ECONOMIC OPERATORS

Who they are and how they are affected by the MDR

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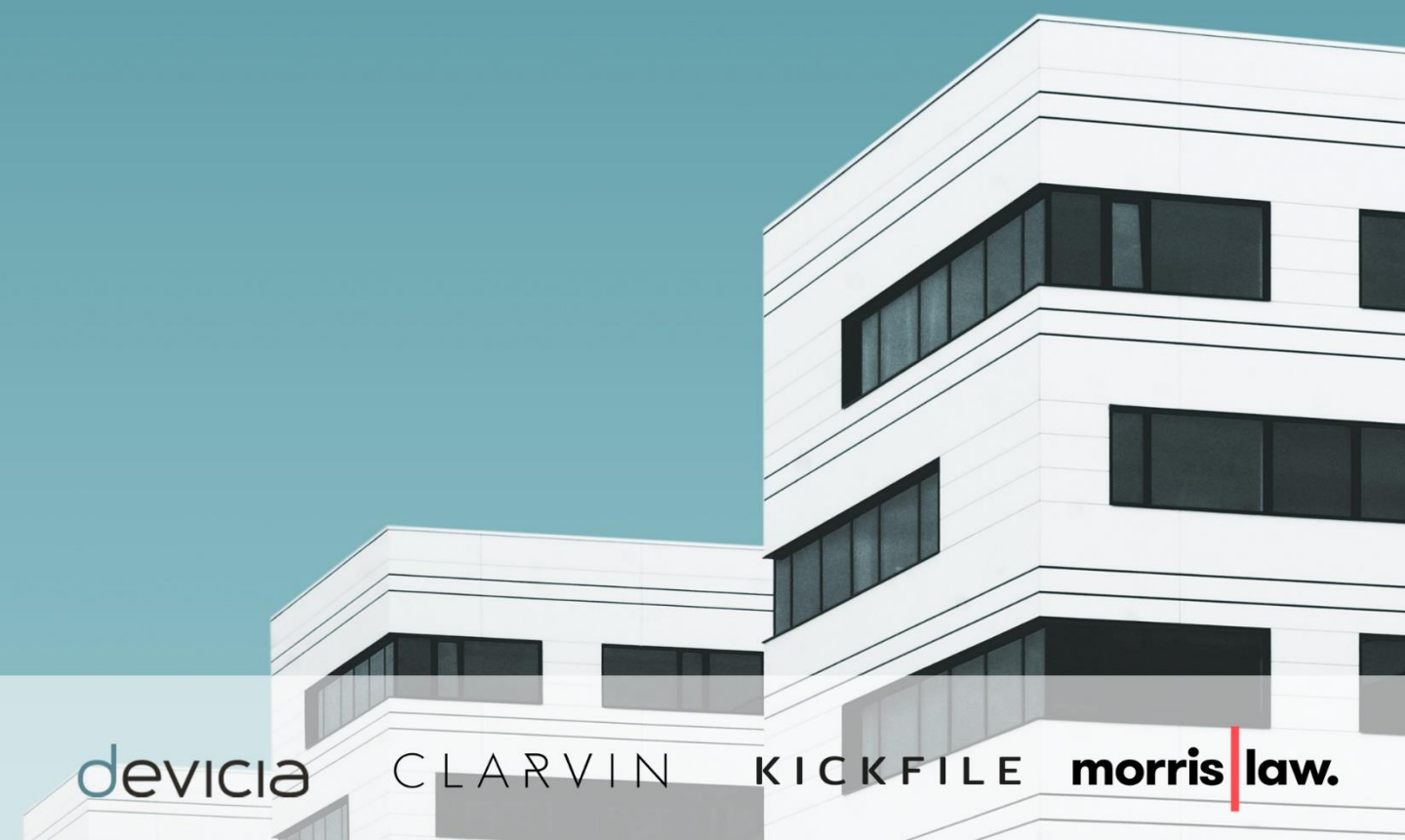

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INTRODUCTION

The European Medical Device Regulation (MDR) has brought the responsibilities of Economic Operators into focus, and adds new requirements for all actors in the medical device supply chain. In this white paper, the first in a series of papers co-authored by Clarvin, Devicia, Kickfile and Morris Law, an overview of the requirements for each of the different actors defined as Economic Operators will be provided. The most significant changes for Economic Operators when transitioning from the Medical Device Directive (MDD) to the MDR are highlighted.

