

EU Medical Device Regulation – The Level of Convergence and Impact on Regulatory Complexity

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Abstract: The Medical Device Regulation (MDR) entered into force in 2017 and became applicable in 2021. In the context of Europeanization and the European Union (EU) multilevel governance system, regulations are used as a means of unification. The EU has gradually increased the degree of convergence in medical devices, even though medical devices pertain to the health sector, which is within the Member States' competence. Despite MDR being a regulation, its preamble states that its aim is to harmonize rules for the placing on the market and use of medical devices on the EU market. This article analyzes the level of convergence introduced by the MDR and its impact on regulatory complexity. Our findings demonstrate that many relevant elements, such as mandatory CE marking, reached the level of unification, whereas some that are still to become legally effective, such as the European database on medical devices (EUDAMED), went further and reached the highest level – supranational and integral joint administrative capacities. Unlike the expected inverse correlation between EU convergence and regulatory complexity, our findings revealed that due to delays in bringing into effect certain unifying elements, de facto, MDR introduced additional constraints compared to the previous Medical Device Directive (MDD) framework. This leads to the main finding of this research, which is that the MDR convergence increase has led to a conflicting outcome – an increase in regulatory complexity.

1. Introduction

The European Union (EU) is a *sui generis* entity comprising 27 Member States (MSs). The EU has no constitution or statute as the highest founding law. Instead, two treaties are considered the EU's constitutional acts: the Treaty on the European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).¹ These treaties play a pivotal role in the EU's multilevel governance structure and, among others, distribute competences between MSs and EU institutions. The aims set in the treaties are achieved through the EU's legal acts. According to Article 288 TFEU, the EU can adopt regulations, directives, decisions, recommendations, and opinions to exercise its competences.²

A regulation is a binding legislative act that must be applied in its entirety across the EU. A directive is a legislative act that sets out a goal that EU countries must achieve; however, each MS can devise its own laws to reach this goal.³ In the context of the EU being a multilevel governance entity, regulations and directives provide a basis for unification and harmonization.⁴ These processes are means of creating European Administrative Space, which could be defined as “a set of principles, standards, policies and rules that, as a predominately informal ‘acquis’, should target countries towards the Europeanization of values, principles, processes and norms through convergence, harmonization and unification.”⁵ Harmonization refers to the compatibility of the law, that is, of one country's legal system with a certain law or legal system of another entity; the EU achieves this by adopting directives.⁶ On the other hand, unification is the process of creating legal norms by means of a single law and legal system in the EU. This is

¹ Jacques Ziller, “The Nature of European Union Law,” in *Tratado de Derecho de la Union Europea*, vol. 4, eds. José María Beneyto, Belén Becerril, and Jerónimo Maíllo (Madrid: Aranzadi, 2011), 1365.

² European Union, *Consolidated versions of the Treaty on European Union and the Treaty on the functioning of the European Union – Charter of Fundamental Rights of the European Union*, Publications Office, 2010. Treaty on the Functioning of the European Union (TFEU), Article 288.

³ Ibid.

⁴ Vilim Bouček, *Europsko međunarodno privatno pravo u euointegracijskom procesu i harmonizacija hrvatskog međunarodnog privatnog prava* (Zagreb: Manualia Universitatis Studiorum Zagrebiensis, 2009), 9 – translated by the author.

⁵ Bruno Nikolić and Polonca Kovač, “The European Administrative Space between Ideals and Reality,” in *The Science of Public Administration*, eds. Janez Stare and Mirko Pečarič (Ljubljana: Faculty of Public Administration, 2021), 622.

⁶ Bouček, *Europsko međunarodno privatno pravo*, 9.

achieved by adopting regulations.⁷ Lately, there has been a noticeable trend towards more frequent use of a unification approach instead of harmonization of the EU law, which is reflected in the application of regulations by which the legislature repeals previously valid directives. Examples of these are visible in highly regulated sectors, such as construction, medical devices, automotive, personal protective equipment, beauty industry.⁸ This leads towards an increase in EU convergence. The highest level of convergence should lead to the institutionalization of autonomous and independent joint administrative capacities at the EU level.⁹

This article examines two research questions regarding the EU being a multilevel governance entity. Firstly, it examines the level of Europeanization, i.e. EU convergence reached within the MDR framework. In its preamble, MDR states that its objective is to harmonize rules for placing medical devices on the market and putting them into service in the EU. However, the legislator has not used a directive to harmonize the regulations, as was previously done with the Medical Device Directive (MDD).¹⁰ Instead, the legislator has employed a regulation, which is a unification tool. Based on a qualitative analysis, this research will examine relevant elements of medical device conformity and lifecycle management to determine the level of convergence of the MDR framework. Based on these findings, the article will further evaluate the relationship between convergence and regulatory complexity in medical devices. It will determine whether the presumed increase in convergence introduced by the MDR has led to a presumed decrease in regulatory complexity. Regulatory frameworks ensure that safety and effectiveness are being evaluated, while at the same time, they present barriers that can hold up innovative processes.¹¹ The literature review revealed a lack of research on regulatory complexity.¹² Recent research

⁷ Ibid., 10.

