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EU Medical Device Regulation (2017/745) and In Vitro Diagnostic Medical Device Regulation (2017/746) - Impact on international registrations

Middle East and Africa focus

Considerations for a harmonised approach for handling changes arising from the transition to EU MDR and IVDR

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Introduction

In 2017, the European Union adopted Regulations (EU) 2017/745 (EU MDR) and (EU) 2017/746 (EU IVDR) with the aim of creating a robust, transparent and sustainable regulatory framework for medical devices and in vitro diagnostic (IVD) medical devices that is recognised internationally[1]. The EU MDR replaced the Medical Devices Directive 93/42/EEC (EU MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) and became applicable on 26 May 2021. The EU IVDR replaced the IVD Medical Devices Directive 98/79/EC (EU IVDD) and became applicable on 26 May 2022[2].

The EU MDR and EU IVDR introduced major updates to the European regulatory framework effectively leading to more information being available about medical devices. This modernisation introduced several changes to the regulatory documentation required to place medical devices and IVDs on the European Union (EU) market. The impact of the transition to the EU MDR and IVDR extends well beyond Europe as CE marking, recognised as evidence of compliance with EU legal requirements, is widely used to support medical device and IVD registrations in international markets[3]. The extent of the impact varies across jurisdictions depending on their specific regulatory requirements[4]. It is also important to note that not all changes apply to all medical devices and IVDs in the same way. Therefore, changes to regulatory documentation because of the EU MDR/IVDR are likely to vary from device to device.

The transition to EU MDR and EU IVDR, their subsequent respective amendments (Regulation EU 2023/607, Regulation EU 2022/112 and Regulation EU 2024/1860), as well as the complexity of the requirements under the Regulations, have proven challenging to navigate also to non-EU regulators.

1) Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices, European Commission (December 2024)
2) Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices, European Commission (December 2024)
3) Transition to EU IVD Regulation (EU) 2017/746 and considerations for non-EU regulatory authorities on managing the impact to product registration, MedTech Europe (May 2022) & Impact of changes under the new EU Medical Devices Regulation (EU) 2017/745 to international registrations, MedTech Europe (May 2020)
4) Impact of the MDR Amendment on countries recognizing EU CE marking, Mecomed (March 2023)

Looking at the impact on the Middle East and Africa (MEA) region, where CE marking serves as a major regulatory reference supporting domestic registrations, the following challenges linked to the transition to EU MDR/IVDR can be highlighted:

(1) **Change management** challenges arising from differing interpretations of significant and non-significant changes and the lack of internationally harmonised guidance. In the absence of a harmonised framework and, in many cases, clear national guidance, identical changes may be assessed differently across jurisdictions, leading to inconsistent regulatory requirements, increased compliance burden, and delays in implementing device changes.

(2) **Complex transition timelines and additional documentation requirements** to demonstrate validity of Notified Body certificates (CE-certificates) for legacy devices[5].

(3) **Making devices bearing a CE marking under the Directives available concurrently with devices 'CE marked' under the Regulations.**

(4) **Certificate of Free Sale — lack of a harmonised format and unpredictable timelines for issuance of Certificates of Free Sale.** The long and unpredictable timelines impact regulatory submission planning and often lead to delayed market access in the MEA countries requiring Certificate of Free Sale in regulatory or tender submissions.

Despite these challenges, MEA remains one of the regions where the CE marking and related regulatory documentation are used extensively to support registrations at the national level. In practice, the CE marking is used in various ways to support market access, from formal reliance, including recognition, to use of EU MDR/EU IVDR regulatory documentation and Certificate of Free Sale (CFS) in support of national registrations.

The Middle East and Africa (MEA) region and the impact of EU MDR and EU IVDR

Change management

The MEA region is characterised by a dynamic regulatory landscape, with numerous new regulatory frameworks under development across various countries. In the past decade, many countries have embarked on establishing new regulations for medical devices, though there are fewer regulations that are catering specifically for IVDs. In some countries IVDs fall under the scope of other regulations.