Disclaimer

The information provided in this white paper is the authors' interpretation of the regulatory framework for Economic Operators and shall not constitute legal advice. An individual interpretation must be made in each specific case. Hence, readers are responsible for their interpretation and should assess and interpret the requirements based on their specific medical device(s) and operations.

EXECUTIVE SUMMARY

One of the most significant changes for Economic Operators is the extended focus on compliance across the supply chain of medical devices. All parties involved in the manufacturing and distribution of medical devices to and/or within the European Union (EU) need to identify their role(s) in the supply chain and comply with their obligations and responsibilities under the MDR.

Significant changes to the responsibilities of Economic Operators include:

Manufacturer: while still bearing the utmost liability for its products, this liability is now shared with the other Economic Operators.

Authorised representative: the Authorised Representative will take on more risk and liability.

Distributor: Several new obligations are introduced under the MDR that Distributors have not been accustomed to previously. In fact, certain measures taken by the Distributor may result in the Distributor assuming the obligations incumbent on Manufacturers.

Importer: The introduction of a new role in confirming the compliance of devices and must now meet specific requirements and verify information from the Manufacturer.

ECONOMIC OPERATORS – KEY TOPICS

The extended focus on responsibility throughout the supply chain means that each Economic Operator has a role to play in verifying compliance of medical devices with the MDR.

The table below provides an overview of the responsibilities of each Economic Operator under the MDR. Several of the responsibilities in the table are linked to EUDAMED, which consists of the following six interconnected modules:

1. **Actor registration**
2. **Unique Device Identifier (UDI)/Devices registration**
3. **Notified Bodies and Certificates**
4. **Clinical investigations and performance studies**
5. **Vigilance and post-market surveillance**
6. **Market Surveillance**

On December 1, 2020 the actor registration module of EUDAMED was made available. It will enable Economic Operators to submit the information necessary to obtain a single registration number (SRN). The SRN will provide EU-wide unique identification of Economic Operators.

Economic Operator / Responsibility	Manufacturer	Authorised Representative	Importer	Distributor
Product design and development	X			
Manufacture and assembly	X			
Technical documentation	X	X		
Handling, storage and distribution	X		X	X
Corrective actions	X	X	X	X
UDI labelling	X	X	X	X
Complaints	X			X
PMS	X	X	X	X
PRRC	X	X		
EUDAMED registration	X	X	X	

MANUFACTURER

Under the MDR, Manufacturers will continue to bear the utmost liability for their products although this liability is now shared with other Economic Operators involved in the supply chain of the products. The Manufacturer is also responsible for appointing a Person Responsible for Regulatory Compliance (PRRC) within its organisation, or in the case of micro or small size enterprises, to have such a person at their disposal. Manufacturers should review existing agreements with Economic Operators in the supply chain and evaluate their ability to continue to act as compliant partners under the MDR.

In relation to clinical investigations, it is worth noting that the responsible party for a clinical investigation is changed with the introduction of the MDR from a Manufacturer or Authorised Representative under the MDD, to a Sponsor under the MDR (the Sponsor will frequently be the Manufacturer or Authorised Representative). In the case of Investigator-Initiated Studies (IIS), where the Manufacturer intends to use the investigation results for regulatory purposes, the Manufacturer is advised to ensure that the investigator is aware of the requirements imposed on a Sponsor by the MDR.

AUTHORISED REPRESENTATIVE

An Authorised Representative will take on more risk and liability under MDR compared to the MDD, which should be clear in the mandate between the Manufacturer and the Authorised Representative. It can also be noted that where the Manufacturer is not established within the EU and has not complied with the Manufacturer obligations laid down in MDR, the Authorised Representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the Manufacturer. The Authorised Representative shall also ensure continuous access to a PRRC.

For clinical investigations, national or regional regulations can require a Sponsor to select a local or legal representative if the Sponsor is not resident in the country/ies in which the investigation is to be carried out. The legal representative will be responsible for fulfilling the Sponsor’s responsibilities in the respective country/ies and any communication with the legal representative will be considered a communication with the Sponsor. Most commonly this applies to Manufacturers not established in the EU who are required to find a legal representative to carry out a clinical investigation in the EU.