⁸ Nika Gavrilovic, *Europski pravni okvir za uređenje motornih vozila i analiza novosti koje donosi Uredba EU 2018/858 o homologaciji i nadzoru tržišta motornih vozila* (Zagreb: University of Zagreb, Faculty of Law, 2020), 5–6.

⁹ Nikolić and Kovač, “The European Administrative Space,” 627.

¹⁰ EU(1993) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (O.J.E.C. L169, 12 June 1993).

¹¹ Jeroen H.M. Bergmann, “The Emerging Field of Medical Regulatory Technology and Data Science,” *Prosthesis* 4, no. 2 (2022): 170.

¹² Ibid.

findings demonstrate a need for better metrics regarding regulatory complexity in general, defining complexity within regulations, and determining an appropriate level of regulatory complexity.¹³ Despite limited research on regulatory complexity, we can indicate scientific publications which analyze this topic from different angles. Arnould, Hendricusdottir, and Bergmann measured regulatory complexity in terms of the readability of the text and demonstrated that the MDR regulatory complexity is higher than that of the MDD.¹⁴ Whereas, de Lucio and Mora-Sanguinetti state that the concept of complexity refers to problems regarding the “form” rather than the specific topics covered by regulation and examine three dimensions of complexity: quantity (because the corpus is too broad), linguistic (because norms are ambiguously or poorly drafted), and relational (complexity deriving from how rules are connected to each other).¹⁵ On the other hand, some researchers did not define regulatory complexity¹⁶ or would use several terms that can add up to complexity or can be evaluated as independent elements, such as regulatory constraints, outlays, delays, and uncertainties.¹⁷ This research defines regulatory complexity as the application of norms in an interdisciplinary environment under the existing legal system measured by human and financial resources invested into fulfilling a regulatory requirement. Regulatory complexity is higher when more resources and/or activities are necessary to conform to a regulatory requirement than before the introduction of regulatory changes. Regulatory complexity could be significant for evaluating the medical device framework’s efficiency and effectiveness. Examples of regulatory complexity are administrative constraints or otherwise burdens, such as an MS’s registration of a CE-marked medical device already placed and registered in another MS, repetition of

¹³ Ibid.

¹⁴ Arthur Arnould, Rita Hendricusdottir, and Jeroen Bergmann, “The Complexity of Medical Device Regulations Has Increased, as Assessed through Data-Driven Techniques,” *Prosthesis* 4, no. 3 (2021): 318–30.

¹⁵ Juan de Lucio and Juan S. Mora-Sanguinetti, “Drafting ‘Better Regulation’: The Economic Cost of Regulatory Complexity,” *Journal of Policy Modeling* 44, no. 1 (2022): 163–83.

¹⁶ Iraj Daizadeh, “The Impact of US Medical Product Regulatory Complexity on Innovation: Preliminary Evidence of Interdependence, Early Acceleration, and Subsequent Inversion,” *Pharmaceutical Research* 40, no. 6 (2023): 1541–52.

¹⁷ Richard B. Stewart, “Regulation, Innovation, and Administrative Law: A Conceptual Framework,” *California Law Review* 69, no. 5 (1981): 1283.

the same or analogous activities on several horizontal and vertical levels, such as report submission, etc.

The structure of this article is as follows. Part I evaluates levels of convergence of relevant MDR elements of medical device conformity and lifecycle management to determine the MDR framework's level of convergence. Both MDD and MDR elements will be examined.

Based on the findings from Part I, Part II places the MDR's convergence level in a relationship with regulatory complexity. In Part II, the article will evaluate whether a convergence increase leads to increased or decreased regulatory complexity in the medical device field.