The EU MDR and EU IVDR and their respective amendments have not gone without implications for device registrations in the region. The impact of the EU Regulations appears to be connected to the introduction of changes arising from the EU MDR and IVDR as manufacturers transition their medical devices/IVDs from compliance under the Directives to the Regulations. Examples of changes that are of most relevance for international registrations as a result of the transition to EU MDR/IVDR include changes to the device's classification, instructions for use (IFU), labelling, or intended purpose[6].

Manufacturers need to assess the effect of changes on a case-by-case basis. **Change management entails a risk-based approach, where changes that are largely administrative are distinguished from those that may impact the device's safety and or performance, and/or its risk profile**. One example where the effect of changes arising from the transition to EU MDR/IVDR might require careful analysis concerns change to the intended purpose, which in case of certain IVDs can be expected to differ from the claims made under IVD Directive. However, in case of changes due to the transition to EU IVDR in particular, it is important to understand that the change to the intended purpose may be driven by the clinical evidence requirements that are laid down by the EU IVDR. According to the EU IVDR, intended purpose needs to be supported by robust clinical evidence. Therefore, depending on the type of evidence the manufacturer has available to support the claim, the intended purpose description might need to be amended for certain IVDs transitioning to compliance under EU IVDR.

5) Legacy devices - are defined as Medical Devices, Active Implantable Medical Devices and in vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC, Directive 90/385/EEC or Directive 98/79/EC and that continue to be placed on the market after the date of application of Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR).

6) Consult previous MedTech Europe publications:
May 2022: 'Transition to EU IVD Regulation (EU) 2017/746 and considerations for non-EU regulatory authorities on managing the impact to product registrations', available on MedTech Europe's website [hyperlink]
May 2020: 'Impact of changes under the new EU Medical Devices Regulation (EU) 2017/745 to international registrations' available on MedTech Europe's website [hyperlink]
May 2020: 'Impact of changes under the new EU IVD Regulation (EU) 2017/746 to international registrations', available on MedTech Europe's website [hyperlink]

Another example relevant for international registrations are changes to classification. While under the EU MDR few devices have moved to a higher class compared to the Directives (e.g., software), the EU IVDR fundamentally changes the classification system that has been in place under the IVD Directive.
This is due to the need to enhance patient safety, take account of the technological progress since the Directive has been adopted and to ensure alignment with internationally endorsed principles. The classification of the device will determine the applicable conformity assessment requirements and Notified Body oversight.
Generally, this will not have an impact on the performance of the devices. Classification will be reflected in the technical documentation[7].

Other changes worth mentioning that are arising from the transition are changes to labelling. These types of changes need to be assessed individually so that they are categorised and can be notified appropriately according to the local requirements in MEA[8].

In practice, for international registrations, these changes may lead to:

(1) a notification of the change by the manufacturer without the need for approval by the local regulator,

(2) a variation in the manufacturer's submission,

(3) a new submission requiring approval from the local regulator, depending on the local requirements, or

(4) no additional action if there are no specific local requirements that would trigger option 1, 2 or 3.

Considering the nature of the majority of changes arising from the transition to the EU MDR and IVDR being mostly administrative, making more information available about the devices and the volume of notifications that can realistically be expected as devices transition from Directives to Regulations, **regulators are encouraged to consider a pragmatic and risk-based approach for managing changes arising from the transition to EU MDR/IVDR to avoid any unintended disruptions to devices' supply.**

Managing the impact of the transition on international registrations can prove challenging to navigate without specific guidance, which can create divergent interpretations of change management.

To streamline the transition process and support manufacturers in complying with the new requirements in a timely and efficient manner while ensuring access to medical technologies, **a harmonised approach to what constitutes a significant and non-significant change is needed**. Changes that do not affect safety and/or performance of the device, such as administrative changes arising only from the transition to EU MDR and IVDR, should be considered as '**non-significant**' or '**minor**' changes, whereas changes that could reasonably be expected to affect the safety and/or performance of a device should be considered as '**significant**'.

