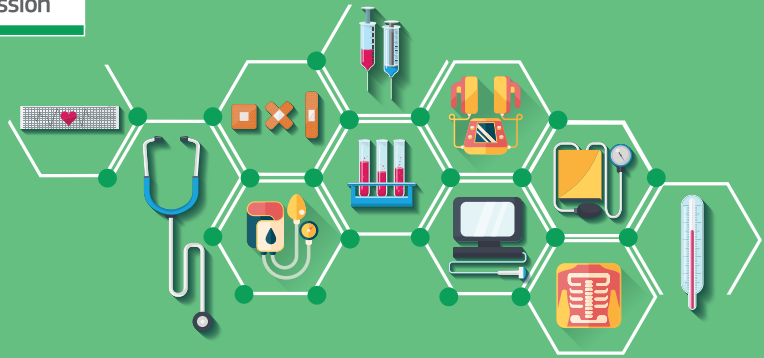




# New EU rules to ensure safety of medical devices



## EXISTING RULES

**Outdated rules** – rules on medical devices date back to the 1990s and don't reflect the technological progress made since then

Control of high-risk devices such as implants relies **on national Notified Bodies** – separate bodies risk inconsistency

Clinical trials taking place in more than one Member State are subject to **multiple national assessments**

Most aesthetic products, such as coloured contact lenses, are **regulated as general products**

**Only one in five** *in vitro* diagnostic medical devices is checked by a Notified Body before they are placed on the market

European database contains **limited** information on medical devices that is not publicly accessible

**Varying and often limited** information on implanted devices available to patients

In case of harm resulting from medical devices, compensation is **not guaranteed** if, for example, manufacturer goes bankrupt

**Multiple registration procedures** might be required for medical devices in different EU countries

## NEW RULES

**Up-to-date rules** – new rules take into account technological progress and drive innovation

Control of high-risk devices such as implants involve also **panels of independent experts** at EU level

Clinical trials taking place in more than one Member State will be subject to **a single coordinated assessment**

Many aesthetic products are **regulated as medical devices and subject to stricter controls**

**Four out of five** *in vitro* diagnostic medical devices are checked by a Notified Body before they are placed on the market

European database contains **extensive** information on medical devices, most of which is publicly available

An **"implant card"** for implanted devices gives patients more information

A financial mechanism **ensures patients are compensated** in case defective medical devices harm them

**Simplified procedure** allows manufacturers to register their device only once at the EU level