The European Association of Medical devices Notified Bodies

MDCG Oct 14th meeting

Notified Bodies Top 5 topics

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❖Introduction

The top 5 topics are a selection of the MDCG 2022-14 topics

Notified Bodies Top 5 topics

❖AGENDA

1. Classification disputes & art 61.10 criteria
2. Practical & consistent Guidances
3. Notified Bodies decisions makers
4. Streamline the processes
5. Digitalisation of files

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❖Topic 1: Classification disputes & art 61.10 criteria

- Classification disputes – EU wide – Article 51 MDR / Article 47 IVDR
- A single process and committee to handle all qualification and classification issues - classification disputes, borderline decisions, updates to MDCG guidance on classification and communications.
  - Rapid publication of any classification decisions taken by the committee in a publicly accessible register (as ´successor´ of Borderline & Classification Manual/Helsinki Procedure).
- A single process and committee to develop specific criteria for devices allowed to fall into Article 61(10). This will allow shorter and less expensive reviews, which could address some of the criticisms of NBs in public.
- Notified Bodies to provide expert opinion to support decision making for qualification and classification and for Art 61(10). It will also harmonise some divergences across the EU.

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❖Topic 2: Practical & Consistent Guidance documents

- **Focus on Practical Aspects and Priority Topics while drafting MDCG guidance documents (**MDCG 2022-14- topic 11 and 17)
- **Consideration of all risk-classes of devices when guidance documents are drafted**
- **Remove inconsistencies and/or duplications and provide cross-reference between MDCG guidance documents.**
- **Establish a quick process to ´fix´ minor inconsistencies and to adapt to practical experiences (change management process)**

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❖Topic 3: Notified Body decision makers (a.k.a “Employed by”)

- Availability of highly educated and trained personnel, especially in key regulatory and decision making roles, is an essential element for Notified Bodies to keep or enhance capacity.
- National or even regional labor markets cannot adequately meet the demand for such specialists.
- Notified Bodies with a global presence have established stringent procedures to control key regulatory roles across multiple locations.
- MDCG 2019-6 rev 4 has not led to sufficient clarification. Notified bodies are not allowed to utilize their personnel located outside their Member State.
- If the “employed by” issue remains unresolved, it creates further difficulty for Notified Bodies for capacity building, employee succession and development.

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❖ Topic 4: Streamline the processes

- **Avoid assessment duplications during the certification cycle**
  - **TD and SS(C)P review is duplicate work.**
  - Consider a sampling approach, with the aim to have a general monitoring / overview.
  - specific criteria defined.
  - **Individual vigilance cases and PSUR review.**
    - Clarify role of Notified bodies and Competent Authorities.
- **IVD authorisation processes**

  Reconsider how EU 2017/2185 is applied.
  Simplify five dimensional IVDR competence coding.
  Minimise the IVP and IVD codes.
  Make relevant IVT codes for IVD manufacturing.
  Opportunity to incorporate AI relevant 'S' codes for MD and IVD devices.
- **NBOG 2017-2 update to MDCG document**
  - Should alleviate current authorisation burden

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❖ Topic 5: Digitalisation of files

- **Develop legislation that is digital friendly.**
- **First step: Open-source digital Technical Documentation format.**
- **Allow Conformity Assessment of "data" not "documents".**
- **e.g. MDR Plans:**
  - Strategy for regulatory compliance;
  - Risk Management Plans;
  - Clinical Development strategy;
  - Clinical Evaluation Plan;
  - Clinical Development Plan;
  - Clinical Investigation Plan;
  - Post Market Surveillance Plans;
  - Post Market Clinical Follow-Up Plan.

  IVDR Plans:

  Strategy for regulatory compliance;
  Risk Management Plans;
  Plans for Performance Evaluation;
  Post-market Performance Plans;

  Clinical Performance Plans;
  Post Market Surveillance Plans;
  Post Market Performance Follow-Up Plan.
- **e.g. Intended Purpose:**
  - IFU, Marketing materials, Clinical/Performance evaluation report, Risk management documentation, Declaration of conformity, SS(C)P, PSUR, EUDAMED, ...

Thanks for your attention

Questions

&

Answers