8). As a result, at the time of the MedTech survey, 70 % of submitted applications for QMS and Technical Files (TF) certificates are still under review by Notified Bodies (MedTech Europe 2022, p. 10).

SMEs

Small and medium-sized enterprises (SMEs) account for 24 % of the medical devices expected on the market by 26 May 2025 (MedTech Europe 2022, p. 7) but 15 % to 30 % percent of SMEs do not have access to an MDR-designated Notified Body (MedTech Europe 2022, p. 3). Also the certification progress is slower: On average 13 % of MDR-certificates have been issued already and only 7 % have been issued for SMEs (MedTech Europe 2022, p. 7). This may indicate that smaller device manufacturers and startups are more likely to have problems with stricter rules for large scale clinical testing (Bretthauer et al. 2023, p. 3) or have problems to allocate the costs of certification, time and resources (MedTech Europe 2022, p. 16). This may lead to an oligopoly in the market. Startups and SMEs are often drivers for innovation, leading to higher patient safety and better access to medical devices for patients. A large group of manufacturers might dominate the medical device market even stronger, leading to losses in novel products and methods, due to a loss of competition driven innovation on the market (Malvehy et al. 2022, p. 363).

Innovation

This loss of innovation is also indicated in the number of devices which switched to a MDR certificate. About 500’000 devices were covered by an MDD/AIMDD certificate but only 70’000 devices switched to an MDR certificate and only 6’000 devices considered new or innovative are certified. 101 companies from the MedTech survey have already chosen to launch about 4’300 new devices outside instead of the EU. This corresponds to the survey indicating that 46 % of all companies responding deprioritized the EU as market for first approval (MedTech Europe 2022, p. 17).

Clinical Trials, Post-Market Surveillance and Recalls

Clinical Trials

The MDR has increased its requirements for clinical trials. For all Class III devices and many Class IIb devices, clinical trials must be undertaken. In contrast, under FDA regulations, only Class III devices must receive pre-market approval, i.e., meet stringent medical trial and evidence requirements. Under FDA Class I and II medical devices are mostly cleared through 510(k) Premarket Notification and have to provide medical trials and evidence if the intended use or functions differ from the predicate device substantially (Bretthauer et al. 2023, p. 3).

Post-Market Surveillance

The effects of post-market surveillance on patient safety are also topics in research. Experts argue that health professionals might regard adverse effects as natural or do not report incidents, as they regard them as unnecessary or unfeasible. Also, industry sometimes does not respond to safety issues and even in large hospitals, it is possible that insufficient knowledge about reporting systems leads to less reporting. A new reporting mechanism and stricter requirements might lead to more effort in reporting and responding. Nonetheless, it is not guaranteed that this will lead to better learnings for medical devices in general, as the data is observational and causalities are not necessarily given (Shatrov and Blankart 2022, p. 5).

Recalls

If a medical device may pose a risk to patients, manufacturers are required to notify the appropriate authorities immediately. This obligation exists in the USA, the countries of the EU as well as in Switzerland. Furthermore, there are databases in which these reports are recorded.

Studies were conducted to determine how many recalls of medical devices there were, under which regulations the certifications of the medical devices took place and the extent of the respective incidents. This chapter summarizes the results of studies that researched recalls under FDA and MDD certification, as well as software-related recalls.

Zuckerman et al. analyzed the FDA's high-risk list of device recalls from 2005 to 2009 and determined whether the devices were approved through PMA, 510(k) or were exempt from

FDA review. The result was that between 2005 and 2009, 113 recalls were determined by the FDA to cause serious health problems or death. 21 (19 %) have been approved through the PMA process, 80 (71 %) through the 510(k) process and 8 (7 %) were exempt from any FDA regulation. Out of the 80 510(k) processed devices, 13 were classified as risk Class III, even though devices in this class have to go through the stricter PMA process (Zuckerman et al. 2011, p. 1008).