2. Europeanization of the Medical Device Sector – From Competence Creep to Harmonization

To understand the convergence of the medical device framework, it is important to know the arena within which it has been built. In this article, medical device(s) are defined as medical technology and medical equipment, as per the definition of medical device from EU legislation based on the MDD¹⁸ and MDR.¹⁹

Competence creep is a phenomenon whereby the EU somehow manages to legislate and/or otherwise act in areas where it has not been conferred a specific competence.²⁰ Competence creep is associated with the EU's broad interpretation of a certain legal provision.²¹ This form of competence creep is primarily concerned with the positive intervention of the EU institutions, i.e. notably the exercise of legislative powers. However, the EU can also trigger other intervention methods. At the same time, one may also conceive competence creep in a broader sense, meaning that MSs must always comply with the EU law, although the competence lies with the MSs.²² Health law and regulating medical devices are pioneering examples of this

¹⁸ See: MDD, Article 1.

¹⁹ See: MDR, Article 2.

²⁰ Stephen Weatherill, "Competence Creep and Competence Control," *Yearbook of European Law* 23, no. 1 (2004): 5.

²¹ *Ibid.*, 5–6.

²² *Ibid.*

phenomenon.²³ Based on TEU and TFEU, health is a sphere that falls within MS competence. In 1993, the Treaty of Maastricht introduced the first formal EU health competence. Article 129 EC (previously EEC) provided powers for the EU to contribute towards a high level of human health protection by encouraging cooperation between MSs and, if necessary, lending support to their action.²⁴ As correctly annotated by Hervey and de Ruijter, “prohibition on harmonization of national laws, in the legal text that attributes legislative powers to the EU, underlines the paradox that was part of the health competence from its inception.”²⁵ Although there were significant amendments in 1999’s Treaty of Amsterdam and 2007’s Lisbon Treaty, which encompass obligations of the EU to ensure a high level of human health protection in all Union activities, it has been observed that

the key constraints to the Union’s competence provisions in health reiterate that there is no Union power to harmonise national law or policy in order to protect or improve human health, or directly to protect public health, however, Articles 2–6 TFEU describe at least 6 forms in which competence creep may take place, which all take place in areas where Member States have retained authority.²⁶

We can trace the beginnings of EU regulation in the medical device sector as early as 1985. In 1985, the EU introduced a Council resolution on a new approach to technical harmonization and standards (New Approach Resolution).²⁷ The New Approach Resolution does not explicitly mention medical devices but provides a basis and guidelines for standardising and harmonising industrial products. The first step of the EU’s harmonising activity in the sector took place in 1990, when the European Commission (EC) introduced the Active Implantable Medical Devices Directive (AIMDD),²⁸ while in 1993, the same year as the above-mentioned Treaty of Maastricht,

²³ Tamara Hervey and Anniek de Ruijter, “The Dynamic Potential of European Union Health Law,” *European Journal of Risk Regulation* 11, no. 4 (2020): 729.

²⁴ *Ibid.*, 728.

²⁵ *Ibid.*, 729.

²⁶ *Ibid.*, 728.

²⁷ EU(1985) Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (O.J.E.C. C136, 4 June 1985).

²⁸ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (O.J.E.C. L189, 20 July 1990).

enacted MDD. MDD's preamble references Article 100a EEC as the legal basis which obliges the EEC to issue directives to support the establishment and functioning of the Common Market. This change has *de jure* and *de facto* led to the harmonization of medical device legislation and standardization of the devices. AIMDD and MDD are New Approach Directives.²⁹

Amendments to medical device legislation took place in several stages; in 1998, 2000, 2002, 2003 and 2007 for MDD,³⁰ and in 1993, 2003 and 2007 for AIMDD.³¹ Meddev guidance documents (MEDDEVs) are the EC's official guidance for medical devices. The MEDDEVs promote a common approach to be followed by manufacturers and notified bodies (NB(s)) involved in conformity assessment procedures.³² Several MEDDEVs were issued from 1994 to 2019.³³ For example, in 2004, Evaluation of medical devices incorporating products containing natural rubber latex;³⁴ in 2010, Classification of medical devices³⁵ and Guidelines on clinical investigation;³⁶ in 1998, for medical devices with a measuring function;³⁷ in 2012, Guideline for authorized representatives;³⁸ in 2013, Guidelines on a medical devices vigilance system;³⁹ in 2016, on qualification and classification of stand-alone software,⁴⁰ etc. Therefore, we agree with Hervey and de Ruijter

²⁹ See: "The New Approach Directives includes a large number of Directives, whose common element is that they rely principally on self-certification through the application of the well-known CE-marking on compliant products," European Union Agency for Cybersecurity, accessed December 23, 2023, <https://www.enisa.europa.eu/topics/risk-management/current-risk/laws-regulation/e-business/new-approach-directives>.

