The challenge of regulating medical devices

COCIR 60 years anniversary, Brussels

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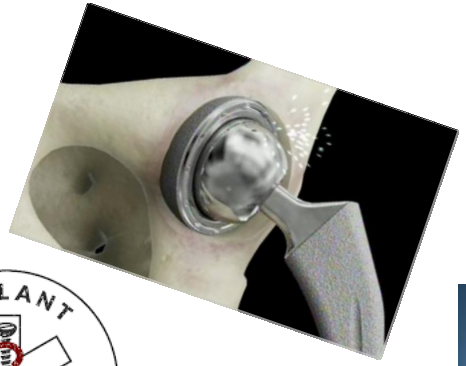
Environment



IMDRF International Medical Device Regulators Forum

IMPLANT FILES

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

9-2-2012 26-9-2012 05-05-2017 26-11-17 November 2019 MDR 26-05-2020 IVDR 26-05-2022 05-2024

New legislation - new challenges

- Complexity and detail of requirements
- Information and awareness
- Coordination and governance
- Timelines and capacity

Our objectives

- Close cooperation with national authorities
- Stakeholder cooperation and engagement
- Promote consistent and clear interpretation on key issues
- Information campaign - guidance
- Monitor developments

Progress update (rolling plan)

- **Governance**
  - ✓ MDCG (Nov. 2017) – 13 MDCG technical subgroups – 3 COM DG:s
- **Notified Bodies**
  - ✓ Designation structure (Nov. 2017)
- **Scientific structures**
  - ✓ Expert panels, expert laboratories and reference labs (ongoing).
  - ✓ Call for experts closes 24.11 2019.
- **New EUDAMED**
  - ✓ Delay
- **UDI system**
  - ✓ 8 guidelines published, nomenclature and issuing entities selected
- **Mandate for revision of standards** (Q4 2019)
- **Communication campaign**

With CAMD:

- **Implementation roadmap**
- **Clarification of certain transitional provisions**

(Re-)designation of notified bodies

- Applications received by COM: 50+
- 40+ Joint Assessments
- 9 designated (7 MDR+2 IVDR)

Implementing/delegated acts

80 empowerments for implementing and delegated acts (including Common Technical Specifications – CTS)

Next in line:

- Standardisation mandate (Q4 2019)
- CTS on reprocessing of single-use devices (Q4 2019)
- CTS on devices without medical purpose (Q1 2020)
- EUDAMED
- EURLs (task/criteria, fees and designation)

Guidance documents

27 published, examples: Notified bodies, UDI Registration procedure and timelines, application of article 54(2), incident form, implant card, PRRC, EMA Q & A on application of Art. 117 MDR…

60+ in the pipeline: classification rules, clinical evaluation, vigilance, medical software/apps…

Critical issues

- Availability of notified bodies
- Establishment of Eudamed
- Resources and expertise

In addition:

- MRA:s, Customs Union Agreements, unilateral CE-acceptance, trade agreement negotiations
- Brexit
- Media interest

European Commission

Call for expression of interest

Expert panels on medical devices and in vitro diagnostic devices

27 September – 24 November 2019

European Commission

Useful links

- **ec.europa.eu**

  > growth > sectors

  > register of Commission expert groups > mdcg

  > law > better-regulation > have-your-say

- **camd-europe.eu**

  > MDR/IVDR implementation