A later study by Dubin et al. published in 2021 analyzed the timeframe from 1 January 2008 to 31 December 2017. They analyzed the amount of recalled devices, the share of devices and the share of devices with Class I recall. Afterwards they compared the number of total recalls and researched the number of devices with multiple recalls, as well as the total number of Class I recall events during this period. Their data counted for 28'246 devices which received 510(k) clearance and 310 devices with PMA. It showed that 10.7 % percent of recalled devices cleared through 510(k) accounted for 5.2 % of total Class I (high-risk) recalls. 3.4 % of all 510(k) cleared devices had multiple recalls. 27.1 % percent of PMA devices had recalls and 5.2 % of all PMA devices had Class I recalls. 8.4 % of all PMA devices had multiple recalls (Dubin et al. 2021, p. 4).

Published in 2016, Hwang et al. analyzed safety alerts and recalls of devices approved in the EU through CE-marking (under MDD) between 2005 and 2010 and also introduced in the USA. They identified 206 devices out of which 63 % were approved first in the EU. The unadjusted safety alerts and recalls for the devices first introduced to the EU market was 27 % in comparison to 14 % for devices first introduced to the USA. Also the adjusted hazard ratio for safety indicated a higher risk for devices first introduced to the EU market (Hwang et al. 2016, p. 4).

Not only the total number of recalls but also the number of software related recalls was analyzed in literature. Ronquillo and Zuckerman identified medical devices that were recalled from 2011 through 2015 primarily due to software related defects. Their researched showed that during this period, 627 software devices were subject to recalls, with 12 devices subject to high-risk recalls. Of these 12 devices 11 entered through 510(k) clearance and 1 was exempt from regulatory review (Ronquillo and Zuckerman 2017, p. 536).

3. Method

In this chapter, the author presents the selected software products, where the data used came from, and the method used for the evaluation. Due to a lack of available information, the analysis did not consider Picture Archiving and Communication Systems (PACS) as originally planned.

a. Case Selection

For this study two mobile applications, which are available on the EU-market as a Class I or IIa medical device were selected. These devices are selected, to show the impact of regulatory differences between the USA and Switzerland on low to medium risk software medical devices. The author will focus on the software functions within these medical devices to show, which functions would be exempt from regulatory oversight under FDA-regulation and therefore differ in regulatory oversight with the MedDO/MDR.

The selected medical devices are:

Producer	**kaia health software GmbH**	**GET.ON Institut für Online Gesundheitstrainings GmbH**
Product Name	KAIA Back Pain	HelloBetter Vaginismus Plus / HelloGina
Risk Class (MDR)	IIa (BFARM 2023)	I (EUDAMED 2022)
Risk Class (FDA)	Low-risk device under FDA enforcement discretion (Digital Therapeutics Alliance unknown)	Wellness product (HelloGina unknown)

Table 2: Selected Devices

KAIA Back Pain

KAIA Back Pain is a health application, aiming at helping users with the rehabilitation of non-specific back pain. The exercises can be done by the patients on their own after a medical diagnosis by a medical doctor. Under MDR, the device is classified as a risk Class IIa medical device. In the USA, it is a low-risk device under FDA enforcement discretion. It uses artificial intelligence to assess, whether the exercise movement was done correctly by the clients.

HelloBetter Vagnismus Plus / HelloGina

The second digital health application assessed in this thesis is HelloBetter Vaginismus Plus (brought to the US-market under the name HelloGina). It is classified as a Class I device under the MDR and is not considered a medical device on the US-market. It is an online psychological program to improve vaginal penetration ability during sexual intercourse. It uses psychoeducation and uses strategies from cognitive behavioral therapy.

b. Data Collection

The data collection is restricted to medical devices which have been assessed under MDR regulation already and are listed either in EUDAMED or have been listed as a digital health application by the German Federal Institute for Drugs and Medical Devices (BFARM).

Necessary information on the devices were obtained through Database research of BFARM, EUDAMED and the FDA medical device databases. Furthermore, through internet research, as the websites of the manufacturers were examined for information on the devices functions and intended uses. The information for the analysis of the functions was obtained through document research of the MDR, Medical Device Coordination Group (MDCG)-guidelines, FDA-regulations and the policy guidelines issued by the FDA.

The analysis faced limitations due to a lack of available information from the manufacturers as they are reluctant to disclose details about their products.