³⁰ Consolidated text: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, accessed February 26, 2024, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20031120>.

³¹ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, accessed February 23, 2024, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31990L0385>.

³² Guidance MEDDEVs, accessed February 23, 2024, https://health.ec.europa.eu/system/files/2022-01/md_guidance_meddevs_0.pdf.

³³ Ibid.

³⁴ MEDDEV 2.5/9 rev.1 Evaluation of medical devices incorporating products containing natural rubber latex, February 2004.

³⁵ MEDDEV 2.4/1 rev.9 Classification of medical devices, June 2010.

³⁶ MEDDEV 2.7/4, Guidelines on clinical investigations: a guide for manufacturers and notified bodies, December 2010.

³⁷ MEDDEV 2.1/5 Medical devices with a measuring function, June 1998.

³⁸ MEDDEV 2.5/10, Guideline for authorised representatives, January 2012.

³⁹ MEDDEV 2.12/1 rev.8 Guidelines on a medical devices vigilance system, January 2013.

⁴⁰ MEDDEV 2.1/6 Qualification and classification of stand alone software, July 2016.

that many harmonising measures were adopted in the EU's health law and policy through the 1990s, 2000s and 2010s.⁴¹ MDR references TFEU's Article 114 on the free movement of goods and Article 168 (4)(c): "measures setting high standards of quality and safety for medicinal products and devices for medical use as the legal basis." The preamble further states that MDR's aim is to ensure the smooth functioning of the internal market for medical devices, taking as a base a high level of protection of health for patients and considering the small- and medium-sized enterprises, as well as setting high standards of quality and safety for medical devices. Both objectives are linked, and neither is secondary to the other. As regards Article 114 TFEU, MDR harmonizes the rules for placing on the market and putting into service in the EU single market, thus allowing them to benefit from the principle of free movement.⁴² MDR entered into force in 2017 but became applicable in 2021. There have been three amendments to the MDR in April 2020,⁴³ December 2022,⁴⁴ and March 2023.⁴⁵ These amendments introduced changes such as changes to Article 120 (changes in deadlines concerning transitioning from MDD to MDR compliance and changes to sell-off provisions).⁴⁶

⁴¹ Hervey and de Ruijter, "The Dynamic," 731. Moreover, the EU started working on the MDR in 2012, and the final text was adopted in 2017. Since then, more than 100 MDCG (Medical Device Coordination Group) guidance documents have been published.

⁴² MDR, Preamble.

⁴³ Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.

⁴⁴ Commission Delegated Regulation (EU) 2023/502 of 1 December 2022 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies.

⁴⁵ 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.

⁴⁶ Amendments: M1 Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 (O.J.E.C. L130, 24 April 2020, p. 18), M2 Commission Delegated Regulation (EU) 2023/502 of 1 December 2022 (O.J.E.C. L70, 8 March 2023, p. 1), M3 Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 (O.J.E.C. L80, 20 March 2023, p. 24). Corrections: C1 Corrigendum (O.J.E.C. L117, 3 May 2019, p. 9, 2017/745); C2 Corrigendum (O.J.E.C. L334, 27 December 2019, p. 165 (2017/745)).

Having a broader scope than the MDD, MDR addresses the entire life-cycle of a medical device. For example, increased requirements for clinical evaluation and investigations,⁴⁷ implementation of a system for identification and traceability of medical devices (the Unique Device Identification system (UDI)),⁴⁸ European database on medical devices (EUDAMED),⁴⁹ strengthening requirements for post-market surveillance and post-market clinical follow-up.⁵⁰

3. Level of Convergence of the Medical Device Framework

This part of the article will analyse the level of convergence of relevant elements of medical device conformity and lifecycle management to determine MDR's level of convergence. The level of convergence will be assessed using a qualitative research method. MDD and MDR elements and the de facto state will be examined, as some MDR elements are not legally effective. Levels of Europeanization, i.e. the level of convergence, will be assessed against the methodology from Nikolić and Kovač presented in the Figure 1.⁵¹

MDR has been applicable since 2021, whereas some elements are still ineffective. For example, all devices except for class I devices⁵² do not need to be compliant with the MDR but can remain on the market as MDD-compliant devices for a determined time under Article 120 MDR⁵³ and implementation and usability of EUDAMED platform.⁵⁴ In addition to delaying the legal effect of certain provisions, lack of clarity of some norms (such as device classification, economic operators' responsibilities, Unique Device Identification assignment, post-market surveillance and

⁴⁷ See: MDR, Chapter 6.