Complex prolonged timelines and additional documentation requirements to demonstrate validity of Notified Body certificates (CE-certificates)

To address the concerns related to the slow transition to the EU MDR/IVDR, Regulation (EU) 2023/607, Regulation (EU) 2022/112 and Regulation (EU) 2024/1860 have been adopted to extend the transition timelines to allow for a smooth transition from the Directives to the Regulations and avoid market disruptions by putting in place several transitional provisions. Most notably, **the amendments introduced the possibility for manufacturers to continue producing legacy devices** (i.e., devices which are CE marked under the Directives – MDD/AIMDD/IVDD). For devices falling under the scrutiny of a Notified Body, this is enabled through the extension by law of the validity of CE certificates issued under the Directives by a Notified Body. For devices that were self-declared, as it was the case for the majority of IVDs under the Directives, the transitional provisions equally apply provided that the devices will require Notified Body intervention under the EU Regulations and a valid Declaration of Conformity was issued by the manufacturer before the relevant date of application. **In practice, this means that even if the date of the CE certificate issued under the Directives has expired, the amendments allow for the continued placing on the market of the majority of devices beyond the Regulation's Dates of Application (2021 for EU MDR, 2022 for EU IVDR), under a certain set of conditions**.

7) Impact of changes under the new EU IVD Regulation (EU) 2017/746 to international registrations – MedTech Europe, May 2020.
8) Transition to EU IVD Regulation (EU) 2017/746 - MedTech Europe, May 2022.

Devices may continue to benefit from the transition provisions provided they remain compliant and safe, implement key regulation requirements (e.g. safety, registration, post-market surveillance and vigilance obligations), and progress towards full certification under the regulations within the prescribed deadlines[9].

While the amending Regulations were much needed, they added a new layer of complexity for international registrations.

In the EU, in order to demonstrate eligibility for an extended transition period, manufacturers can provide regulators with a "self-declaration" to demonstrate that the conditions for the application of the extended transition period are met for the device(s) in question[10]. The manufacturer's self-declaration may be supported by a **"confirmation letter"** provided by a Notified Body, however, such letter is not a mandatory legal requirement in the EU. Manufacturers may also provide evidence of having lodged an application and concluded a written agreement with a Notified Body by other means (e.g., copy of relevant documents)11. However, it is important to underline that **the sole legal obligation for manufacturers is to provide the self-declaration**[12] for which a template is available. All other supplementary documents are optional for proving that the conditions of the extended transition period are met for a given device, device group or category[13].

In the MEA region, the demonstration of the validity of "extended" CE certificates is one of the most widespread challenges related to the EU MDR/IVDR amendments. Despite the manufacturers' self-declaration being officially recognised in the EU, many local non-EU regulators tend to request additional documentation to support the decision and acceptance of the extension of the certificate, contributing to longer registration lead times[14]. Based on the experience from industry, the following documents have been requested in addition to manufacturer's self-declaration:

(1) Notified Body Confirmation Letter

(2) EU Certificates of Free Sale

(3) Written and signed contract between a Notified Body and the manufacturer

While non-EU regulators might feel compelled to verify the validity of extended CE certificates beyond manufacturer's self-declaration, it is also relevant to highlight that the **additional requirements** aimed at validating the regulatory documentation by means of e.g., Notified Body confirmation letter, **come with additional burden** which can be significant and that in practice contributes to delayed access.

For devices placed on the market under EU MDR/IVDR, EUDAMED database will enable access to certificates issued by Notified Bodies. The use of EUDAMED became mandatory as of 28 May 2026 and the database will become populated progressively. However, EUDAMED is not expected to contain certificates for legacy devices. Therefore, there is a need for a pragmatic approach to accepting the extended CE certificates for legacy devices, for example, such as the approach practiced in the EU – requiring manufacturer's self-declaration.