After the MDR has been binding since May 26, 2021, and has set a transitional period for the recertification of existing products for May 26, 2024. This period has been extended to the end of 2027 for products with a higher risk and 2028 for medical devices with a medium to low risk. This increased the challenges to obtain reliable information about the devices.

c. Data Analysis

To assess possible differences in bringing medical devices to the market from third countries, the author compares the functions of the health applications listed by the manufacturer and assesses for each function, whether they constitute a medical device function and if these functions would constitute a medical device under the MDR. Furthermore, the author assesses, if these functions constitute a medical device function, or a function within the enforcement discretion under FDA regulations.

4. Results

HelloBetter Vagnismus Plus / HelloGina

Intended Use

The most important difference between the marketing for the Swiss/EU-market and the US-market is the intended use. Under MDR, the device is marketed as a medical device and for the US-market it is a wellness device. On both markets these functions are given (not conclusive): Treatment of Vaginismus, Cognitive behavioral therapy, Pelvic floor exercises, Education and Coaching.

Comparison of HelloBetter Vaginismus Plus with FDA guidance document

In the following, each function of the mobile application will be described and afterwards compared to possibly corresponding functions which are either considered a medical device by the FDA, the FDA considers enforcement discretion or is not a medical device function.

The function will be listed with a, b, c, … and afterwards the function is written in bold. The possibly corresponding function from the FDA guidance is listed after each software function of the application.

a. **Information**: The online course provides thorough psychoeducation on sexual dysfunction, presenting effective techniques for better vaginal penetration during intimacy. Material is conveyed through interactive mediums such as videos, audios, texts, and illustrations.

Enforcement Discretion: "Software functions that provide periodic educational information, reminders, or motivational guidance to pregnant people, smokers trying to quit, or people recovering from addiction" (FDA 2022b, p. 24).

Not a Medical Device Function: "Software functions that are intended for general patient education and facilitate patient access to commonly used reference information" (FDA 2022b, p. 18).

Interim Summary: This software function is very unlikely to be seen by the FDA as one that can lead to classification as a medical device, since it does not fulfill any characteristics of a medical device.

b. **Exercises**: Participants are guided through various exercises to think about their own situations and try new ways of thinking and acting. The online program mainly teaches step-by-step vaginal insertion exercises to help reduce fear and create positive sexual experiences. It also helps address worrying thoughts and includes relaxation and pelvic floor strengthening exercises.

Not a Medical Device Function: “Provide tools to promote or encourage healthy eating, exercise, weight loss, or other activities generally related to a healthy lifestyle or wellness;”

Conclusion: As the intended use of the medical device specifically states that this software application is a wellness device, it is not considered to be a risk towards the patient’s health.

c. **Diary**: Participants can maintain an online journal to record and ponder their thoughts, actions, emotions, and how they're progressing with the exercises.

Not a Medical Device Function: “Software functions that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness” (FDA 2022b, pp. 19–20).

Interim Summary: An online diary is not to be considered a medical device function.

d. **Other entries**: In the online program, participants are encouraged to think about their personal circumstances and goals, and to adjust their actions accordingly. They can access these insights anytime, ensuring their individual growth stories remain central to the program.

Not a Medical Device Function: “Software functions that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness” (FDA 2022b, pp. 19–20).

Interim Summary: As the previous device function, this constitutes the same type of function as an online diary.

e. **Example persons**: In the online program, fictional course characters guide participants, showcasing content, sharing their experiences, and offering inspiration and support. These characters, inspired by real-life cases of individuals with vaginal penetration issues, help illustrate the exercises. Participants can choose if they want to read these case studies and select which ones interest them.

Enforcement Discretion: "Software functions that provide periodic educational information, reminders, or motivational guidance to pregnant people, smokers trying to quit, or people recovering from addiction" (FDA 2022b, p. 24).

Interim Summary: As this is not the same type of general wellness information as in the first function and is patient specific, this might constitute a medical device function. But the FDA also includes patient-specific functions for self-empowerment and patient-centered health care not a medical device (FDA 2022b, p. 18) and even if considering the symptoms might constitute a medical device, the enforcement discretion regarding periodic information for people with different health situations such as pregnancy and addiction might include this function for enforcement discretion as well.

f. **Intermediate evaluation**: Participants can periodically assess their vaginal penetration ability. This allows them to track symptoms and therapy progress, which can then be reviewed and discussed with relevant medical professionals like doctors, gynecologists, or psychotherapists if needed.