IMPORTER

The Importer is an Economic Operator responsible for placing medical devices from a third country on the EU market. Importers will now need to confirm compliance of devices under the MDR and must meet specific requirements and verify information from the Manufacturer.

Where an Importer considers or has reason to believe that a device is not in conformity with the MDR requirements, the Importer shall not make the device available on the market until it has been brought into conformity. Furthermore, the Importer shall inform the Manufacturer and the Manufacturer's Authorised Representative of the non-conformance. Where the Importer considers, or has reason to believe, that the device presents a serious risk or is a falsified device, it shall also inform the Competent Authority of the Member State in which the Importer is established.

DISTRIBUTOR

Economic Operators acting solely as Distributors will find that a range of obligations are introduced under the MDR. While Distributors may not be jointly and severally liable in case of nonconformity in the way that the other Economic Operators are, Distributors will still play an important role. In this regard, it is also important to know that certain measures taken by the Distributor may in fact result in the Distributor assuming the obligations incumbent on Manufacturers. As a Distributor, you are not obliged to register in EUDAMED.

GDPR

The general data protection regulation (GDPR) applies to the processing of personal data and becomes relevant if the Economic Operators process personal data. Hence, it is important that each Economic Operator identifies if, where, how, and why, they process personal data. Understanding the role in relation to the personal data being processed is crucial in ensuring compliance with the GDPR and the fair treatment of individuals. This is important in most businesses and industries but even more so for Economic Operators discussed here, since they often process sensitive personal data when acting in the supply chain of medical devices, for instance relating to clinical investigations, handling of adverse events, market surveillance, vigilance, and post-market surveillance.

SUMMARY OF ACTIONS

The following actions should be considered by each Economic Operator in relation to its products:

- ❑ **Ensure sufficient time and resources are allocated for Economic Operator compliance**
- ❑ **Identify all relevant Economic Operators for each product**
- ❑ **Ensure all identified Economic Operators are MDR compliant and committed to maintaining compliance. If an Economic Operator will not commit to the new responsibilities, consider replacing the Economic Operator in question**
- ❑ **Revise old, or preferably, put in place new agreements prepared from an MDR-perspective**
- ❑ **Coordinate activities amongst all the Economic Operators in order to streamline the process, increase efficiency and reduce risk and liabilities**
- ❑ **Stay up-to-date with EUDAMED developments**

NEED HELP WITH REGULATORY COMPLIANCE?

Clarvin, Devicia, Kickfile, and Morris Law - a group of Life Science experts - offer full service for all your medical device compliance needs. We can advise you on clinical and regulatory strategies for your medical device, and can support you with everything from agreements, clinical investigation strategy and design, implementation of Quality Management Systems, and in establishing Technical Documentation for your device. Please see our contact information on the last page.

Definitions

Authorised Representative means any natural or legal person established within the Union who has received and accepted a written mandate from a Manufacturer, located outside the Union, to act on the Manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Regulation (2017/745).

Distributor means any natural or legal person in the supply chain, other than the manufacturer or the Importer, that makes a device available on the market, up until the point of putting into service.

Economic Operator means a Manufacturer, an Authorised Representative, an Importer, a Distributor or the person referred to in Article 22(1) and 22(3) of the Regulation (2017/745).

Importer means any natural or legal person established within the Union that places a device from a Third Country on the Union market.

Manufacturer means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

MDD Medical Device Directive (93/42/EEC).

MDR Medical Device Regulation (2017/745).

Third Country means a country that is not a member of the EU as well as a country or territory whose citizens do not enjoy the EU right to free movement, as defined in Art. 2(5) of the Regulation (EU) 2016/399 (Schengen Borders Code).

Sponsor means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation.

Personal Data means any information relating to an identified or identifiable person. Crucial is that the personal data, individually or in combination with other information, can be linked to a living person. Personal information is social security number, name and address. Encrypted data and various types of electronic identities, such as IP numbers and cookies, are also personal data if they can be linked to persons. Information that has been coded, encrypted or pseudonymized but which can be attributed to a person using supplementary information is also personal data.

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