9) Impact of the IVDR and MDR Amendment on countries recognizing EU CE marking, Mecomed (2025)

10) Manufacturer's Declaration in relation to Regulation (EU) 2023/607 & Regulation (EU) 2024/1860, MedTech Europe (2023, 2024)

11) Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices, European Commission (December 2024)

12) Manufacturer's Declaration in relation to Regulation (EU) 2023/607 - MedTech Europe

13) Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices, European Commission (December 2024)

14) Q&A on extension of the MDR transition period and removal of the "sell-off" period, European Commission (July 2024) & Extension of the IVDR transitional periods – Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices, European Commission (July 2024)

Making devices bearing CE marking under the Directives concurrently available with devices 'CE marked' under the Regulations

In the EU, medical devices and IVDs with CE marking under the MD, AIMD, or IVD Directive and are eligible for the applicable transition period may continue to be placed on the market using certificates and declarations of conformity issued under those Directives, provided the relevant transition conditions are met. **These legacy devices may coexist with devices 'CE marked' under the EU MDR and EU IVDR**[15].

During the transition period, devices compliant with the Directives and those compliant with the Regulations have the same legal status and may be simultaneously placed on or made available on the EU market[16]. However, legacy devices must also comply with certain requirements of the applicable Regulation (MDR/IVDR), including post-market surveillance, vigilance reporting, and other quality and safety obligations.

To ensure the continuous supply of medical technologies and timely patient access, it is recommended that devices with CE marking under the MDD, AIMDD, or IVDD and those with CE marking under the EU MDR or IVDR be permitted to be placed on the market concurrently, with equal legal status throughout the applicable transition period.

Certificate of Free Sale

Certificates of Free Sale (CFS) is a critical document in regulatory and market access pathways in many MEA countries, where CFS is commonly required to demonstrate that a medical device or IVD can be legally marketed in its country of origin. However, variability in the content of CFS, lack of a standardised format across the EU, and often long and unpredictable timelines for issuing CFS across Member States complicates regulatory submission planning and introduces uncertainty into market entry strategies. As many countries in the MEA region require a valid CFS as part of regulatory registration or public tender submissions, delays in obtaining the document can postpone device registration, limit participation in procurement opportunities, and ultimately delay patient access to essential medical technologies.

Greater harmonisation and predictability in the issuance of CFS would improve regulatory efficiency and facilitate timely access to medical technologies in international markets.

Main Takeaways

Despite the challenges brought by the transition to the EU MDR/IVDR and their respective amendment Regulations, CE-marking remains an important regulatory reference used in the MEA region to support device registrations and access to market. Based on industry research carried out in 2025, CE-marking and related regulatory documents can be used to support device registrations for medical devices in 63 out of 67 countries in the MEA region, while for IVDs it is 23 out of 66 countries, which is due to fewer IVD-specific frameworks in the MEA region. CE-marking is generally used by local economic operators to register devices locally therefore facilitating the process of importation and distribution, where applicable. This process is supported by the acceptance of EU MDR and EU IVDR technical documentation. In certain cases, depending on how CE-marking is used to support domestic registration, it can lead to the simplification of the registration route to varying degrees, depending on the country.

15) Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices, European Commission (December 2024)
16) Factsheet for healthcare professionals and health institutions, European Commission (December 2024)

The transition to the EU MDR and EU IVDR has not only impacted European manufacturers but has had a widespread effect on international registration processes in non-EU jurisdictions. With a variety of local regulations not specifically designed for dealing with administrative changes arising from the transition to the EU Regulations, and in many cases lacking a specific variation guideline and/or regulatory capacity, this process does not always prove easy nor fast. **Thus, a risk-based approach to change management is needed to ensure the continued supply of medical technologies to healthcare systems in non-EU countries**.