Not a Medical Device Function: "Software functions that are specifically marketed to help patients document, show, or communicate to health care professionals regarding potential medical conditions" (FDA 2022b, p. 22).

Interim Summary: Even though this might be considered analyzing patient-specific medical device data, it is most likely to be considered a software function relating to the functions as in

a diary and communication with health care professionals via chat. Therefore, this is most likely not a medical device function.

g. **Feedback**: During the online therapy program, a skilled HelloBetter psychologist offers written feedback on participants' progress after each session through the app's messaging feature. This individualized support ensures both patient safety and the best use of the online course.

Not a Medical Device Function: “Software functions that are specifically marketed to help patients document, show, or communicate to health care professionals regarding potential medical conditions” (FDA 2022b, p. 22).

Interim Summary: As in the intermediate evaluation, this function does most likely not constitute a medical device function.

Conclusion: The mobile health application “HelloBetter Vagnismus Plus” which is on the US-market as a wellness-product called “HelloGina” and in Switzerland a class I medical device, could be brought to the Swiss market without labeling it as a medical device, even though the functions of the device are the same in the US and Swiss market.

KAIA Back Pain

Intended Use

The intended use as stated for the US-market on their website is corresponding to the intended use on the digital directory of BFARM such as (not conclusive): The multidisciplinary rehabilitation of non-specific back pain that has persisted for longer than 4 weeks, using the app

with or without current or past supervision from medical professionals and a prior medical examination that has to be done to excluded causes for back pain that would require specific treatment.

Comparison of KAIA Back Pain with FDA guidance document

a) **Movement**: The daily therapy program is built around physical exercises. Kaia Back Pain tailors the best exercises for clients daily, using information from their initial questionnaire and feedback after each session.

Enforcement Discretion: The FDA's enforcement discretion also includes software functions which facilitate supplemental clinical care, also by promoting exercise. (FDA 2022b, p. 14)

Interim Summary: Even though the exercises might turn this application into a medical device, the FDA would probably decide not to regulate this function.

b) **Questionnaire**: Clients begin their therapy with a questionnaire to assess their initial condition. Based on their responses, KAIA gains insights into their back pain, allowing for personalized workout adjustments to meet their needs.

Not a Medical Device Function: "Software functions that are specifically marketed to help patients document, show, or communicate to health care professionals regarding potential medical conditions" (FDA 2022b, p. 19).

Interim Summary: This function might not lead to a classification as a medical device as well.

c) **Kaia Motion Tracking Technology**: Kaia's Motion Tracking Technology uses the device's camera to analyze participants' movements during physical exercises. It

provides instant feedback and tips for improving the accuracy and effectiveness of each exercise.

Medical Device Function: The FDA guideline describes in page 26 a device function which could turn this application into a medical device:

Software functions (typically mobile apps) that transform a mobile platform into a regulated medical device and therefore are the focus of FDA's regulatory oversight:

These mobile apps use a mobile platform's built-in features such as light, vibrations, camera, or other similar sources to perform medical device functions (e.g., mobile medical apps that are used by a licensed practitioner to diagnose or treat a disease) (FDA 2022b, p. 26).

Interim Summary: It is arguable whether the above cited medical device function, which is in the FDA's regulatory oversight, applies to the KAIA Motion Tracking Technology. Nonetheless, using artificial intelligence to correct a person's posture during back exercises could impose a low risk to the patient's health and therefore to an interest for the FDA to classify the device as a medical device Class I.

d) **Relaxation Practices**: Kaia Back Pain offers two relaxation techniques: mindfulness and progressive muscle relaxation. Clients can opt in or out of these techniques by selecting or deselecting the respective courses in the course overview.

Interim Summary: Depending on the kind of relaxation practices, the same categories as for Movement might apply. As it is very likely that relaxation practices are self-management and wellness centered, it is most likely not a Medical Device Function.

e) **Knowledge**: In the knowledge session, Kaia Back Pain educates participants about the origins and impacts of back pain. Gaining insight into the root causes equips them to tackle their pain more effectively. This section offers detailed information on back pain and potential relief strategies through interactive text and brief videos. The content is

delivered in an engaging chat format, where participants can navigate through various options, choosing the topics they're most interested in exploring further.