⁴⁸ Ibid., Article 27.

⁴⁹ Ibid., Articles 30, 31, 33, 34.

⁵⁰ Ibid., Chapter 7; Ann-Kathrin Carl and David Hochmann, "Impact of the New European Medical Device Regulation: A Two-Year Comparison," *Biomedical Engineering/Biomedizinische Technik* (2023), 1.

⁵¹ Nikolić and Kovač, "The European Administrative Space," 627.

⁵² In accordance with Article 51 MDR, medical devices are divided into the following classes: I, IIa, IIb and III, taking into account the intended purpose of the device and its risks. For more information on class I medical devices, see MDCG 2021–24 Guidance on classification of medical devices.

⁵³ MDR, Article 120.

⁵⁴ Ibid., Article 33.

	Subject of Europeanisation	Dimensions of Europeanisation	Levels of Europeanisation
1	Beliefs and values	Transition of principles common to most MS to the EU level	Convergence of objectives
2	Public governance processes through institutional cooperation	Formulation and implementation of overarching and sectoral public policies	Convergence in approaches (e.g. obligatory public participation) and harmonisation
3	Norms or legal coordination	Uniform principles of administrative law and common rules	Harmonisation (transposition of directives into national law) and unification (basic acts, EU regulations)
4	Institutions: a) sectoral, b) horizontal.	Integral European administration, through sectoral regulations and EU agencies to uniform actions (e.g. EU semester).	Supranational and integral PA, i.e. umbrella joint bodies in the EU and intensification of authorities (bodies) of the EU in multilevel governance

Fig. 1. Degrees of Europeanization through subject, dimensions and gradual stages of development (Bruno Nikolić and Polonca Kovač, “The European Administrative Space between Ideals and Reality,” in *The Science of Public Administration*, eds. Janez Stare and Mirko Pečarič (Ljubljana: Faculty of Public Administration, 2021), 627).

vigilance requirements, significant changes, conformity assessment procedures) presents additional issues. To mitigate these issues, EC-chaired groups were established to provide additional guidance for interim and long-term application of MDR. For example, the Medical Device Coordination Group (MDCG) and Notified Bodies Oversight (NBO).⁵⁵ As a result of the forum, guidance documents are often issued. These are important soft laws for administrators and industry stakeholders as they provide

⁵⁵ See: Medical Device Coordination Group Working Groups, accessed December 26, 2023, https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en.

clarification on specific subjects.⁵⁶ This research will also base its assessment on MDCG 2021–1 Rev.1 Guidance on harmonized administrative practices and alternative technical solutions until EUDAMED is fully functional (MDCG 2021–1). Some MDCG guidance documents, such as the MDCG 2021–1, provide interim rules that should govern the activities of stakeholders until all MDR elements are legally effective.

Selected elements of medical device conformity and lifecycle management that have been assessed concern CE marking, conformity assessment procedure, registrations, and reporting:

- CE marking is common for New Approach Directive products and was introduced by the MDD. It facilitates Europeanization based on the EU's free movement of goods. The product should be EU-compliant once it is CE-marked. Nonetheless, MSs may impose additional regulatory constraints depending on the product class.
- EUDAMED is introduced by Article 33 MDR. It contains six modules that should facilitate the collation and processing of information to register products and economic operators, UDIs, NBs, certificates, etc. Therefore, EUDAMED tackles several elements the legislator raised to the EU level.⁵⁷

The elements were assessed and placed in the table 1 below based on Nikolić and Kovač scheme.

Table 1. Assessment of the convergence level of relevant medical device conformity and lifecycle management elements.

MDD	MDR, upon becoming entirely legally effective	Currently in practice, de facto state	Level of convergence
Element: Obtaining CE marking			
Through an NB, designated on the EU level. Therefore, MDD introduced unifying effects.	Through an NB, designated on the EU level.	All MDR provisions are currently legally effective in this respect.	Process for obtaining CE marking is the same in all MSs. We can conclude that this element is unified within the EU and that MDD has already achieved unification.

⁵⁶ See: MDR, Article 105, on the tasks of MDCG.

⁵⁷ MDCG 2021–1, p. 2.

