Major provisions of the new medical devices regulations

European Society of Cardiology

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The new regulatory framework in the field of medical devices is expected to ensure…

1. Better protection of public health and patient safety
2. Legal certainty and innovation-friendly environment
3. More transparency and patient empowerment
4. A more European approach

1. Better protection of public health and patient safety

- ✓ **Stricter pre-market control** of high-risk devices with the involvement of a pool of experts at EU level.
- ✓ Inclusion of **certain aesthetic devices** within the **scope**.
- ✓ **Reinforced designation and oversight** processes of **notified bodies.**
- ✓ Reinforcement of the rules on **clinical evaluation** (and performance evaluation) and **clinical investigation** (and performance studies)
- ✓ **Stricter rules for "substance-based" devices**
- ✓ **New classification system for IVDs** based on international guidance (80% of IVDs to be assessed by a Notified Body)
- ✓ Stricter requirements related to the **use of hazardous substances** for certain devices
- ✓ Introduction of a **UDI system**

2. Legal certainty and innovation-friendly environment

- ✓ Use of a **EU regulations** as a regulatory tool
- ✓ **Clarification of the scope** for both MD and IVDs.
- ✓ Stronger role for the Commission in the context of decisions on the **regulatory status of products**.
- ✓ Clarification of the specific regime applicable to **devices manufactured and used in the same health institution**.
- ✓ Clarification of the **role and responsibilities of economic operators**.
- ✓ New dedicated rules for **medical software and medical apps**.

3. More transparency and patient empowerment

- ✓ Establishment of a comprehensive EU database on medical devices **(EUDAMED)** with large part of information to be made publicly available
- ✓ Introduction of an EU-wide requirement for an **'implant card'** to be provided to patients containing information about implanted medical devices
- ✓ **Summary of safety and clinical performance** for all Class III and implantable devices available in EUDAMED
- ✓ New obligations for manufacturers and authorised representatives, aimed at **protecting damaged consumers/patients**

4. A more European approach

- ✓ **Registration of devices and economic operators** at the EU level
- ✓ **Improved coordination between Member States** in the fields of **vigilance and market surveillance**.
- ✓ Confirmation and strengthening of the **EU joint assessment** procedure for notified bodies
- ✓ Introduction of a **coordinated assessment of clinical investigations** conducted in more than one Member State

Thank you
for your attention