Not a Medical Device Function: “Software functions that are intended for general patient education and facilitate patient access to commonly used reference information” (FDA 2022b, p. 18).

Interim Summary: The software function described above is educational and therefore not a medical device function.

Conclusion: KAIA Back Pain is a health application brought to the market under MDR regulation as a risk Class IIa device. Even though the KAIA website does not specifically state whether it is an FDA-regulated medical device, its intended use states, that it is intended to be used for the treatment of unspecific pain. A diagnosis is excluded from its intended use. The motion tracking technology supports the assumption that it can be a medical device under FDA-regulation, even though it might be considered low risk. The risk class under FDA regulation could differ substantially from the risk class under MDR-regulation (FDA possibly Class I and MDR Class IIa).

5. Discussion

Damian Müller raised concerns about the feasibility of the new MDR and IVDR regulations, suggesting that it may take several years for these to become operational. The SFC, on the other hand, is optimistic about the MRA being in place in the short to medium term. As the status quo shows, an update of the MRA between Switzerland and the EU is not in sight. Therefore, the SFC was instructed to implement a regulation, allowing medical devices from third countries being introduced to the Swiss market.

In this chapter, the author will discuss the insights from the background chapter and discuss the possible consequences for the Swiss population.

As the survey by MedTech Europe revealed, the industry expects a sharp decline in the future supply and innovation of medical devices. Over 50% anticipate reductions in their portfolio, with 33% already discontinuing some products. It can therefore be assumed that an increased supply of medical devices approved in third countries can have a positive effect on the shortage of medical devices.

Designated bodies which existed under the MDD, are required to undergo reapproval under the MedDO. This resulted in fewer Designated Bodies, leading to limitations in certification capacities. The certification duration has also increased, with some manufacturers facing certification processes exceeding 24 months. If the industry would be given a pathway to bring medical devices on the Swiss market without undergoing the conformity assessment through Designated Bodies, an increase of supply can be expected.

Small and medium-sized enterprises (SMEs) represent 24% of medical devices expected by 2025. However, many SMEs lack access to MDR-designated Notified Bodies, and their certification progress is slower. Stricter rules and higher costs could potentially cause SMEs, often innovation drivers, to face challenges, leading to an oligopoly in the medical device market.

In terms of innovation, a significant reduction in devices transitioning to MDR certification was noted. Many companies have opted to launch new devices outside the EU, with 46% deprioritizing the EU as their primary market.

As innovation is not only future accessibility to medical devices but also improvement of current processes and devices, it should be a factor in assessing patient safety. Many innovators introduce their products on the US-market first already. Providing them a possibility to bring these products on the Swiss market through third country clearance could give Switzerland an advantage in future patient safety.

No statement can be made that medical devices that would enter the Swiss market through FDA approval would pose a risk to patient health. Even though studies found that of 113 recalls deemed to cause serious health issues or death by the FDA, 19 % were approved through the PMA process, 71 % through the 510(k) process, and 7 % were exempt from FDA regulations

(Zuckerman et al. 2011). There is no evidence that FDA-cleared products are generally riskier for patients as Hwang et al.'s research (2005-2010) compared devices approved in the EU through CE-marking (under MDD) and introduced in the USA. They found that devices first launched in the EU had a 27% safety alert and recall rate, compared to 14% for those first introduced in the USA.

The analysis of health applications showed different interests between the FDA and regulatory authorities in Switzerland and the EU regarding the supervision of health applications. Switzerland and the EU have stronger concerns about the impairment of patient safety through low-risk devices. The analysis showed the possibility for manufacturers and developers to choose an argumentation alongside the FDA policy recommendations to bring devices to the market where Switzerland and the EU have interest in a conformity assessment (KAIA health back pain is a Class IIa device under MDR regulation).

6. Implications for Policy

This chapter will point out regulatory problems that may arise in the case of approval of medical devices from third countries.

The implications and recommendations for policy will be categorized on the macro level, which focuses on questions as certifications, audits etc. and the micro level, which focuses on topics within the hospital such as power outlets or user's manuals.

Macro Level: (eventually change macro to federal and micro to business?)