MDD	MDR, upon becoming entirely legally effective	Currently in practice, de facto state	Level of convergence
Element: EC conformity assessment procedure for medical devices			
EC conformity assessment procedure is mandatory, except for allowing registration in the MS based on national justified derogation, as per Article 11 MDD. Therefore, MDD introduced harmonising effects for this element.	EC conformity assessment procedure is mandatory, except for allowing registration in the MS based on national justified derogation, as per Article 59 MDD.	All MDR provisions are currently legally effective in this respect.	EC conformity assessment procedure is mandatory, except for derogation cases where MSs may allow devices on their market based on national derogation. Therefore, we can conclude that this element is harmonized within the entire EU, which MDD has already achieved.
Element: Medical device registration at the MS level			
National registration in (each) MS that requires device registration is permissible under the national laws of MSs.	Once EUDAMED is effective, the national authority where the first registration takes place will relate to EUDAMED, and hence, that first registration will be transferred to the EU level, i.e. it will be applicable to the entire EU. Therefore, once EUDAMED is effective, only 1 registration will be needed for the entire EU. Before placing a device, the manufacturer, under the rules of the issuing entity referred to in Article 27(2), assigns a Basic UDI-DI as defined in Annex VI to the device and provides it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.	EUDAMED is expected to be implemented in 2029. According to MDCG 2021–1, the registration of devices starts to apply 24 months after the date of publication of the notice of full functionality of EUDAMED. Until then, both MDD and MDR devices will continue being registered on MS(s) level(s). See MDR preamble, paragraph 98. Moreover, as per Article 31(3) MDR, when applying to NBs for conformity assessment, manufacturers must use the SRN, which is obtained through EUDAMED.	As EUDAMED is still not effective, MSs may still require device registration. If there is a need for conformity assessment via NB, SRN must be obtained via EUDAMED. Therefore, we can conclude that this element is harmonized. Moreover, we can conclude that this element requires duplication of activities on vertical and horizontal levels: - Devices must be registered on the MS level; - SRN must be obtained through the applicable module on EUDAMED (EU level). Upon EUDAMED becoming effective, based on the current version of MDR, this element will reach the level of unification as EUDAMED will present supranational joint administrative capacities. Therefore, there will be no need for repetition of analogous activities.
Registration of manufacturers, authorized representatives, and importers			
Authorized representatives, EU manufacturers and importers must register with the competent authority of the MS. Non-EU manufacturers must be registered with the competent authority of their authorized representative. Therefore, MDD introduced harmonising effects for this element.	The competent authority of the MS obtains a single registration number (SRN) from the electronic system referred to in Article 30 and issues it to the manufacturer, the authorized representative, or the importer. SRN must be used when applying to an NB for conformity assessment and for accessing EUDAMED to fulfil other obligations.	As EUDAMED is not yet effective, MDD provisions referring to the MS provisions are applicable; see MDR preamble, paragraph 98.	This element has reached the level of harmonization. There is still a high degree of horizontal cooperation of multiple competent authorities. Upon EUDAMED becoming effective, based on the current version of MDR, this element will reach the final level of unification as EUDAMED will present supranational joint administrative capacities. There will be no need for repetition of analogous activities.

MDD	MDR, upon becoming entirely legally effective	Currently in practice, de facto state	Level of convergence
Element: Incident reporting			
Incident reporting goes through the manufacturer's NB. Therefore, MDD introduced harmonising effects for this element.	Incident reporting goes through EUDAMED to the manufacturer's NB.	MDD set-up is being applied in practice. In the interim, manufacturers and NBs are advised to agree on how that information is provided to the NB which issued the certificate for the device in question and may continue with the same procedures used under the MDD.	This element has reached a harmonising effect. Activities are coordinated by an NB and depend on the NB. Upon EUDAMED becoming effective, based on the current version of MDR, reports of serious incidents will be automatically transmitted to the NB that issued the certificate for the device in question through EUDAMED. Therefore, once EUDAMED is effective, this element will reach the final level of unification. There will be a decrease in the multiplication of analogous activities.
Element: vigilance (and post-market surveillance)			
MDD vigilance and post-market surveillance required notification of incidents to the MS competent authority. EC published guidance MEDDEV 2.12/1: Guidelines on a medical device vigilance system. ⁵⁸ The latest was in 2019. Therefore, MDD introduced harmonising effects for this element.	Concepts of vigilance and post-market surveillance are divided. Reporting through EUDAMED.	Until EUDAMED is effective, reporting must be done to the MS competent authority.	In practice, activities must be notified to the MS competent authority. Upon EUDAMED becoming effective, vigilance reports will be submitted to EUDAMED instead of the MS competent authority of incidents. Therefore, once EUDAMED is effective, this element will reach the final level of unification. There will be a decrease in the multiplication of analogous activities.

