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