In addition, the following **considerations** would contribute **to minimising the risk of disruption to devices' supply and the administrative burden**, both for the regulators and for the applicants:

- Categorising changes using a **risk-based framework**, where regulatory oversight is proportionate to the potential impact on safety and performance of the device.
- Allowing notification of multiple non-significant changes for one product in a **single submission**.
- **Not limiting to the number of listings** in one change notification submission if the changes are the same.
- For non-significant changes - enabling **immediate implementation** of changes without the need for regulatory approval.
- In cases where the approval of changes is required, i.e., significant change, a **fast-track review** is recommended through the recognition of references of approval by other jurisdictions.
- Providing a **reasonable transition period** (e.g., a minimum period of six months) during which both the updated device versions and those produced prior to change approval can be manufactured, imported, and distributed.
- Allowing the **coexistence of devices** with CE-marking under the EU Directives and the EU Regulations on the market during the extended transition periods without additional requirements or further time limitations[17].
- **Coordination with customs authorities** to prevent potential issues at the point of importation and ensuring the continuity of supply.
- Considering information in **EUDAMED** for devices in compliance with EU MDR/IVDR, e.g., notified body certificates, as a useful source of regulatory information for non-EU regulators.

Furthermore, **a regulatory alignment on what is a 'significant' compared to a 'non-significant' change would further contribute to the harmonisation of change management across international jurisdictions**, therefore minimising the risks of supply disruption and streamlining administrative processes.

The Global Harmonisation Working Party (GHWP) guidance on Change Management is a helpful reference[18], which also aligns with the World Health Organisation's (WHO) Annex 3 Global Model Regulatory Framework for medical devices including *in vitro* diagnostic medical devices[19]. The Medical Device Coordination Group (MDCG) has also published a guidance on change management for legacy devices (MDCG 2020-3 rev.1 for medical devices, and MDCG 2022-6 for IVDs)[20]. An International Medical Devices Regulatory Forum (IMDRF) guidance on change management would be desirable to serve as an internationally recognised reference.

17) Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices & Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices & 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

18) Final_WG_1_WG_2_WG_3_Change_management_to_registered_Medical_Devices_4454483a2d.pdf, GHWP December 2024

19) Annex 3 WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices (March 2023)

20) MDCG 2022-6 "Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR" (May 2022) & MDCG 2020-3 rev. 1 "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" (May 2023)

Conclusion

In the MEA region, the transition of the EU MDR/IVDR has introduced both opportunities and challenges, particularly connected to device registration, change management, challenges arising from classification changes, importation and documentation requirements. Moreover, in the region these are met with a fast-evolving and dynamic regulatory landscape. To better face this fast-evolving and heterogeneous environment, enhanced dialogue and cooperation amongst local and international stakeholders, and in particular between regulators, is key.

In summary, we call for:

(1) A harmonised and risk-based approach to accommodate changes derived from the transition to the EU Regulations, as the majority of them do not impact the safety and performance of devices, rather they lead to more information on medical devices and IVDs being available - Changes arising from the transition to EU MDR/IVDR that are not expected to influence safety and/or performance of the device, should be considered as non-significant.

(2) Acceptance of both EU MDD/AIMDD/IVDD and EU MDR/IVDR devices on the market having equal status until the end of the transition period, both at regulatory as well as procurement levels.

(3) Stronger collaboration and communication with local and international stakeholders, in particular between regulators – EU and non-EU regulators

The need for a harmonised and risk-based approach to regulatory changes stemming from the transition to the EU MDR/IVDR is evident. To achieve regulatory agility, a shift in mindset is necessary: from Triple A (Act As Always) to Double A (Appropriate & Adequate). This will ultimately allow to accommodate administrative changes while ensuring continued supply and patient access to life saving medical technologies.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

www.medtecheurope.org.

About Mecomed

Mecomed is the medical devices, imaging and diagnostics trade association serving as the voice of international medical technology (MedTech) manufacturers and their regional partners across the Middle East & Africa. Mecomed aims to bring all healthcare stakeholders together to improve the quality of people's health through the timely introduction of MedTech innovations, which ultimately benefits the MEA region community. We foster good citizenship and promote ethical business behavior, working proactively with governments, regional bodies and healthcare professionals to deliver quality solutions for better patient outcomes.

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