The Impact of the New European Union Medical Devices Regulation (EU MDR) 2017/745 and MDR 2017/746

An overview of selected changes and their impact on device manufacturers

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Introduction

The European Economic Area (EEA) — which includes the European Union (EU) and three of the four states of the European Free Trade Association (EFTA) — has long been considered one of the largest global medical device markets. For device manufacturers, gaining and maintaining access to this important market is an obvious objective. However, this also requires staying on top of regulatory changes to ensure timely product certification.

The current form of the EU's regulatory framework for medical devices has been shaped — to a large degree — by the introduction of three key directives over the past two decades:

(1) **Medical Devices Directive (MDD)**
   93/42/EEC
(2) **Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC**
(3) **In Vitro Diagnostic Devices Directive (IVDD) 98/79/EC.**

These device directives represented a significant regulatory leap by providing essential elements for a harmonized registration process and certification requirements for medical devices. Also, these directives further helped advance the EU's single market strategy\(^1\), which envisions seamless regulatory and economic practices across all member states.

\(^1\) The single market strategy: [http://ec.europa.eu/growth/single-market/strategy_en](http://ec.europa.eu/growth/single-market/strategy_en)
The publication of the new Medical Devices Regulations MDR (EU) 2017/745 (MD/AIMD) and MDR (EU) 2017/746 (IVD) are an evolutionary step towards greater transparency and harmonization. In addition, these MDRs impose stricter controls and refined requirements to allow more effective device traceability.

To achieve these objectives, the new regulations promote a much stronger product-life cycle approach with a focus on proactively managing both device safety and performance. Nonetheless, the new regulations also recognize the impact that technological advancements, continuous innovation in product design, and the evolving healthcare systems brought over the past two decades. Overall, the publication of the new regulations is a major milestone in advancing the single market strategy and achieving the EU’s vision for balancing regulatory concerns with economic opportunities.
Timeline

**MDR 2017/745 (MD/AIMD)**
- Being replaced
- Being amended

1. Medical Devices Directive 93/42/EEC
2. Active Implantable Medical Devices Directive 90/385/EEC

**MDR 2017/746 (IVDD)**

1. In-Vitro Diagnostic Devices Directive 98/79/EC
2. Commission Decision 2010/227/EU
The implementation follows an incremental conformance timeline, which allows a more feasible transition for all affected parties. However, the new MDRs introduce several requirements that necessitate a coordinated transition and collaboration between device manufacturers, notified bodies, regulatory authorities, and authorized representatives (if applicable).

### Transition timeline for MDR (EU) 2017/745 (MDR & AIMDR)

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>MDR published</td>
</tr>
<tr>
<td></td>
<td>MDR comes into effect</td>
</tr>
<tr>
<td></td>
<td>Notified Bodies are able to first apply for designation</td>
</tr>
<tr>
<td>2020</td>
<td>Only certificates per the new MDR are being issued</td>
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<tr>
<td></td>
<td>Certificates per MDD/AIMDD Annex IV/4 become void</td>
</tr>
<tr>
<td>2024</td>
<td>All certificates per MDD/AIMDD become void</td>
</tr>
</tbody>
</table>

### Transition timeline for MDR (EU) 2017/746 (IVDR)

<table>
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<tr>
<td></td>
<td>All certificates per IVDD become void</td>
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<tr>
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Key Changes

The new MDRs provide greater structure and control for medical devices. Many of the changes can be grouped into logical focus areas to help better understand the impact of the new MDRs. The below illustration depicts the focus areas that are impacted by the key changes.

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**Designation of Notified Bodies**

The (re-)designation requirement for Notified Bodies has a direct impact on the transition timeline and actually shortens the practical time available to complete all necessary activities. Notified Bodies were first able to apply for designation under the new MDRs on November 26, 2017.

Moreover, the more stringent designation process is estimated to take several months to undergo (possibly a full year), affecting the actual time available for device manufacturers to submit marketing authorizations under the new MDRs. In addition, the initial wave of designation applications will likely cause a backlog due to the bandwidth limitations that Regulatory Authorities will face in processing all designation applications.
There is also concern that the (re-)designation requirement and Brexit would reduce the pool of available designated Notified Bodies and potentially require device manufacturers to find a new Notified Body or hold off implementation until their current Notified Body has been designated under the new MDR.

Voluntary change of a Notified Body is covered in Article 58 of the MDR 2017/745.