We can conclude that MDD has already introduced Europeanization, i.e. EU convergence into the medical device field by providing a legal basis which converges MSS' beliefs, values, objectives, processes for MS cooperation and, finally, harmonized national legislative acts that regulate medical devices (see below Figure 2), as notated by Hervey and de Ruijter.⁵⁹ We can also conclude that MDD reached the third level of convergence, as per the Nikolić and Kovač table, where legal coordination and uniform principles of administrative law and common rules contribute to harmonization and unification.

⁵⁸ MEDDEV 2.12/1: Guidelines on a medical device vigilance system (MEDDEV 2.12/1, rev. 8).

⁵⁹ Hervey and de Ruijter, "The Dynamic," 731.

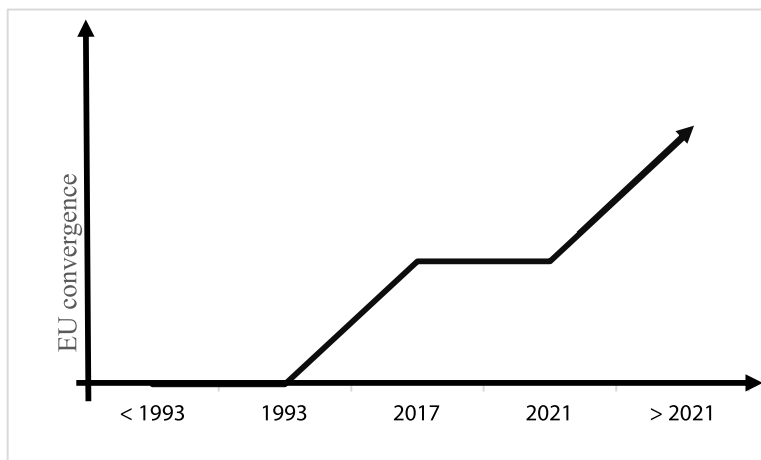


Fig. 2. EU convergence increase.

For example, several MEDDEVs were issued between 1994 and 2019. Since then, more than 100 MDCG guidance documents have been published. From 1993 until today, several public administration approaches contributed to the convergence:

- Normative – mandatory CE marking, MDR as the applicable, hard law, and soft laws being written by MDCG, NBO and other EC-chaired groups.
- Political – political agreement towards increasing EU convergence, demonstrated by continuous participation of MS representatives and MS-elected experts in the MDCG, NBO and other bodies.
- Cultural – healthcare, safety of patients, safety, efficiency, and availability of devices as the core values and objectives of MDD and MDR.
- Economical – willingness to create a basis for free circulation of CE-marked devices and eliminate MS provisions that constrain freedom of movement.

As observed in Table 1, MDR increased some elements to unification (registration of devices and economic operators; incident reporting,

vigilance, and post-marketing reporting). Despite MDD being in force for over 25 years and MDR being a unification tool regulation, our findings reveal that MDR reached its objective – harmonization. Regulation as a tool to (only) harmonize and not unify is noticeable in the EU's regulation of other products, such as Personal Protective Equipment Regulation⁶⁰ and Cosmetics Regulation.⁶¹

4. Relationship between the Level of Convergence and Regulatory Complexity in the Medical Device Framework

In 1993, MDD introduced mandatory CE marking of medical devices. On top of the CE compliance route, each MS can derogate from CE marking and any other MDD conformity rule. This is possible as health is an MS competence. MDR follows this logic. Regardless of it, CE marking a device is the only path for clearing the devices for their placement in the (entire) EU single market. This norm itself introduces a significant decrease in regulatory complexity, as it avoids national marking or other demonstration of conformance in each MS, as was the case before MDD. This significantly decreases administrative burdens and, therefore, regulatory complexity, which is in line with our presumption that increasing convergence decreases regulatory complexity.

Despite this, some MSs still require registration of devices on the MS level, such as Italy, Spain, Portugal, Croatia, Greece, etc. This presents a direct obstacle to the free movement of medical device goods, as per Article 26 TFEU. In line with our definition, this can be considered as regulatory complexity. EUDAMED will eliminate this constraint, as registration will be transferred to the EU level, i.e. to EUDAMED, as soon as registration in the first MS occurs. This will significantly decrease regulatory complexity, as stakeholders will not have to register and re-register devices in every MS whenever there is a significant change to a device

⁶⁰ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, see Preamble, paragraph 1.