The most important issue to address will be the status of Switzerland as a third country in the respective country which medical devices will be placed on the Swiss market. Under the MDD, Switzerland part of expert groups, such as the Competent Authorities Medical Devices, which was even led by Switzerland in 2005 (Swissmedic 2005). Currently, Switzerland is seen as a third country by the EU which leads to the situation, that experiences and concerns from

Switzerland is not considered by EU-countries. This leads to a complete dependence on EU decision making without consulting possibilities for Switzerland.

This dependence is also evident in access to product recalls. It is in the interest of both Switzerland and the third country that incidents and near misses caused by medical devices are communicated in a timely manner to the authorities of the other countries where these products are also used. When Switzerland imports products from third countries, it must be ensured that there is a rapid flow of information in the event of restrictions to patient safety, so that action can be taken in favor of patient safety.

When third country products will be brought to the Swiss market, the international cooperation regarding medical devices will be even more significant. Currently, Switzerland is granted the status of Official Observer at Management Committee Meetings by the IMDRF. International cooperation must be further expanded, for example by updating and developing MRAs. Content of these MRAs should not only be restricted to conformity assessment aspects but also MRAs to avoid duplicate inspections as in the pharmaceutical industry (Swissmedic 2023) or the mutual recognition of auditing and the monitoring of manufacturing (FDA 2023).

International agreements could solve problems before they arise, such as regulating the import through certified importers, or if additional requirements still need to be added such as a "certification light". It must be considered though, that any additional requirements for import dampen the positive effects towards accessibility of medical devices.

Responsibilities regarding device failures and reporting must be clarified and if possible standardized, not only on the regulatory level but also for health care facilities. To create a workable set of rules for healthcare facilities, the reporting pathways must be kept as simple as possible to avoid the need for these facilities to report to multiple countries at once.

Another topic is data protection. Laws and regulations regarding data protection can differ substantially between countries. Manufacturers for medical devices follow protection laws of their target country. Placing third countries' products on the Swiss market would expose them new regulations not incorporated into their devices. This concern affects not only the producers but also the patients of the countries where these products are used.

Micro Level:

The implementation of third-country products will also pose challenges for regulators at the micro level. This subsection highlights potential challenges and should be seen as an example list.

Devices manufactured solely for the US-market will probably not be provided with an instruction for use (or user's manual) in German, French or Italian. It must be clarified who is responsible for the translations and who can be held liable for the translations.

If a device is imported which was not meant for the Swiss market, the power outlet and required voltage might differ from the Swiss norms, leading again to the need of clarification of responsibilities.

Regulators will also need to find a solution on how to find regulatory equivalence. For example, if a manufacturer is only liable for the cooperation of its products with FDA-approved products (for example, an X-ray device manufacturer who insists on FDA-approved monitors to display the images). To avoid additional expenses here, work could be done on mutual recognition for this.

7. Limitations and Outlook

In this thesis it was originally planned to analyze Picture Archiving and Communication Systems (PACS) from different risk classes apart from health applications. However, this had to be discarded, as there is a great lack of information from the public (e.g. EUDAMED) as well as from the manufacturer side, which did not allow a well-founded analysis. Establishing contact with manufacturers was not possible, neither by phone nor by email, and therefore led to a focus of the work on health applications. A possible explanation for this behavior may be that some of the information required for classification is sensitive information that manufacturers are reluctant to disclose.

Since these are selected medical devices, no generalization can be assumed. In addition, the policy recommendations and guidelines of the MDCG and FDA are not binding, but merely provide guidance for manufacturers.

Patient safety is a broad term and treatment in a master's thesis may have been too imprecisely defined. This can also be seen from the fact that the original approach of defining a concept of patient safety in terms of medical device functions and their risk classification ultimately became a broad treatise on fundamental issues of regulatory cooperation. In addition, the MDR has only been binding for a short period of time, so there are no substantiated studies on a change in patient safety as a result of its implementation.

For future research, a stricter definition of patient safety should be chosen. Nonetheless, it would be dependent on the availability of research regarding the improvement of patient safety through the implementation of the MDR.

This paper may provide some ideas for future policy analysis accompanying the introduction of third country-medical devices into the CH-market.

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