**ISO 13485/2016**
The latest version of the ISO 13485 quality standard was officially released on March 1, 2016. Some of the key modifications involve greater quality assurance and risk-based decision making as well as improved harmonization with regulatory requirements. The three-year transition period for updating current Quality Management Systems by March 2019 may have initially seemed like a reasonable timeframe to implement required quality practices. However, with the publication of the new MDRs, the combined transition effort has become much more complex. The European Committee for Standardization (CEN) recently published CEN/TR 17223:2018 to offer guidance on the interdependencies between the new MDRs and the latest release of the ISO 13485 standard.

**Device Type Expansion**
Products for which device manufacturers claim only aesthetic or non-medical purposes will now fall under the scope of MDR 2017/745. The MDR does state that defining common specifications will be necessary to provide clarity for affected products. This means that device manufacturers might need to ensure conformity for some of their product types that previously were not included.

**Re-Classification**
Although standalone software has been classified under the medical device directives for some time, the new MDR 2017/745 provides a more refined definition based on the purpose and the ability of software to support health-affecting decisions.
For example, software that generates data used for diagnostic purposes or to support therapeutic decisions is now categorized as a Class IIa device. In addition, depending on the capabilities to actively support diagnostic or therapeutic decisions, selected software might be categorized as a Class IIb or even Class III device. In contrast, software that enables the use of an IVD device or influences the use of an IVD device would fall within the same class as the IVD device itself.

However, the (re-)classification impact on IVD devices goes further than software. MDR 2017/746 introduces seven (7) classification rules and four (4) risk-based classes. The four IVD device classes A, B, C, and D defined in Article 47 follow the recommended letter-based convention for IVD devices defined by GHTF². Class “A” representing the lowest risk and Class “D” the highest risk. Article 48 provides additional context for the conformity assessment of the risk-based classes.

The following list-based classifications, as defined per the obsolete IVDD 98/79/EC, are affected and require re-classification to correspond with the new IVD device classes B, C, and D:

- Self-Testing IVDs
- List A (per Annex II)
- List B (per Annex II)

Unfortunately, the re-classification is not a trivial one-to-one remapping exercise. This means that IVD device manufacturers must carefully assess the applicable new class since the list-based classes do not directly correspond with the risk-based, letter classes. Annex VIII of MDR 2017/746 provides the rules that IVD device manufacturers should use to re-classify affected products.

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² Global Harmonization Task Force (GHTF)
Clinical Evidence
Medical device manufacturers will need to provide stronger pre-market and post-market clinical evidence for Class III implantable devices and Class IIb active devices. In addition, device manufacturers will need to confirm (re-evaluate) whether clinical equivalence is adequate or actual clinical investigation is required for Class IIa and Class IIb devices. MDR 2017/745, Article 54, covers the procedure for clinical evaluation consultation for selected Class III and Class IIb devices. Article 55 notes the requirement for Notified Bodies to inform Competent Authorities of issued certificates for affected Class III and Class IIb devices.

UDI Surveillance
The new MDRs introduce several new practices that affect surveillance, audits, and reporting. These requirements aim to establish greater control for managing product safety and effective identification of potential adverse or unexpected product events to allow timely corrective actions if applicable.

Medical devices will require a Unique Device Identifier (UDI) to allow effective post-market traceability with the aim to improve critical safety-related and product-life cycle activities. Devices that are part of a performance study are exempt from the UDI requirement.

Audits
Notified Bodies are required to conduct routine, unannounced audits of device manufacturers and their facilities. These unannounced audits must occur at least every five years, and more frequently if appropriate to address non-conformances and product-related safety concerns. This change gives Notified Bodies greater regulatory oversight and control. Annex IX of the MDRs provides the context for audits of device manufacturers and their QMS as well as requirements for related technical documentation.
Reporting (EUDAMED)
Overall, pre-market and post-market reporting requirements are becoming more stringent and comprehensive. The objectives of the expanded reporting requirements are to establish greater transparency for all affected parties and provide timely as well as easy access to complete information through a centralized mechanism. The reporting through the European Database on Medical Devices (EUDAMED) is mandatory for all device manufacturers and also involves input from other participating parties such as Notified Bodies and Members States. The EU Commission anticipates going live with the refined EUDAMED database on May 25, 2020. It is important to note that the go-live date might shift depending on the readiness of the database, which includes developing rules and data conventions. In addition, per Article 123(d) Manufacturers, Authorized Representatives and Importers are given six (6) months from the go-live date of EUDAMED to comply with the reporting requirements and upload affected data.

