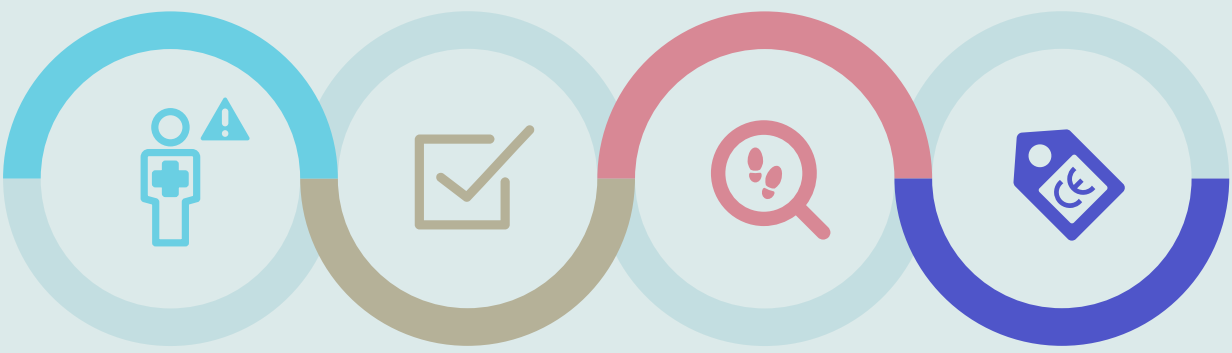
Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR)

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



Increase clinical investigation requirements and manage risk to ensure patient safety

Reinforce surveillance and management of the entire MD and IVD life cycle

Improve transparency and traceability

Reduce ambiguity with clear classifications and definitions

SOME OF THE NEW FEATURES:

Unique Device Identifiers (UDIs)

European Database on Medical Devices EUDAMED

An implant card for patients, with information on implanted medical devices

Stricter pre-market control for high risk devices

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

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

Authorised representatives, importers, distributors

The roles and responsibilities have been clarified and reinforced to ensure the legal compliance of devices 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 on the DG GROW website: https://ec.europa.eu/growth/sectors/medical-devices_en

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Internal market, Industry, Entrepreneurship and SMEs