

## Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)

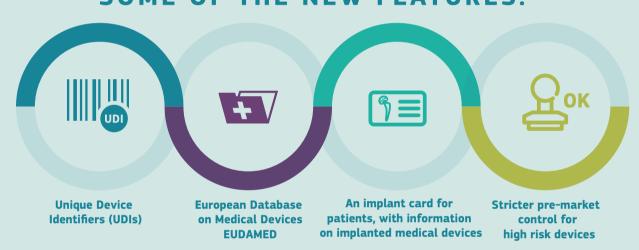
The European Commission has adopted 2 new Regulations – the Medical Devices Regulation (MDR) and the In Vitro Diagnostic

Medical Devices Regulation (IVDR) - to bring EU legislation up to date with medical advances and to ensure better protection of public health and patient safety.

## THE NEW REGULATIONS



## SOME OF THE NEW FEATURES:



## **SOME THINGS TO KEEP IN MIND...**

## **Manufacturers**

The new Regulations better reflect recent scientific and technological advancements and will strengthen the image and value of CE marked devices

**Authorised** 

representatives,

The roles and responsibilities have been

compliance of devices on the market

## **Procurement** ecosystem

The procurement of Directive-compliant devices can continue until the transition ends (2025)



#### **Authorities in** non-EU/EEA states

All actors impacted by the Regulations must be informed of the changes and timelines in order to avoid any disruption on the market

## Reprocessing of single-use devices

Strict conditions have been introduced in the case of reprocessing single-use medical devices

# Healthcare professionals and health institutions

Healthcare professionals and health institutions will benefit from improved transparency on clinical and vigilance data through EUDAMED

## **Patients**

Patients will benefit from the increased safety and performance of devices, and from more information surveillance and transparency on devices on the EU market

For a complete overview of the impact of the new Regulations and the roles and responsibilities of all stakeholders, check the Medical Devices section in the **European Commission website** 

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