Timeline for EUDAMED

Anticipated go-live date for new EUDAMED database

Anticipated compliance with new reporting requirements

3 http://eumdr.com/eudamed/
Staff Qualifications
Previous regulations did not provide a great level of detail on the required qualifications for personnel involved in compliance activities. This is changing with the new MDRs and the specific qualifications as well as primary responsibilities are outlined in Article 15. Moreover, device manufacturers must identify at least one person responsible for regulatory compliance:

- This person must have specific expertise, qualifications, and the necessary experience to be qualified for that role (this is outlined in the MDR)
- If multiple persons support regulatory compliance activities and perform respective tasks, all affected persons must meet the required qualifications
- Micro and small enterprises can use permanent external, qualified persons as appropriate

Certification
Devices certified under the old medical device directives require recertification.

MDR 2017/745, Article 120 provides two exemption scenarios based on the certification date of the existing certification.

For in-vitro devices, the departure from a list-based approach and shift towards a risk-based classification requires certification by a Notified Body for most IVD manufacturers, hence the longer transition period of five years compared to three years for MD/AIMD devices.

Exemptions
(MDR 2017/745, Article 120)

“Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.”

“Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.”
Conclusions

Each device manufacturer must carefully assess the implications of the new requirements for its respective product portfolio. There is no one-size-fits-all strategy or approach, mainly because medical devices include different device classifications and represent such a large and diverse market segment. In addition, the specific circumstances applicable to a device manufacturer might require different measures and a different transition strategy. A successful transition strategy must therefore consider key milestones, the interdependencies that these milestones impose, and the unique constraints as well as conditions that each device manufacturer might face.

For example, the re-designation of Notified Bodies under the new regulations is part of the same time period during which device manufacturers have to implement the necessary changes to comply with the new MDRs. Likewise, when ISO 13485/2016 was released in 2016, device manufacturers were given three (3) years to make the required changes to their Quality Management System (QMS). In other words, compliance with the latest release of ISO 13485 overlaps with the transition period for the new MDRs.

Moreover, if a Notified Body does not receive re-designation in time, device manufacturers might have to find a new Notified Body, which could involve additional challenges and cause further delays. In contrast, IVD manufacturers whose products fall within Classes B, C, and D will have to find a Notified Body to recertify their products under the new MDR 2017/746. Ideally, the same Notified Body can be utilized for their products’ CE mark certifications and for their QMS’ ISO 13485/2016 certification.

These examples highlight that a successful transition strategy must consider interdependencies and potential obstacles in order to avoid unnecessary delays of essential transition activities. Furthermore, existing product inventories that were certified under the medical device directives add another decision challenge as the deadline for full compliance with the MDRs approaches:

▶ Is there enough time to sell products certified under the old device directives before the transition period expires?
▶ Should affected products be re-certified under the new regulations to avoid purging current inventories because of non-compliance?
> Or, is a combination of selling some product types and re-certifying other product types the best approach?

These are not simple challenges and several factors will define what makes the most sense. For instance, it might be appropriate to re-certify profitable, slower-moving products and clear inventories for faster moving products (if there is still time left). In some instances, device manufacturers might want to purge inventories and take a loss if recertification or upcoming new product releases promise a greater return on investment and would provide a net gain despite an inventory purge.

A significant effort will also involve creating new documentation and updating current documentation, which will impose its own demanding challenges on the transition strategy team. Especially product documentation and related labeling (including software) will require translation and localization to comply with the language requirements of each member state. This further means that translation activities must be planned for and accommodated in the transition roadmap. Moreover, translations tend to be part of the final phase of regulatory activities, which means that they will be on the critical path of the transition plan. Getting translation partners involved early on in the process will help mitigate the risk.

It is also apparent that the development of the new MDRs and specified requirements takes advantage of technological advancements that were made in the past two decades. These advancements offer new opportunities and ways to track and monitor medical products during pre-market and post-market activities. The available infrastructure and logistical capabilities to generate and manage clinical and non-clinical information also increase demands on all involved parties. It will take much longer than the respective transition periods for all involved parties to experience the same level of familiarity and routine that they have with the outgoing device directives.

Therefore, the new MDRs require careful assessment of key details and proper planning to ensure a successful transition. Some details are still undefined and require further discussion such as the specific EUDAMED data reporting methodology and data structures.
Identifying and organizing all applicable requirements and their implementation sequence should help define the transition roadmap. Close collaboration with regulatory third parties, regulatory authorities, and suppliers should also provide some assistance in refining the transition strategy.

References


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