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Download the whitepaper: http://bit.ly/2SU1nlx

# Unprecedented regulatory shift for Economic Operators

*Latest whitepaper from Maetrics helps clarify the new requirements for Economic Operators as the May 26, 2020 Date of Application for EU Medical Device Regulation approaches*

February 2020 - Maetrics, a leading international life sciences regulatory and compliance consultancy, has launched a whitepaper explaining the new (and changed) responsibilities for Economic Operators required by the new EU Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR). The whitepaper looks at the changes in regulations concerning all four Economic Operator entities, highlighting the impact on Importers and Distributors as they face entirely new requirements.

This whitepaper has been published at a critical time for the medical devices industry as the Date of Application for the EU MDR approaches (26th May 2020), at which point all Manufacturers will have to identify and confirm compliance of their Economic Operators. Failure to do so may cause serious ramifications further down their supply chains. The whitepaper aims to draw attention to the fact that three out of four Economic Operators are now legally and severally liable for devices sold on the market. This is an unprecedented change in regulation, with potential serious consequences for those entities involved if compliance is not achieved; in particular legal action and loss of market access.

Whilst the industry continues to clarify and implement the EU MDR requirements, there is confusion around the expectations of Economic Operators, especially for Importers and Distributors. In this paper, Maetrics aims to raise awareness of this new regulatory landscape and the potential challenges that Manufacturers, Authorised Representatives, Importers and Distributors need to address for compliance.

Beth Crandall, Managing Director, Global Solutions Delivery Leader, comments: “One of the biggest trends which we are seeing in the industry is companies needing help to map their overall supply chain, so they can confidently say for example, who the contract manufacturers are, who is serving the role of the Authorised Representative, who is responsible for bringing the product to market and who will be distributing it from there. Each entity has an essential role to play, and that is why we want to raise the discussion about this fundamental change facing life sciences companies.”

The key points in this whitepaper entitled, *Economic Operators: Whose Problem Is It Anyway?*:

- The new Economic Operator definitions and how EU MDR affects the Manufacturer, Authorised Representative, Importer and Distributor;
- The importance for Manufacturers to map their supply chain and how to understand regulatory requirements so devices can be safely placed on the EU market;
- How Economic Operators can expect to successfully navigate new verification responsibilities;

- The benefits of taking a strategic approach to Economic Operator compliance, and what pillars businesses can put in place to implement effectively.

The full whitepaper is available to download here: http://bit.ly/2SU1nlx.

Steve Cottrell, President at Maetrics comments: “With the new EU MDR, the repercussions of non-compliance by Economic Operators has direct legal implications on the other involved entities. Manufacturers, Authorised Representatives and Importers now share in the legal responsibility for the compliance of devices on the market, underlining the importance for companies to be on top of this significant regulatory change.

“Regulatory and quality teams are already stretched thin – it could be too easy for this to slip down the priority list. Examining the health of their supply chain and assessing compliance with the new Economic Operator requirements is now essential – and the clock is ticking. Maetrics is already a trusted EU MDR partner to many leading medtech companies and we are poised to support them with regulatory and quality solutions.”

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**About Maetrics**

Founded in 1984, Maetrics is a global life sciences consulting firm focused exclusively on regulatory, quality, and compliance solutions for Medical Device, Diagnostic, Pharmaceutical and Biotechnology companies. With offices throughout Europe and North America, Maetrics can assist with local, regional, or global compliance needs. www.maetrics.com