⁶¹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, see Preamble, paragraph 1(4).

or economic operators.⁶² The MS registration elements are still applied in practice as EUDAMED legal effectiveness has been postponed to approximately 2029.⁶³ While because of EUDAMED postponement, certain MDD harmonising elements remain effective, such as national registration, the industry is already applying certain MDR elements in parallel, e.g. UDI and SRN, which require one to register (through already available modules) on EUDAMED.⁶⁴ Therefore, we can conclude that stakeholders must perform the same or similar activities on both MS and EU levels. Some activities, such as national registration, must be repeated in several MSs. This leads to increased regulatory complexity and is an obstacle to the free movement of devices within the EU.

Figure 3 shows that increasing convergence is a general direction of EU policymakers and legislators. However, we observe that MS public administrations are not ready to concede their national registration system or implement unification tools. Within currently applicable legislation and under the EU public policy, there are many obstacles that public administrators should tackle to bring MDR into practical application, namely, to facilitate EUDAMED.

Our findings further demonstrate that several elements of MDR, such as economic operator and product registration, incident reporting and vigilance reporting, solely harmonize activities on the MS level instead of utilising EU tools, which could serve as a one-stop shop for the entire EU. In this sense, further convergence would be beneficial for all stakeholders because it would further decrease regulatory complexity:

- Economic operators – no multiplication of activities in every MS.
- Administrators – decreased workload as many activities will take place at another MS or EU level.

⁶² Significant changes are determined based on MDCG 2020–3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD, March 2020.

⁶³ See: https://health.ec.europa.eu/system/files/2023-10/md_eudamed_roadmap_en.pdf.

⁶⁴ Article 31 MDR requires economic operators to register to obtain a Single Registration Number or “SRN”. Article 29 requires manufacturers to upload information about each device, including its UDI information.

- With decreased regulatory complexity, more devices can be expected on the single market, increasing competition. Lastly, this will increase medical device availability and patient safety, which are MDR goals.

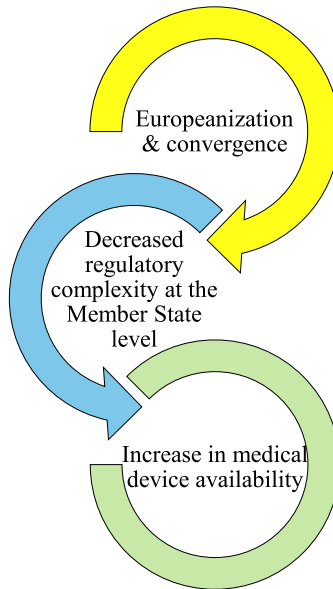


Fig. 3. Convergence – complexity – availability flow.

5. Conclusion

Regulation is the EU's legislative act used to reach unification. MDR, with its main objective to harmonize national laws, undoubtedly increased convergence, but it has not reached the level of unification nor supranational joint administrative capacities. However, some elements aim towards this direction. This matches the degree of convergence evaluated in this research. Therefore, MDR has reached its objective – harmonization. Moreover, MDR has the same level of convergence as MDD. In this third level, there is legal coordination among MSs per uniform administrative law principles and common rules.

Regulation as a means to (only) harmonize and not unify is noticeable in some other sectors, such as personal protective equipment and cosmetics. It is important to note that certain relevant elements of the MDR framework have already been unified, such as CE marking and EC conformity assessment procedures. We can also conclude that once relevant aspects of the MDR become effective, which rely upon EUDAMED, the MDR framework will reach the fourth and final convergence level, where EUDAMED will present supranational joint administrative capacity.

Finally, our findings demonstrate that the increased convergence in the medical device framework introduced by the MDR led to a conflicting outcome – instead of the expected decrease in regulatory complexity, it increased complexity. Table 1 shows that although the MDR has been applicable since 2021, several key elements are still ineffective due to EUDAMED delay. This increases regulatory complexity as regulatory requirements must be fulfilled on several horizontal and vertical levels. This should not be the case in multilevel governance systems. It is of utmost importance that policymakers, legislators, administrators, and experts work hand in hand when developing reforms that should converge the EU framework and avoid delays as they contribute to conflicting and unwanted outcomes.

While this article demonstrates the Europeanization and convergence level of the EU medical device framework and places convergence in relationship with regulatory complexity, it has certain limitations. The basis of the article is in a multilevel governance perspective, where the article does not discuss different EU integration processes. This paper opens exciting avenues for future research, such as the relationship between decreased regulatory complexity at the MS level and increased medical device availability.

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