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Preparing for the new In Vitro Diagnostic Regulation (IVDR) in Europe

Maetrics reveals the implications for medical device manufacturers and how to address them as the new IVDR comes into force

January 2018 – The new European Union In Vitro Diagnostic Medical Device Regulation (IVDR) was approved by the European Parliament on the 5th of April 2017 and published in the Official Journal of the European Union on the 5th of May 2017. This new regulation will repeal Directive 98/79/EC as well as Commission Decision 2010/227/EU. It will have binding legal force throughout the EU and will be implemented in all Member States simultaneously.

In order to help manufacturers understand the imminent changes and how to comply, Maetrics, a leading international consulting firm focusing on providing life science companies with deep quality, compliance and regulatory solutions, has published a free step-by-step whitepaper that is available to download here: http://bit.ly/2DOKq7h

The IVDR will inevitably bring about important changes to the industry as the number of definitions of an IVD has been increased to 74 and the text is more specific in defining different types of diagnostic procedures. This means that some manufacturers will come under scrutiny for CE Marking that was not previously regulated. It is imperative that manufacturers understand the full impact of the IVDR on their business and do not delay developing a strategy to ensure compliance.

Peter Rose, Managing Director in Europe at Maetrics, explains: “It is evident that complying with the IVDR is a significant business issue, particularly as regulatory control over conformance with the requirements is ever-increasing. This guide will take manufacturers through the impending changes, highlight the important practicalities of implementation and provide a suggested pragmatic approach.”

The guide is written by Maetrics’ in-house experts, Brian Moan and Norm Rabin. Their long-standing experience and knowledge in the areas of medical device and in vitro diagnostic compliance means they can provide a solid foundation for building a strong compliance road-map for the IVDR. With endorsements from the industry, including the Association for British Healthcare Industries, this paper aims to help medical device companies who wish to get a real handle on the major changes that the new IVDR brings and the practical implications for manufacturers and distributors of IVD products.

The guide covers:

- Scope & definitions of the IVDR;
- Classification and Conformity Assessments requirements;

- Market access of legacy products;
- Technical documentation;
- Clinical evidence, performance evaluation, and performance studies;
- Vigilance and Post Market Surveillance (PMS);
- Mandatory product liability insurance;
- Transparency;
- Supply Chain Management;
- Labeling;
- UDI System Introduction.

Steve Cottrell, Maetrics' President, comments: "Our in-house experts are passionate about supporting our clients through these momentous times of regulatory change. The introduction of the IVDR means that manufacturers are going to have to go back to the drawing board to re-evaluate their compliance strategies in order to ensure they are sufficiently prepared. We are pleased to share the insight and expertise with the industry and hope this guide will provide a springboard for IVD companies to continue providing their critical devices to the healthcare market while ensuring patient safety and remaining compliant."

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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.